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Water Quality Guidance for the Great Lakes System: Supplementary Information Document (SID)

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FOREWORD

On March 23, 1995, EPA published the final Water Quality Guidance for the Great Lakes System in the Federal Register. In addition to the Guidance itself, the Federal Register publication included: a brief summary of the process for developing the final Guidance; a summary of the final Guidance; a summary of the consultation with the U.S. Fish and Wildlife Service under the Endangered Species Act; a summary of EPA's analyses pursuant to the Regulatory Flexibility Act and the Paperwork Reduction Act; and a summary of EPA's response to Executive Order 12866.

The purpose of this Supplementary Information Document (SID) is to provide a more detailed description of the final Guidance, including a statement of the basis and purpose of the final Guidance; a discussion of the major changes from the proposal; and an analysis of issues raised in comments received on the proposed Guidance and subsequent documents in the Federal Register.

The SID is divided into 12 major sections and further divided within the sections into numerous subsections (see list of major sections below and the table of contents). Each subsection presents a summary of the proposal for that issue, significant comments received (with EPA's response to each), and the requirements for the final Guidance for that issue. Responses to all comments received are provided in the Response to Comment document with is available in the docket for the final Guidance.

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I. BACKGROUND

A. Description of Resource

The Great Lakes are a unique natural resource that have played a vital role in the history and development of the United States and Canada. The Great Lakes consist of Lakes Superior, Huron, Michigan, Erie and Ontario and their connecting channels (i.e., the Saint Mary's River, Saint Clair River, Detroit River, Niagara River and the Saint Lawrence River to the Canadian Border). The Great Lakes plus all of the streams, rivers, lakes and other bodies of water that are within the drainage basin of the Lakes collectively comprise the Great Lakes System.

The Great Lakes span over 750 miles across eight States--New York, Pennsylvania, Ohio, Michigan, Indiana, Illinois, Wisconsin and Minnesota--and the Province of Ontario. The Lakes contain approximately 18 percent of the world's and 95 percent of the United States' fresh surface water supply. The Great Lakes are a source of drinking water and energy, and are used for recreational, transportation, agricultural and industrial purposes by the more than 46 million Americans and Canadians who inhabit the Great Lakes region, including 29 Native American tribes. Over 1,000 industries and millions of jobs are dependent upon water from the Great Lakes. The Great Lakes System also supports hundreds of species of aquatic life, wildlife and plants along more than 4,500 miles of coastline which boast six National Parks and Lakeshores, six National Forests, seven National Wildlife Refuges, and hundreds of State parks, forests and sanctuaries. The prominent features of the Great Lakes can be seen when the Earth is viewed from outer space.

Although each of the Lakes is an interrelated and interdependent component of the Great Lakes System, the Lakes vary in size, retention times, and existing water quality. Lake Superior, the northernmost Lake, is the largest, deepest, coldest and most pristine of the Great Lakes, while Lake Erie is the smallest, shallowest, and the most susceptible of all of the Great Lakes to the effects of urban and agricultural activities. Lake Superior also has the longest retention time--the average time it takes for one molecule of water to exit the system--of 173 years, while Lake Erie has the shortest at 2.7 years. Lake Huron alone acts as a drain for 51,700 of the 201,000 square miles comprising the Great Lakes basin. Lake Ontario, the easternmost Lake, eventually receives all of the outflow from the other Great Lakes. The waters of four of the Great Lakes--Superior, Huron, Erie and Ontario--are shared by the United States and Canada; only Lake Michigan is located wholly within the United States.

State and provincial Natural Heritage programs, which have been established throughout the Great Lakes basin for the purpose of identifying elements (i.e., natural ecological communities or individual species) of biological diversity requiring protection, have identified 131 elements of global significance within the Great Lakes basin that are crucial to maintaining the region's biological diversity (The Nature Conservancy, 1994). Of these, 31 are natural ecological community types. The remaining 100 consist of plants, insects, mollusks, fish, birds, reptiles and one mammal. All of these species are either critically imperiled, imperiled or rare on a world-wide basis. Nearly half (47 percent) are present either exclusively or predominantly within the basin, or are the best examples of their respective species. All 131 elements provide some of the most visible examples of the biological character of the Great Lakes System. The continued existence of these species depends upon their ability to survive in the Great Lakes basin.

B. Environmental Problems in the Great Lakes System

1. Historical Nature of Environmental Problems in the Great Lakes System

The Great Lakes Basin Ecosystem--the interacting components of air, land, water and living organisms, including humans, that live within the Great Lakes drainage basin--is a very young, yet remarkable, ecosystem in geological terms due to the physical and biological characteristics discussed above. The species which inhabit the Great Lakes basin reside in a wide range of habitats. Many of the features and processes that provided the environment for these species to initially migrate to this region, adapt to its physical characteristics, and evolve into even more unique and diverse species are also susceptible to the multiple environmental stressors that humans have placed, and continue to place, upon this important ecosystem.

The Tribal relationship with the Great Lakes has been well documented since being noted by the earliest Europeans to come into contact with the indigenous people of the area. The Great Lakes System played an integral role in Tribal sustenance, stories, culture and spirituality to an extent unmatched by any other group.

Early settlement and related economic activities drastically changed portions of the Great Lakes System. The clearing of land for agricultural purposes, commercial fishing, and industrialization placed a combination of physical, biological and chemical stresses upon the Great Lakes Basin Ecosystem, some of which continue today.

By the late 1800s, all of the available agricultural lands within the basin had been cleared and settled. This harvesting and clearing of the Great Lakes basin landscape imposed the first significant human stress condition upon the Great Lakes Basin Ecosystem. Temperatures in tributary streams rose and entire forest systems, as well as wetlands and prairies, were frequently lost as a result of these early logging and agricultural practices. Also lost were thousands of acres of critical habitat for wildlife. The loss of this habitat caused many species to migrate to other areas or simply to perish due to this physical alteration of the Great Lakes Basin Ecosystem (The Nature Conservancy, 1994). In addition to the above factors, dams and watercourse modifications, human disturbance of breeding and nesting locations, soil erosion and the silting of spawning areas, primarily due to urbanization and shoreline development pressures, were responsible for reductions in suitable fish, avian and wildlife habitat.

The construction of several canals from the beginning of the 1800s and ending with the construction of the St. Lawrence Seaway in the 1950s connecting the various Great Lakes, several of their waterways and the St. Lawrence River during this same time period also impacted the Great Lakes System. Although these canals provided a valuable form of transportation for the industries and populations located within and around the Great Lakes basin, they also provided a mechanism for the unintentional introduction of exotic (i.e., non-indigenous) species such as the alewife (Alosa psuedoharengus), the sea lamprey (Petromyzon marinus), the Euroasian river ruffe (Gymnocephalus cernuus), and more recently, the zebra mussel (Dreissena polymorpha). Once these exotic species entered the Great Lakes System, they altered the natural biotic system by not only competing with native species for sustenance, but also by serving as those species' prey.

Great Lakes' fish were an important resource valued by both the early Native American and European settlers. Commercial fishing flourished throughout the mid- to late-1800s. Near the end of the century, however, the commercial fishing industry experienced a multitude of stresses from the introduction of exotic species, overfishing, loss of habitat, and pollution. This combination of physical, biological and chemical stressors eventually impacted the commercial fishing industry in the Great Lakes beginning in the late nineteenth century.

Despite the amount of general social and economic changes, wild rice harvesting, hunting, gathering, inland shore and landlocked fishing continue to be viable economic and cultural pursuits for modern Great Lakes Native American communities. There are presently more than 100 Tribal commercial fishermen operating on the Great Lakes. In 1992, the Tribal commercial fish harvest on U.S. waters of Lake Superior was more than 600 tons.

Additionally, traditional wild rice harvesting of landlocked, flowing, and inland Lake Superior shore waters is an economic, subsistence and cultural mainstay of the annual cycle of life for Native American (and non-Native American) people in Minnesota, Wisconsin and Michigan. Hunting of waterfowl and small and large mammals is also very important to Tribal peoples for subsistence and cultural reasons.

The wastes that resulted from industrial and other activities that prevailed in the basin during the late 1800s and early to mid-1900s placed additional stresses upon the Great Lakes. Iron and steel manufacturing, salt brine production, copper and iron mining, paper making, power generation and chemical manufacturing facilities utilized the natural resources and waterways of the Great Lakes in their industrial and transportation processes. Metals, organic compounds and other chemical substances were introduced into the Great Lakes System as a result of this industrialization. In addition, the growth of the human population in the Great Lakes basin and the corresponding disposal of domestic wastes also contributed to the overall degradation of Great Lakes water quality.

By the mid-1900s, both the fishing quality and the water quality in the Great Lakes basin were succumbing to these physical, biological and chemical stresses. For example, increased loadings of nutrients to the Great Lakes had dramatically stimulated the growth of green plants and algae. When these materials decomposed, the Lakes experienced decreased levels of dissolved oxygen in bottom waters, which in turn, caused the displacement of certain species of insects and fish from the affected areas of the Great Lakes Basin Ecosystem. Environmental managers determined that a lakewide approach to limit the loadings of phosphorous was the key to controlling the excessive algal growth in the Great Lakes.

The presence of environmentally persistent, bioaccumulative, chlorinated organic contaminants was observed and identified as a serious environmental threat in the 1960s (Tanabe, 1988; Stevens et al., 1989). Beginning in 1963, adverse environmental impacts in the form of poor reproductive success and high levels of DDT/DDE were observed in herring gulls in Lake Michigan (Environment Canada, 1991). Expanded pollution control programs were instituted in an attempt to stem and reverse the adverse effects posed by the presence of these chemicals. Although individual and concerted actions taken by citizens, industries, governments and private organizations helped to reduce the threats posed by these stressors on the Great Lakes Basin Ecosystem, human activities still adversely impact this important natural resource.

2. <u>Current Trends of Environmental Problems in the Great Lakes System</u>

a. <u>Impacts From Chemical Contamination.</u> In spite of the fact that the Great Lakes contain 5,500 cubic miles of water that cover a total surface area of 94,000 square miles, the Lakes are sensitive to the effects of a wide range of pollutants from all sources, both point and nonpoint. In particular, the Great Lakes are susceptible to relatively non-degradable, bioaccumulative chemicals because of the Lakes' unique physical, chemical and biological characteristics. Examples of these characteristics include: (1) long hydraulic retention times (i.e., relatively closed systems); (2) low biological productivity; (3) low suspended solids concentrations; (4) great depth; and (5) the presence of self-contained fish and wildlife populations dependent on the Great Lakes System for water, habitat and food. Taken together, these characteristics result in such pollutants remaining in the system for long periods of time and bioaccumulating in fish and wildlife tissue at concentrations which are orders of magnitude above the ambient concentrations in the water column. Once these pollutants are released into the Great Lakes System, they will cycle within the System for decades, exerting biological effects and presenting relatively high levels of risk to aquatic life, wildlife and humans which inhabit the Great Lakes basin.

The internal responses and processes that operate in the Great Lakes because of their depth and long hydraulic residence times mean that pollutants recycle between biota, sediments and the water column. As a result, the Great Lakes may still be experiencing the effects of historic discharges. In certain circumstances, for example, water column concentrations may be more affected by the total mass of pollutants in the Lakes rather than the loadings from point sources. Additional discussion of the characteristics and processes affecting contaminant levels in the Great Lakes is provided in the preamble to the proposed Guidance (58 FR at 20807-20817).

Scientists have detected 362 contaminants in the Great Lakes System. Of these, approximately one third have toxicological data showing that they can have acute or chronic toxic effects on aquatic life, wildlife and/or human health (IJC, 1991). Chemicals that have been found to bioaccumulate at levels of concern in the Great Lakes include, but are not limited to, PCBs, mercury, DDT, dioxin, chlordane, and mirex. The main route of exposure to these chemicals for humans is through the consumption of Great Lakes fish (Colborn et al., 1990).

Potential adverse human health effects resulting from the consumption of contaminated fish include both the increased risk of cancer and the potential for systemic or noncancer risks such as kidney damage. EPA has calculated health risks to populations in the Great Lakes System from consumption of contaminated fish based on exposure to eight bioaccumulative pollutants: chlordane, DDT, dieldrin, hexachlorobenzene, mercury, PCBs, 2,3,7,8-tetrachloro-p-dioxin (TCDD), and toxaphene. These chemicals were chosen based on their potential to cause adverse human health effects (i.e., cancer or disease) and the availability of information on fish tissue contaminant concentrations from the Great Lakes.

Based on this data, EPA estimates that the lifetime cancer risks for Native Americans in the Great Lakes System due to ingestion of contaminated fish at current concentrations range from 1.8 times 10^{-3} (1.8 in one thousand) for Lake Superior, to 3.7 times 10^{-2} (3.7 in one hundred) for Lake Michigan. Estimated risks to low income minority sport anglers range from 2.5 times 10^{-3} for Lake Superior, to 1.2 times 10^{-2} for Lake Michigan. Estimated risks for other sport anglers range from 9.7 times 10^{-4} for Lake Superior, to 4.5 times 10^{-3} for Lake Michigan (Regulatory Impact Analysis of the Final Great Lakes Water Quality Guidance. 1995. EPA 820-B-95-011) (RIA), Chapter 6). In comparison, EPA has long maintained that one times 10^{-4} (one in ten thousand) to 1 times 10^{-6} (one in one million) is an appropriate range of risk to protect human health.

EPA also estimates a high potential risk of systemic injury to populations in the Great Lakes basin due to ingestion of fish contaminated with these pollutants at current concentrations (RIA, Chapter 6). The systemic adverse health effects associated with the assessed contaminants are described in appendix E of the RIA.

While it is not possible to state conclusively that low-level exposure to these chemicals is or is not associated with adverse human health reproductive effects, evidence from wildlife studies (Fox, 1992; Flint and Vena, 1991) and epidemiological investigations of occupational exposures to these chemicals indicates that they may be able to alter human reproduction. Epidemiological studies that have addressed adverse pregnancy outcomes in populations in the Great Lakes have shown some potential effects of concern

(Swain, 1991; Fein et al., 1984; Smith, 1984), while other studies have shown little or no effects (Dar et al., 1992).

Additionally, new research into the ability of several organochlorine compounds to mimic hormones has recently been published (Environment Canada, 1991). Studies have shown that PCBs (Korach et al., 1988) and DDE and DDT (McLachlan et al., 1987) have been found to have weak estrogenic abilities. There has been speculation among researchers that an increased incidence of breast cancer may occur among women exposed to organochlorines (Manz et al., 1991; Falck et al., 1992). However, the link between these compounds and breast cancer has not been clearly established.

As stated earlier, adverse effects observed in fish, birds and mammals in the Great Lakes have been attributed to contaminants. These effects include death, eggshell thinning, reduced hatching success, abnormal behavior, deformities (such as crossed beaks and club feet) and population declines. For several species of birds (e.g., double=crested cormorants, Caspian terns, Forster's terns, common terns, ring-billed gulls, herring gulls) in the Great Lakes, a suite of effects including embryo mortality, edema, growth retardation, and deformities have been reported and considered similar to chick edema syndrome associated with some classes of PCBs (Gilbertson et al., 1991; Fox et al., 1991; Tillitt et al., 1992; Environment Canada, 1991; Mora et al., 1993; Kurita and Ludwig, 1988; Yamashita et al., 1993). More subtle effects, such as abnormalities in the thyroid, endocrine and liver systems, have also been observed in organisms within these populations (Gilbertson et al., 1991; Colborn, 1991). Table I-1 below summarizes the fish and wildlife species thought to be affected by contaminants in the Great Lakes and is available in the docket for this rulemaking.

Of the eleven wildlife species which showed evidence of contaminant impacts in the past, three of these species (bald eagles, cormorants and herring gulls) are providing some evidence of recent improvements (Giesy et al., 1994). Current concentrations of organochlorine compounds in Great Lakes fish and fish-eating birds are less than during the 1960s and 1970s (Giesy et al., 1994). Although these trends for these species are encouraging, persistent toxic chemicals still exist at levels that continue to produce adverse effects on fish-eating wildlife and fish (Giesy et al., 1994).

With respect to Great Lakes fish populations and fish communities, some researchers argue that the effects of contaminants on fish populations and communities are difficult to separate from the effects of overfishing, habitat loss and the introduction of exotic species (Environment Canada, 1991). Great Lakes lake trout populations, for example, have been devastated by overharvesting and the introduction of the sea lamprey, as well as subjected to a variety of impairments from toxic pollutants (Environment Canada, 1991).

EPA recognizes that chemical contaminants are only one of the threats to the health of the Great Lakes Basin Ecosystem. The continued decline of physical habitat and the presence of exotic (i.e., non-indigenous) species, for example, are also of concern. The final Guidance provides a consistent approach for reducing the threat from chemical stressors to the Great Lakes Basin Ecosystem. Other programs and activities are currently being implemented by EPA and other Federal and State agencies to address biological, chemical and physical problems in the Great Lakes (see section I.D below).

TABLE I-1 Species of Fish and Wildlife Thought to be Affected by Contaminants in the Great Lakes

Species	Population Decrease	Alterations in Recruitment	Repro-duction Effects	Mortality	Eggshell Thinning	Behavioral Changes	Congenital Malformation	Bio-chemical Changes
Mink	X	?	X	X	NA	NE	NE	NE
Otter	X	?		?	NA	NE	NE	NE
Double-crested Cormorant	X	?	X	?	X		(X)	X
Black-crowned Night Heron	X	?	X	?	X		X	X
Bald Eagle	X	?	X	NE	X		NE	NE
Herring Gull			X	X	X	X	X	X
Ring-billed Gull				X			X	NE
Caspian Tern		X	X			NE	X	NE
Common Tern			X		X		X	X
Forster's Tern			X			X	X	X
Snapping Turtle	NE	NE	X	NE	NA	NE	X	NE
Lake Trout			X		NA			X
Brown Bullhead					NA			X
White Sucker					NA		X	X

X = effects documented
NA = not applicable
NE = not examined
? = suspected since populations declined

Source: Environment Canada, 1991

b. <u>Trends in Contaminant Levels.</u> Concentrations of certain bioaccumulative contaminants, such as PCBs, DDT, dieldrin, and oxychlordane, have declined significantly over the past 20-30 years, as evidenced by basin-wide decreases of these pollutants in water, fish, bird eggs, and sediments (DeVault, 1993a; DeVault 1993b; Environment Canada, 1991). These declines are believed to be attributable to bans and restrictions that were placed on the manufacture and use of these chemicals from the late 1960s through the mid-1970s. Decreased chemical levels in the Great Lakes are also attributable, in part, to existing regulatory controls, industrial source controls, and the Lakes' ability to respond to changes in loads following remedial actions (Deposition of Air Pollutants to the Great Waters: First Report to Congress, EPA 453-R-93-055.U.S. EPA, 1994) (Great Waters Report).

Recent water column data for both Lakes Superior and Michigan indicate declines for PCBs are continuing. Pollutant levels for PCBs, for example, declined from 1.73 μg/L to 0.18 μg/L in Lake Superior between 1978 and 1992 (DeVault, 1993). Between 1980 and 1993, PCB levels in southern Lake Michigan also declined, from 1.8 μg/L to 0.2 μg/L. Similar results were observed for DDT, 2,3,7,8-TCDD and 2,3,7,8-tetrachloro-dibenzofuran (TCDF) across the Great Lakes basin, and in levels of mirex found in Lake Ontario. Significant declines in both net loadings and environmental concentrations of lead and mercury have also occurred since the mid-1970s.

Due to difficulties with reliably measuring chemicals at extremely low concentrations in water, scientists have often relied upon fish tissue residues in some species, such as lake trout and walleye, to provide an indication of chemicals in the water column as well as to indicate any changes in water column pollutant concentrations. In the preamble to the proposed Guidance, EPA provided environmental information regarding several bioaccumulative chemicals (e.g., PCBs, DDT) in game fish (58 FR 20809-20816). EPA stated that contaminant levels in fish had showed dramatic declines through the mid-1980s, but were currently fluctuating around a lower level. This conclusion was based on data showing that earlier declines may have been leveling off in recent years (DeVault, 1993).

The lake trout data which were presented in the preamble to the proposed Guidance illustrated that existing PCB levels in such fish were too high to ensure adequate protection of human health and that the rate of decline in fish tissue levels had slowed. Similarly, the data for coho salmon showed that PCB levels in this species remained above the fish tissue concentrations of concern and that the trend of PCBs in this species between 1984 through 1990 had leveled off in both Lakes Michigan and Erie.

In addition to the data presented in the preamble to the proposed Guidance, lake trout data for Lakes Superior and Michigan, and walleye data for Lake Erie, indicate that concentrations of PCBs and DDT initially declined rapidly, but leveled off in the mid-1980s. Similarly, concentrations of PCBs and DDT in Lake Erie walleye showed no significant changes since 1982. PCB and DDT concentrations in lake trout from Lakes Michigan and Superior had not changed significantly since 1986 (DeVault, 1993).

Current trends indicate that many water quality objectives and fish tissue criteria for the protection of human health are still being exceeded (DeVault et al., 1994). In Lake Erie, for example, water column concentrations of both PCBs and DDT declined from 1980 through 1984, and have not changed significantly through 1992, with levels of PCBs still substantially above the fish tissue concentrations of concern (DeVault et al., 1994). PCB and DDT concentrations in coho salmon filets from Lake Michigan showed rapid declines from 1980 through 1983, but increased between 1983 and 1992. See Figures I-1 and I-2. Thus, even though water column concentrations of PCBs continued to decline in Lakes Superior and Michigan through the early 1990s, an increase or lack of decline of PCBs has been observed in Lake Superior and Lake Michigan fish tissue residues since the mid-1980s.

The difference between the declining rates of PCBs in the water column concentrations and the fish tissue residues in Lakes Superior and Michigan indicate that these two systems have not reached an equilibrium of existing loads and bottom sediments. One possible explanation provided by DeVault et al. (1994) is that several recent changes to the zooplankton and forage fish communities in the Great Lakes System may be responsible. These changes were observed concurrently with the slowing and reversals in contaminant declines discussed above.

Despite the trends discussed above, the fish tissue concentrations of PCBs described above show that the acceptable fish tissue concentration of 0.1 µg/g for the protection of biological resources is still being exceeded across most of the Great Lakes basin (DeVault et al., 1994). These contaminant concentration levels continue to result in exceedances of State and Provincial human health criteria, potential risks to human health from cancer and noncancer systemic injuries, and fish consumption advisories for PCBs in each of the Great Lakes. Based on this information, further decreases in loadings to the Great Lakes are necessary in order to meet both existing and proposed future water quality objectives and criteria. EPA and the Great Lakes States and Tribes are currently addressing residual pollutant problems in the Great Lakes through a variety of regulatory and voluntary programs, some of which are discussed in section I.D below.

c. Fish Consumption Advisories. Due to the presence of contaminants at levels above current standards or guidelines, elevated contaminant levels in wildlife, and contaminated sediment hot spots (DeVault et al., 1994), fish consumption advisories exist in all of the Great Lakes States, including various waters located in the Great Lakes basin. The Great Lakes States issue these fish contaminant advisories based on a system incorporating and weighing such factors as the type of contaminants found in Great Lakes fish flesh, contaminant levels in fish of various sizes and species, the typical consumption rates of sensitive populations such as sport anglers, nursing and pregnant women, and an evaluation of the human health risks of the potential impacts of these substances.

Pollutants for which these fish advisories are issued include eight of the 22 bioaccumulative chemicals of concern (BCCs) identified in the final Guidance. High-risk groups, which fish consumption advisories are established to protect, include mothers who breastfeed their young, due to the presence of pollutants in human tissue to which babies continue to be exposed after they are born. Also at risk of greater exposure are those sport anglers, Native Americans, and the urban poor who may consume more Great Lakes fish than the average consumption of the basin population as a whole. The Federal government is examining the impacts to these higher-risk populations through a number of studies initiated during 1993 and 1994 by the Agency for Toxic Substances and Disease Registry, within the Department of Health and Human Services. As a result of the factors mentioned above, impacts from fish consumption to higher-risk populations are being taken into consideration in environmental regulation activities, including the final Guidance.

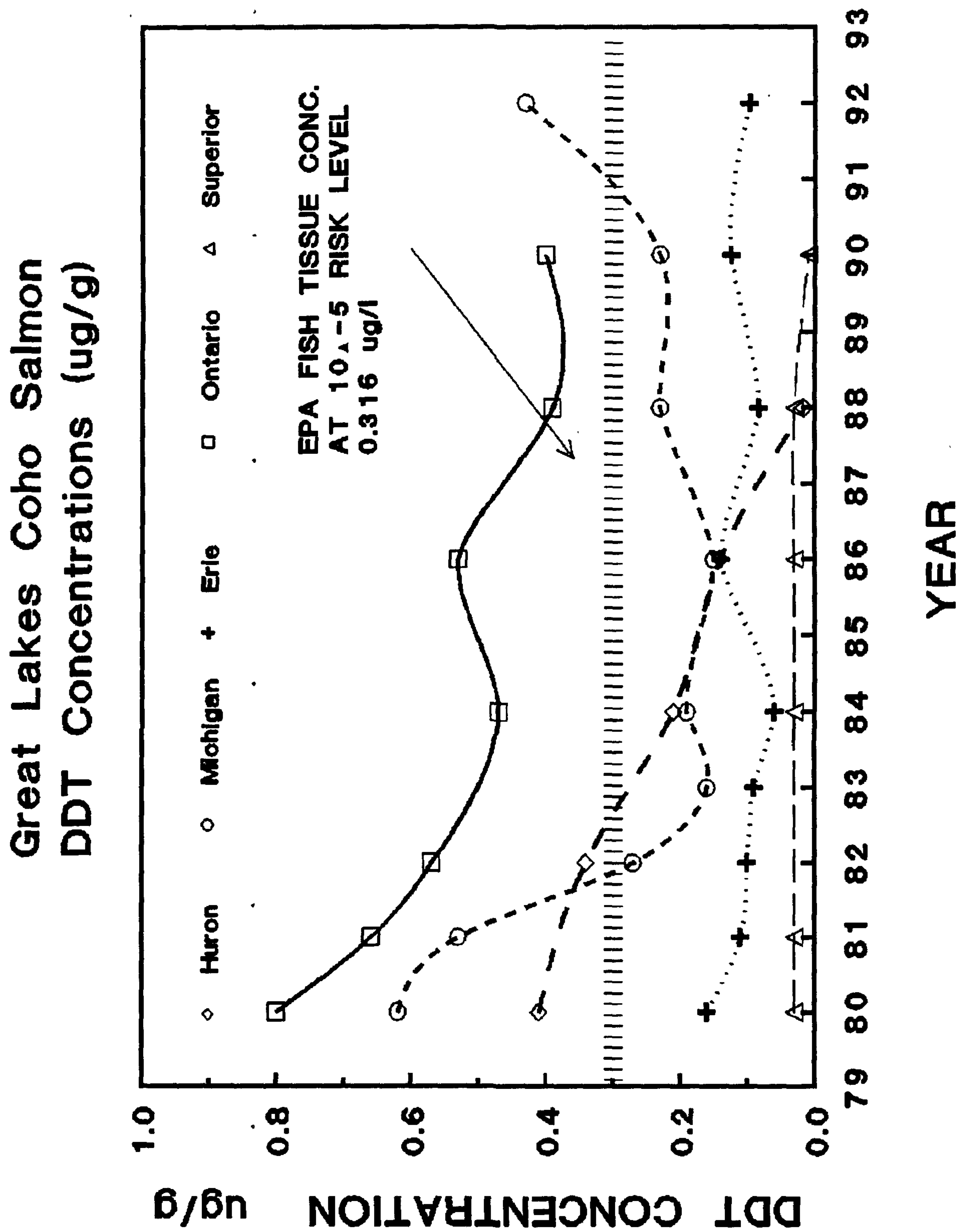

FIGURE I-1 (Devault et al. 1986; Devault, 1993)

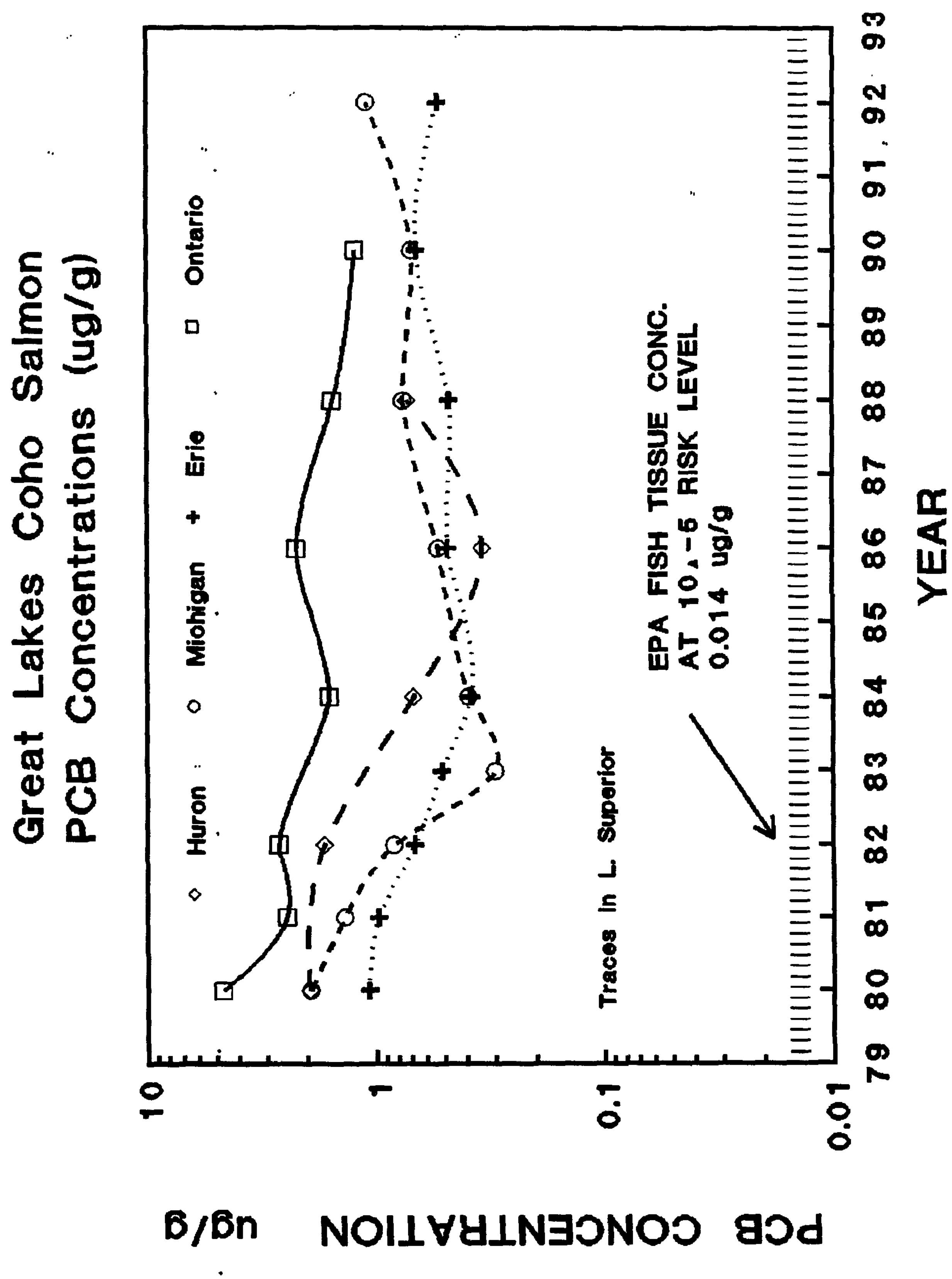

FIGURE I-2 (Devault et al. 1986; Devault, 1993)

C. History of the Great Lakes Water Quality Guidance

1. The Great Lakes Toxic Substances Control Agreement

Against this background of environmental concerns, the Governors of the eight Great Lakes States signed the Great Lakes Toxic Substances Control Agreement (Governors' Agreement) pledging the States' cooperation in studying, managing and monitoring the Great Lakes as an integrated ecosystem in 1986. The purpose of the Governors Agreement was to establish a framework for coordinated regional action in controlling toxic substances entering the Great Lakes System; to further the understanding and control of toxic contaminants; and to develop common goals, management practices and control strategies for toxics to ensure a cleaner and healthier Great Lakes Basin Ecosystem.

The Governors believed that maintaining and improving the quality of Great Lakes waters would sustain water supply systems as well as commercial, manufacturing and recreation industries, while creating new economic development opportunities. They agreed to preserve the value of the Great Lakes by striving to maintain a high standard of water quality when establishing regulatory standards, and committed to continue reducing toxics in the Great Lakes System to the maximum extent possible. For further discussion of the principles outlined in the Governors' Agreement, see the preamble to the proposed Guidance (58 FR 20820).

The Great Lakes Governors also realized that a number of toxic substances control programs and measures had been responsible for achieving significant reductions in certain organic pesticides and metals. These reductions are discussed in more detail in section I.B.2 above. However, the Governors recognized that the complexity of the pollutant problem in the Great Lakes System called for continuing action. In many cases, the Governors believed new and creative initiatives would be required to achieve the goal of prohibiting the discharge of toxic pollutants in toxic amounts in order to protect the water quality of the Great Lakes.

To implement the goals of the Governors' Agreement, the signatory States directed their environmental administrators to jointly develop an agreement for coordinating the control of toxic releases within the Great Lakes System. This coordinated effort between the Great Lakes States contributed to the development of the Great Lakes Water Quality Initiative.

2. The Great Lakes Water Quality Initiative

EPA and the Great Lakes States initiated the Great Lakes Water Quality Initiative (Initiative) in 1989 to further address the environmental concerns identified in the Governors Agreement. The Initiative was intended to provide a forum for Great Lakes States and EPA to develop uniform water quality criteria and implementation procedures for the Great Lakes basin. The participants planned to use the results of this effort as a basis for revising State water quality standards and permit programs pursuant to sections 303(c) and 402 of the Clean Water Act (CWA). Three committees were formed under the Initiative. A Steering Committee, consisting of directors of water programs from EPA's National and Regional offices and the Great Lakes States' environmental agencies, as co-regulators of CWA water quality programs, discussed policy, scientific and technical issues and directed the work of the Technical Work Group. The Technical Work Group, consisting of technical staff from the Great Lakes States environmental agencies, EPA, the U.S. Fish and Wildlife Service and the U.S. National Park Service, prepared proposals for submission to the Steering Committee. The Public Participation Work Group, consisting of representatives from environmental groups, municipalities, industry and academia, observed the deliberations of the other two groups, advised them of the public's concerns, and kept its various constituencies apprised of Initiative activities. These committees are collectively known as the Initiative Committees.

Of particular concern to the Steering Committee were those pollutants which exhibit the potential to produce System-wide impacts. Based upon observed impairments to the Great Lakes, the States believed that these pollutants pose one of the greatest threats to the health of the Great Lakes Basin Ecosystem. The Steering Committee believed that further reductions in loadings of such pollutants from all sources should be pursued. The Steering Committee wanted actions to be taken to ensure that problems with pollutants which could potentially cause impairment of beneficial uses in the Great Lakes Basin Ecosystem would not develop in the future. Therefore, the Steering Committee charged EPA and State staff on the Technical Work Group to define the pollutants that warrant more stringent controls, and to draft additional control approaches for those pollutants. Further discussion on the factors chosen for identifying and controlling such pollutants is provided in section II.C.8 of this document.

3. The Great Lakes Critical Programs Act of 1990

The enactment of the Great Lakes Critical Programs Act (CPA) of 1990 (Public Law 101-596, November 16, 1990) codified the ongoing Initiative effort into the CWA. Section 101 of the CPA (CWA section 118(c)(2)) requires EPA to publish proposed and final water quality guidance for the Great Lakes System which conforms with the objectives and provisions of the Great Lakes Water Quality Agreement (GLWQA) and is no less restrictive than provisions of the CWA and National water quality criteria and guidance. The final Guidance must specify minimum requirements for the waters of the Great Lakes System in three areas: (a) water quality criteria, including numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life and wildlife; (b) antidegradation policies; and (c) implementation procedures. This section also requires Great Lakes States to adopt water quality standards, antidegradation policies and implementation procedures consistent with the final Guidance within two years of EPA's publication of the final Guidance, or be subject to EPA promulgation of the provisions within the same two-year period. (CWA section 118(c)(2)(C)). Further discussion of the CPA is provided in the preamble to the proposed Guidance (58 FR 20823).

The substantive scope of the final Guidance is consistent with the initial 1989 expectations for the original Initiative. The final Guidance includes water quality criteria and methodologies, an antidegradation policy, and implementation procedures that were initially developed through an open, collaborative process by staff from the Great Lakes States and EPA with input from other stakeholders in the basin. The principal changes in the scope of the final Guidance that have occurred since the initial planning for the Initiative resulted from the enactment of the CPA.

4. Principles Underlying the Final Water Quality Guidance for the Great Lakes System

The final Guidance is the culmination of a six-year cooperative effort that included participation by the eight Great Lakes States, the environmental community, academia, industry, municipalities and EPA Regional and National offices. EPA's development of the final Guidance continued the work begun by the Initiative Committees and was guided by the following six general principles:

a. Use the Best Available Science to Provide Protection to Human Health, Wildlife, and Aquatic Life. EPA and the Initiative Committees have been committed to using the best available science to develop programs to protect the Great Lakes System since the beginning of this ambitious project. In the 1986 Governors' Agreement, the Governors of the Great Lakes States recognized that the problem of persistent toxic substances was the foremost environmental issue confronting the Great Lakes. They also recognized that the regulation of toxic contaminants was scientifically complex because the pollutants are numerous, their pathways into the Lakes are varied, and their effects on the environment, aquatic life and human health were not completely understood. Based on the importance of the Great Lakes Basin Ecosystem and the documented adverse effects from toxic contamination, however, the Governors directed their environmental administrators to jointly develop an agreement and procedure for coordinating the control of toxic releases and achieving greater uniformity of regulations governing such releases within the Great Lakes basin.

As discussed further above, the Initiative was subsequently created to begin work on these goals. EPA and the Great Lakes States, with input from interested parties in the basin, began collecting and analyzing data, comparing regulatory requirements and technical guidance in their various jurisdictions, and drafting specific methodologies and procedures to control the discharge of toxic contaminants. The provisions of the final Guidance were based in large part on these prior efforts of the Initiative Committees, and incorporate the best available science to protect human health, wildlife and aquatic life in the Great Lakes System. For example, the final Guidance includes new criteria and methodologies developed by the Initiative Committees to specifically protect wildlife; incorporates recent data on the bioavailability of metals into the aquatic life criteria and methodologies; incorporates Great Lakes-specific data on fish consumption rates and fish lipid contents into the human health criteria; and provides a better methodology to determine the bioaccumulation properties of individual pollutants.

b. Recognize the Unique Nature of the Great Lakes Basin Ecosystem. The final Guidance also reflects the unique nature of the Great Lakes Basin Ecosystem by establishing special provisions for BCCs. The special provisions for BCCs initially developed by the Initiative Committees and incorporated into the final Guidance include more stringent antidegradation procedures, to ensure that these problems are minimized; phase out and elimination of mixing zones for existing discharges of BCCs after 12 years, with limited exceptions, to reduce overall loadings to the Lakes; more extensive data generation requirements to ensure that they are not underregulated for lack of data; and the development of water quality criteria that will protect wildlife that feed on aquatic prey. As discussed in sections I.A and I.B above, it is reasonable and appropriate to establish special provisions for these chemicals because of the physical, chemical and biological characteristics of the Great Lakes System, and the documented environmental harm to the ecosystem from the past and continuing presence of these types of pollutants.

The final Guidance is not only designed to address existing problems, but also to prevent emerging and potential problems posed by additional chemicals in the future which may damage the overall health of the Great Lakes System. The experience with such pollutants as DDT and PCBs indicates that it takes many decades to overcome the damage to the ecosystem caused by even short-term discharges, and that prevention would have been dramatically less costly than cleanup. The elements of the final Guidance provide a coordinated ecosystem approach for addressing possible pollutant problems before they produce adverse and long-lasting basinwide impacts, rather than waiting to see what the future impacts of the pollutants might be before acting to control them. The comprehensive approach used in the development of the final Guidance provides regulatory authorities with both remedial and preventive ways of gauging the actions and potential effects of chemical stressors upon the Great Lakes Basin Ecosystem. The methodologies, policies and procedures contained in the final Guidance provide mechanisms for appropriately addressing both pollutants that have been or may in the future be documented as chemicals of concern. Additional discussion of the characteristics and processes affecting contaminant levels in the Great Lakes and special controls for BCCs is also provided in the preamble to the proposed Guidance (58 FR at 20807-23 and 20844-45) and in section II.C.8 of this document.

c. Promote Consistency in Standards and Implementation Procedures While Allowing Appropriate Flexibility to States and Tribes. Promoting consistency in standards and implementation procedures while providing for appropriate State and Tribal flexibility was the third principle in EPA's development of the final Guidance. A primary impetus for the Governors' Agreement, the Initiative, and the requirements set forth in the CPA was a recognition of the need to promote consistency in the minimum water quality standards, antidegradation policies, and implementation procedures adopted by the Great Lakes States to protect human health, aquatic life and wildlife. Although provisions in the CWA provide for the adoption of and periodic revisions to State water quality criteria, such provisions do not necessarily ensure that water quality criteria of adjoining States are consistent within a shared waterbody. For example, State acute ambient water quality criteria in place in six of the eight Great Lakes States include a range of 1.79 to 15.0 μg/L for cadmium in order to protect against acute effects for aquatic life, and from 0.21 to 1.33 μg/L for dieldrin. Other examples of variations in acute ambient water quality criteria include: nickel, which ranges from 290.30 μg/L to 852.669 μg/L; lindane, with a range of no criteria in place to 1.32 μg/L; and mercury, ranging from 0.5 μg/L to 2.4 μg/L. Similar ranges and disparities exist in the chronic ambient water quality criteria and human health criteria adopted by the Great Lakes States.

Disparities also exist among State procedures to derive individual discharge permits from water quality criteria. Wide variations exist, for example, in procedures for granting mixing zones, interpretation of background levels of pollutants, consideration of pollutants present in intake waters, controls for pollutants present in concentrations below the level of detection, and determination of appropriate levels for the discharge of multiple pollutants. Additionally, when calculating exposure factors in fish that will be consumed by humans and wildlife, some States consider accumulation through multiple steps in the food chain (bioaccumulation) while others consider only the single step of concentration from the water column (bioconcentration). Further disparities exist in different translator methodologies in deriving numeric values for implementing narrative water quality criteria; different assumptions when calculating total maximum daily loads (TMDLs) and wasteload allocations, including different assumptions about background concentrations, mixing zones, receiving water flows, or environmental fate; and different practices in deciding what pollutants need to be regulated in a discharge, what effect detection limits have on compliance determinations, and how to develop whole effluent toxicity limitations.

These inconsistencies in State standards and implementation procedures have resulted in the disparate regulation of point source discharges, which may have led to disputes in the past among the Great Lakes States. In the Governors' Agreement, however, the Governors recognized that the water resources of the basin transcend political boundaries and committed to taking steps to manage the Great Lakes as an integrated ecosystem. The Great Lakes States, as part of the Initiative Committees, recommended provisions that were ultimately included in the proposed Guidance for coordinated review and development based on their extensive experience in administering State water programs and knowledge of the significant differences in these programs within the basin. The final Guidance incorporates the work begun by the Initiative Committees to identify these disparities and improve consistency in water quality standards and permit procedures in the Great Lakes System.

Although improved consistency in State water programs is a primary goal of the final Guidance, it is also necessary to provide appropriate flexibility to States and Tribes in the development and implementation of water programs. In overseeing States' implementation of the CWA, EPA has found that reasonable flexibility is not only necessary to accommodate site-specific situations and unforeseen circumstances, but is also appropriate to enable innovation and progress as new approaches and information become available. Many commenters urged EPA to evaluate the appropriate level of flexibility provided to States and Tribes in the proposed Guidance provisions. EPA reviewed all sections of the proposed Guidance and all comments received to determine the appropriate level of flexibility needed to address these concerns while still providing a minimum level of consistency between the State and Tribal programs. Based on this review, the final Guidance provides flexibility for State and Tribal adoption and implementation of the final Guidance provisions in many areas, including the following:

-- Antidegradation: Great Lakes States and Tribes may develop their own approaches for implementing the prohibition against deliberate actions of dischargers that increase the rate of mass loading of BCCs without an approved antidegradation demonstration. Furthermore, States and Tribes have flexibility in adopting antidegradation provisions regarding non-BCCs.

-- TMDLs: Great Lakes States and Tribes may use assessment and remediation plans for the purposes of appendix F of part 132 if the State or Tribe certifies that the assessment and remediation plan meets certain TMDL-related provisions in the final Guidance and public participation requirements applicable to TMDLs, and if EPA approves such plan. Thus, States have the flexibility in many cases to use Lakewide Management Plans (LAMPs), Remedial Action Plans (RAPs) and State Water Quality Management Plans in lieu of TMDLs.

-- Intake Credits: Great Lakes States and Tribes may consider the presence of intake water pollutants in establishing water quality-based effluent limits (WQBELs) in accordance with procedure 5 of appendix F to part 132, as discussed further in section VIII.E of this document.

-- Site-Specific Modifications: Great Lakes States and Tribes may adopt either more or less stringent modifications to human health, wildlife, and aquatic life criteria and BAFs based on site-specific circumstances specified in procedure 1 of appendix F to part 132, as discussed further in section VIII.A of this document. All criteria, however, must not be likely to cause jeopardy to threatened or endangered species listed or proposed to be listed under the Federal Endangered Species Act (ESA).

-- Variances: Great Lakes States and Tribes may grant variances from water quality standards based on the factors identified in procedure 2 of appendix F to part 132, discussed further in section VIII.B of this document.

-- Compliance Schedules: Great Lakes States and Tribes may allow existing Great Lakes dischargers additional time to comply with permit limits in order to collect data to derive new or revised Tier I criteria and Tier II values in accordance with procedure 9 of appendix F to part 132, as discussed further in section VIII.I of this document.

-- Mixing Zones: Great Lakes States and Tribes may authorize mixing zones for existing discharges of BCCs after the 10-year phase-out period in accordance with procedure 3.B of appendix F to part 132, if the permitting authority determines, among other things, that the discharger has reduced its discharge of the BCC for which a mixing zone is sought to the maximum extent possible. Water conservation efforts that result in overall reductions of BCCs are also allowed even if they result in higher effluent concentrations. These provisions are discussed further in section VIII.C.4 of this document.

-- Scientific Defensibility Exclusion: Great Lakes States and Tribes may apply alternate procedures consistent with Federal, State, and Tribal requirements upon demonstration that a provision in the final Guidance would not be scientifically defensible if applied to a particular pollutant in one or more sites. This provision, in § 132.4(h) of the final Guidance, is discussed further in section II.C.6 of this document.

-- Reduced Detail: In many instances, EPA has revised the proposed Guidance to reduce the amount of detail in the provisions without sacrificing the objectives of the provisions. Examples of such revisions include simplification of procedures for developing TMDLs in procedure 3 of appendix F to part 132, discussed further in section VIII.C of this document, and simplification of procedures for determining reasonable potential to exceed water quality standards in procedure 5.B of appendix F to part 132, discussed further in section VIII.E of this document.

-- Other Provisions: Flexibility is also present in provisions for the exercise of best professional judgment by the Great Lakes States and Tribes when implementing many individual provisions in the final Guidance including: determining the appropriate uncertainty factors in the human health and wildlife criteria methodologies; selection of data sets for establishing water quality criteria; identifying reasonable and prudent measures in antidegradation provisions; and specifying appropriate margins of safety when developing TMDLs. In all cases, of course, State and Tribal provisions would need to be scientifically defensible and consistent with all applicable regulatory requirements.

d. Establish Equitable Strategies to Control Pollution Sources. Many commenters argued that the proposed Guidance unfairly focused on point source discharges. They asserted that nonpoint sources or diffuse sources of pollution, such as air emissions, are responsible for most of the loadings of some pollutants of concern in the Great Lakes, that increased regulation of point sources will be inequitable and expensive, and that the final Guidance will not result in any environmental improvement given the large, continuing contribution of toxic pollutants by nonpoint sources.

EPA recognizes that regulation of point source discharges alone cannot address all existing or future environmental problems from toxic pollutants in the Great Lakes. In addition to discharges from point sources, toxic pollutants are also contributed to the Great Lakes from industrial and municipal emissions to the air, resuspension of pollutants from contaminated sediments, and urban and agricultural runoff, hazardous waste and Superfund sites, and spills. Restoration and maintenance of a healthy ecosystem will require significant efforts in all of these areas. As discussed further in section I.D below, EPA, Canada and the Great Lakes States and Tribes are currently implementing or developing many voluntary and regulatory programs to address these and other nonpoint sources of environmental contaminants in the Great Lakes.

Additionally, EPA intends to use the scientific data developed in the final Guidance and new or revised water quality criteria subsequently adopted by Great Lakes States and Tribes in evaluating and determining appropriate levels of control in other environmental programs. For example, EPA's future biennial reports under section 112(m) of the Clean Air Act will consider the extent to which air discharges cause or contribute to exceedances of water quality criteria in assessing whether additional air emission standards or control measures are necessary to prevent serious adverse effects. Similarly, once the provisions of the final Guidance are adopted by the Great Lakes States or Tribes, they will serve as applicable or relevant and appropriate requirements (ARARs) for on-site responses under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). EPA will also consider the data and criteria developed for the final Guidance, including the information on bioaccumulative pollutants, in developing or evaluating LaMPs and RAPs under section 118 of the CWA and Article VI, Annex 2 of the GLWQA; determination of corrective action requirements under sections 3004(u), 3008(h), or 7003 of the Solid Waste Disposal Act; new or existing chemical reviews under the Toxic Substances Control Act (TSCA); pesticide reviews under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and reporting requirements for toxic releases under the Emergency Planning and Community Right-to-Know Act (EPCRA).

The final Guidance also includes provisions to address the contribution of pollutants by nonpoint sources. First, the water quality criteria to protect human health, wildlife and aquatic life, and the antidegradation provisions apply to the waters in the Great Lakes System regardless of whether discharges to the water are from point or nonpoint sources. Accordingly, any regulatory programs for nonpoint sources that require compliance with water quality standards would also be subject to the criteria and antidegradation provisions of the final Guidance once they are adopted into State or Tribal standards.

Second, several elements of the final Guidance would, after State, Tribal or Federal promulgation, require or allow permitting authorities to consider the presence of pollutants in ambient waters--including pollutants from nonpoint source dischargers--in establishing WQBELs for point sources. For example, permit authorities may consider the presence of other point or nonpoint source discharges when evaluating whether to grant a variance from water quality criteria under procedure 2 of appendix F to part 132. Additionally, the provisions for TMDLs in procedure 3 of appendix F to part 132 address nonpoint sources by requiring allocation of the available load capacity of receiving waters that do not meet water quality criteria among all sources of the pollutant, including nonpoint sources. The development of TMDLs is the preferred mechanism for addressing equitable division of the loading capacities of these nonattained waters. Because TMDLs have not been completed for most nonattained waters, however, the final Guidance promotes the development of TMDLs through a phased approach, where appropriate, and provides for short-term regulatory relief to point source dischargers in the absence of TMDLs through intake credits, variances, and other water quality permitting procedures. These provisions are discussed in sections VIII.B, VIII.C, and VIII.F of this document.

e. Promote Pollution Prevention Practices. The final Guidance also promotes pollution prevention practices consistent with EPA's National Pollution Prevention Strategy and the Pollution Prevention Action Plan for the Great Lakes. The Pollution Prevention Act of 1990 declares as National policy that reducing the sources of pollution is the preferred approach to environmental protection (Pub. L. 101-508, section 6601-6610 104 Stat. 1388, codified at section 13101-13109 West Supp. 1991). When source reductions are not possible, however, recycling, treating and properly disposing of pollutants in an environmentally safe manner complete the hierarchy of management options designed to prevent pollution from entering the environment.

Consistent with the goals of the Pollution Prevention Act, EPA developed the Great Lakes Pollution Prevention Action Plan (April, 1991). The Great Lakes Pollution Prevention Action Plan highlights how EPA, in partnership with the Great Lakes States, will incorporate pollution prevention into actions designed to reduce the use and release of toxic substances in the Great Lakes basin. The Great Lakes Pollution Prevention Action Plan is discussed in more detail in the preamble to the proposed Guidance (58 FR 20827-28).

The final Guidance builds upon these two components of the Great Lakes program by promoting the development of pollution minimization programs in the level of detection, mixing zone elimination, and antidegradation sections of the final Guidance. Also, the decision to provide special provisions for BCCs implements EPA's commitment to pollution prevention by reducing the discharge of these pollutants in the future. This preventive step not only makes good environmental management sense, but is appropriate based on the documented adverse effects that the past and present discharge of these pollutants have produced in the Great Lakes System.

f. Provide Accurate Assessment of Costs and Benefits. In developing the final Guidance, EPA identified and carefully evaluated the anticipated costs and benefits of the major provisions. EPA received many comments on the draft cost and benefit studies conducted as part of the proposed Regulatory Impact Analysis (RIA) required by Executive Order 12291, and its successor, Executive Order 12866. Based upon consideration of those comments and further analysis, EPA has revised the RIA. The results of this analysis are summarized in section IX of this document.

D. Progress on Other Programs to Protect and Restore the Great Lakes System

The final Guidance is only one component of many Federal, State and Tribal programs designed to address environmental contamination in the Great Lakes System. Unacceptably high concentrations of bioaccumulative pollutants, including PCBs, currently exist in fish tissue and sediments through the basin. As discussed further above, these pollutants have the potential to cause significant adverse human health effects, including increased risk of cancer and systemic injuries, as well as to adversely impact the aquatic life and wildlife in this ecosystem.

EPA recognizes that implementation of the final Guidance alone will not solve the existing environmental problems from chemical pollutants in the Great Lakes. Complete restoration of the Great Lakes and achievement of water quality criteria will require significant time, resources, and the scientific expertise of many parties. Other regulatory and voluntary programs are currently underway, however, to prevent or reduce future pollutant loadings and to remediate the averse effects associated with past pollutant discharges to the Great Lakes System. Implementation of the provision in the final Guidance, in conjunction with the activities described below, will provide EPA and the Great Lakes States and Tribes with a comprehensive framework for reducing toxic loadings. In addition, these activities will enable EPA and the Great Lakes States and Tribes to develop cost-effective strategies to further the goals and requirements of the CWA, Great Lakes Toxic Reduction Effort (GLTRE) and GLWQA, and attain the level of water quality necessary to fully protect human health, wildlife and aquatic life in the Great Lakes System.

1. <u>The Great Lakes Toxic Reduction Effort</u>

EPA and the Great Lakes States and Tribes have established a multi-media strategy called the GLTRE to achieve further reductions in the use and release of toxic substances to the Great Lakes System. The GLTRE emphasizes addressing nonpoint sources and wet weather point sources of pollution, and is consistent with the Great Lakes 5-year Strategy discussed in the preamble to the proposed Guidance (58 FR 20826).

The GLTRE has three multi-media tracks. The Pathway track focuses on the primary nonpoint source paths and wet weather sources through which BCCs enter the Great Lakes System. The Virtual Elimination Project focuses on identifying the ongoing uses and sources of the BCCs and identifies specific actions designed to achieve further reductions of these pollutants. The third track, the Lake Michigan Enhanced Monitoring Program, being pursued as part of the Lake Michigan LaMP, is designed to develop a sound scientific basis to guide future pollution prevention and reduction efforts to address toxic pollutants in the Great Lakes.

a. <u>Pathway Track.</u> The first track of the GLTRE has identified five primary wet weather and nonpoint source pathways for BCCs: air deposition; Combined Sewer Overflow (CSO)/stormwater/runoff; contaminated sediments; storage, handling and transport (spills); and leaking waste storage sites. The GLTRE will address any gaps or barriers in existing regulatory and non-regulatory programs designed to prevent and reduce the introduction of BCCs through these five sources. The final product of the GLTRE Pathway Track will be a menu of actions and recommendations aimed at focusing current and emerging program authorities on preventing, controlling and reducing loadings of BCCs; improving reporting, education and outreach; improvements in monitoring and modeling; and risk communication techniques. Actions and recommendations that enhance media-specific or multi-media regulatory gaps and eliminate barriers to effective regulation, including use of the ambient water quality criteria in the final Guidance in other media regulatory programs, will also be addressed. The Pathway track will encourage the prevention of BCC use, recycling and proper disposal of BCCs, as well as the replication of exemplary or innovative prevention and reduction programs. Prevention measures may also include recommendations for bans or sunsets for certain BCCs, if appropriate.

b. <u>Virtual Elimination Project.</u> The goal of the second component of the GLTRE is the virtual elimination of bioaccumulative, persistent toxic substances from the Great Lakes basin. The project identifies the use and release of specific toxic substances in the Great Lakes basin and examines the existing regulatory framework that applies to each substance. The project is designed to provide recommendations for voluntary and incentive-based changes to increase the pace and level of reductions of bioaccumulative toxics. This project is initially focusing on PCBs and mercury for the purpose of finding opportunities to achieve virtual elimination of discharges through voluntary source reductions.

c. Lake Michigan Enhanced Monitoring Program. As discussed in section I.D.4.b below, this program will develop a sound, scientific base of information to guide toxic pollutant load reduction efforts at the State and Federal levels. The Lake Michigan Enhanced Monitoring Program will help determine: loadings of contaminants from tributaries, the atmosphere and open lake sediments; concentrations and fluxes of toxic chemicals in the food web; and the magnification of toxic chemicals concentrations through representative food chains. This work will result in a better understanding of the relative sources and fate of toxic pollutants in Lake Michigan, and will be of use in addressing pollutant concerns in all of the Great Lakes. The results of this program will also be used to make recommendations on regulatory and nonregulatory changes needed to fully achieve water quality standards.

2. Clean Air Act Amendments

Implementation of the major provisions of the Clean Air Act Amendments of 1990 (CAAA) is an integral part of EPA's broader program to protect and restore the water quality of the Great Lakes. Specifically, in response to information indicating that air pollution contributes significantly to water pollution, Congress included section 112(m), referred to as the Great Waters program, in the CAAA. The purpose of the Great Waters program is to evaluate the atmospheric deposition of air pollutants to the Great Lakes, Lake Champlain, Chesapeake Bay, and coastal waters. As required by this provision, EPA completed the Great Waters Report in May, 1994. The Great Waters Report includes information on the contribution from atmospheric deposition of pollutant loadings, the environmental or public health effects of such pollution, the source or sources of such pollution, and a description of regulatory steps EPA plans to initiate under applicable Federal laws aimed at the protection of human health and the environment.

The Great Waters Report observed that water quality conditions in the Great Lakes, among other waterbodies, are greatly improved compared to a few decades ago. Although these improvements are credited to environmental regulatory programs and public and industrial cleanup efforts that are addressing primarily waterborne pollution, the Great Waters Report cautions that the Great Waters ecosystems are far from fully recovered. The Great Waters Report adds that it is now necessary to address the more diffuse sources of pollution, including the air component, in order to attain water quality goals and to ensure protection of human health and the environment.

The Great Waters Report concluded that although specific data may be available for some waterbodies, such as Lake Superior, insufficient data are available to generalize the atmospheric loadings to all waters. Overall, scientists estimate that from 35 to 50 percent of current yearly inputs of a variety of toxic chemicals to the Great Lakes may be from the air. Adverse effects of the chemicals of concern addressed in the Great Waters Report are evident and studies of selected waters show significant proportions of toxic pollution coming from the atmosphere. Although the Great Waters Report noted that uncertainties in current information are significant, and further research is needed to better characterize the information for decisionmakers, adequate information is available to lead EPA to the conclusion that some actions are justified and necessary at this time. Because the linkage between specific sources and subsequent deposition and effects has yet to be demonstrated, however, the kinds of action recommended in the Great Waters

Report focus on the chemicals of concern (e.g., mercury, PCBs, dioxins) rather than on specific sources.

EPA considered the implications of action and of inaction, while recognizing that section 112(m) of the CAAA mandates that EPA should act to "prevent" adverse effects and to "assure protection of human health and the environment." EPA's recommendation is that specified reasonable actions are justified, based on evaluation of the scientific information currently available, and should now be taken, and that research should continue.

Most of the initial actions EPA is undertaking focus on utilizing regulatory mechanisms in the CAAA that are intended to address the most hazardous chemicals. The characteristics of toxicity, persistence, and tendency to bioaccumulate warrant special treatment of the Great Waters pollutants of concern. This is consistent with Congressional intent for those regulatory mechanisms and for section 112(m) of the CAAA.

The Great Waters Report recommended that for specific source categories of particular concern in the Great Lakes area, CAAA section 112(d) maximum achievable control technology ("MACT") standards should be issued ahead of schedule, where possible. It also recommended evaluating whether lesser quantity emission rates, as defined by section 112(a) of the CAAA, should be set for pollutants of particular concern in the Great Lakes System, and considering setting area source standards for some source categories. Following the initial Great Waters Report, the CAAA requires additional reports on a biennial basis. Based on the reports required by section 112(m) of the CAAA, EPA is required by November 15, 1995, to promulgate further emission standards or control measures under section 112 of the CAAA, if necessary to prevent serious adverse effects, or recommend necessary regulatory changes under other applicable Federal legislation.

Between 1992 and 2000, EPA must promulgate technology-based emission standards for all categories of major sources emitting the 189 toxic air pollutants listed in section 112(b) of the CAAA. Area sources will be regulated in those cases that the Administrator determines are justified in order to protect health and the environment. Within eight years of the promulgation of such standards, EPA will evaluate whether the health and environmental risk remaining after the application of the control requirements is significant enough to warrant additional regulatory requirements. To date, EPA has promulgated final technology-based standards for Resource Conservation and Recovery Act (RCRA) treatment, storage and disposal facilities, the synthetic organic chemical manufacturing industry, coke ovens, industrial cooling towers, the dry cleaning industry, halogenated solvent cleaning, magnetic tape production, commercial ethylene oxide sterilizers, and has proposed several more standards including those covering epoxy and polymer resin production, the pulp and paper industry, marine vessels, off-site waste treatment, petroleum refineries, secondary lead smelters, ship building, wood furniture manufacturing, municipal waste combusters, chromium electroplating, and gasoline distribution. New source performance standards have been proposed for several industry categories including synthetic organic chemicals, wastewater and cold-cleaning digesters. The standard for the synthetic organic chemical manufacturing industry alone is estimated to reduce toxic emissions by 510,000 tons a year (59 FR 19410, April 22, 1994). Proposed new source performance standards and emissions guidelines have been published for municipal waste combusters sources greater than 35 MG/day (56 FR 5514), and are scheduled for final promulgation in September, 1995.

Under section 112 of the CAAA, EPA may add additional substances to the list of hazardous air pollutants, including pollutants of concern in the Great Lakes, provided the criteria for additions as identified in CAAA section 112(b) are met. EPA also has discretion to add pollutants when scientific information dictates additions are warranted. Once a pollutant is listed, EPA must set technology-based standards for sources of that pollutant by the year 2000 or within two years of listing, whichever is later.

Section 112(c)(6) of the CAAA provides for a reduction in sulfur dioxide (SO2) emissions from utilities of approximately 10 million tons by 2010. The first phase of these reductions goes into effect in 1995. Not only will a portion of this reduction occur within the Great Lakes, but many of the control technologies likely to be used to achieve these reductions may reduce toxic air pollutants, such as mercury, that are specifically of concern in the Great Lakes System. In addition, under section 112(n)(1)(B) of the CAAA, EPA is conducting a study of mercury emissions from utilities and various other sources, which will include an assessment of the health and environmental effects of such emissions.

EPA will continue ongoing efforts to implement section 112 of the CAAA and other sections of the CAAA and use the results of the Great Waters Report in the development of policy and regulations that will reduce emissions of Great Waters pollutants of concern. EPA also recognizes the need for an integrated multimedia approach to the problem of air deposition and will utilize authorities beyond the CAAA to reduce human and environmental exposure to pollutants of concern.

3. ARARs and the Superfund Program

Section 121 of the CERCLA (or Superfund) establishes cleanup standards for remedial actions. Under CERCLA, remedial actions must attain a degree of cleanup that assures protection of human health and the environment. For any hazardous substances remaining on-site, the remedy must attain any applicable or relevant and appropriate standard, requirement, criteria, or limitation promulgated under any Federal or State environmental law, or any promulgated State standard requirement, criteria or limitation that is more stringent than the Federal regulations. These requirements are commonly referred to as ARARs. Under CERCLA, a requirement is applicable if the environmental law or regulation directly addresses the circumstances at a site. If not applicable, then a requirement may be relevant and appropriate if circumstances at a site are sufficiently similar to the problems or situations regulated by the requirement that it is well-suited to the site.

Among the CWA regulations that may be ARARs for CERCLA actions are the requirements governing discharges of pollutants to surface waters, including State, Tribal or Federal water quality standards. To be an ARAR, a standard must be promulgated and legally enforceable. The final Guidance is not, by itself, enforceable, and is, therefore, not an ARAR, although it could be treated as a nonbinding policy to be considered in CERCLA actions. Provisions consistent with the final Guidance will become enforceable only when adopted by a State or Tribe as part of its National Pollutant Discharge Elimination System (NPDES) or water quality standards programs, promulgated by EPA in the absence of State or Tribal action, or when included in an NPDES permit. When such adoption or promulgation occurs, those provisions will be ARARs, as appropriate, for on-site CERCLA discharges. Off-site CERCLA discharges must comply fully with all applicable Federal, State or Tribal requirements.

4. RAPs and LaMPs

The United States and Canadian Governments agreed to develop and implement RAPs and LaMPs pursuant to Article VI, Annex 2 of the GLWQA. The development of RAPs and LaMPs is also required by section 118(c)(3) and (4) of the CWA. RAPs, which are designed to address impairments to any one of 14 specified beneficial uses, are being developed for each of 43 designated Areas of Concern (AOCs). LaMPs, which are designed to address loadings of critical pollutants that are currently impairing or have the potential to impair the beneficial uses of the open waters of the Great Lakes, are being developed by EPA in conjunction with the States, Tribes and Canada on a phased basis.

a. RAPs. The RAP process consists of three stages: problem definition and identification of sources and causes of contamination; identification of remedial and preventive actions designed to restore uses;

and implementation of the RAP and the actual restoration of beneficial uses. RAPs are currently under development in all 26 U.S., 12 Canadian and five binational AOCs. To date, 40 of the 43 AOCs have established stakeholder groups, coordinating committees, public advisory councils or some other forum representative of local societal, economic, and environmental concerns. These infrastructures help to facilitate public participation in the RAP process, as well as to coordinate RAP development, implement an ecosystem approach, and build the institutional capacity to restore beneficial uses.

Each RAP is tailored to address the specific pollutant problems that are or may be present at the AOC. The Grand Calumet River/Indiana Harbor Ship Canal and nearshore Lake Michigan, for example, is the only AOC in which all 14 beneficial uses are impaired. Several of these use impairments are caused by the presence of millions to cubic meters of contaminated sediments in the waterway. RAP efforts to eliminate the causes of these use impairments include projects designed to clean up individual segments of the waterway and to prevent their recontamination. The RAP process has developed and obtained funds for a Toxic Pollution Prevention Program on the waterway and the Gary, Hammond and East Chicago Sanitary Districts have formally adopted the RAP's Common Policy on Toxic Pollution Prevention.

Restoration of impaired uses in the Grand Calumet River\Indiana Harbor Ship Canal has progressed mostly by implementing cleanup, pollution prevention, and restoration projects outside of the waterway proper. The RAP process has involved the Indiana Department of Environmental Management's (IDEM) pollution prevention staff, local industry and the general public in implementing a Household Hazardous Waste Collection Project, which began in April of 1994. Agricultural clean sweeps to collect and properly dispose of pesticides were also conducted in 1992 and 1993 in several Northern Indiana counties. Local educators have helped IDEM develop an Enviromobile which stops at area schools to educate school children on ways to prevent pollution while increasing their environmental consciousness. All of these projects directly reduce the causes of several use impairments in the AOC, and some will help to preserve and protect the AOC's globally endangered habitats and their outstanding biodiversity which is among the highest in the Great Lakes.

The Niagara River AOC is located in Erie and Niagara Counties in western New York. Past municipal and industrial discharges and waste disposal sites have been a source of contaminants to the Niagara River. A long history of development has also changed the Niagara shoreline along much of the river, affecting fish and wildlife habitat. Habitat impairment and survival of aquatic life in the AOC have been attributed to PCBs, mirex, chlordane, dioxin, dibenzofuran, hexachlorocyclohexane, polyaromatic hydrocarbons (PAHs), and other pesticides. Contaminated sediments contain metals and cyanides and are a source of use impairments to the AOC.

The Niagara River RAP represents a comprehensive and focused corrective action strategy to: remediate contaminated sediments and hazardous waste sites; continue and enhance monitoring activities; continue point and nonpoint source control programs; and improve fish and wildlife habitat. In particular, EPA and the New York State Department of Environmental Conservation (NYSDEC) are overseeing remediation at three sites along the Niagara River that are considered sources of contaminants causing use impairments in the river. Other efforts currently being pursued under this RAP process include stream water quality monitoring to estimate pollutant loadings, investigations of inactive hazardous waste sites, developing a nonpoint source loading estimation methodology for surface runoff, groundwater migration and atmospheric deposition in conjunction with Environment Canada and the Ontario Ministry of the Environment and Energy (OMEE), developing a water quality enhancement and protection policy to include discharge restriction categories, antidegradation and substance bans; working with the Buffalo Sewer Authority to continue the model development process for system sub-basins; and developing a comprehensive inventory of fish and wildlife populations and habitat. Pursuant to the Niagara River RAP, a large number of sediment remediations/removals, waste site remediations and enforcement actions on the U.S. side of the Niagara River have resulted in significant reductions (i.e., 98 percent of priority pollutants) of loadings to the river. For further examples of RAP activities, see "Progress in Great Lakes Remedial Action Plans" (EPA 905-R-24-020, 1994) available in the docket for the final Guidance.

b. LaMPs. The LaMP process integrates Federal, State and local programs that address loadings of critical pollutants, assess whether these programs ensure attainment of beneficial uses, and recommend media-specific program enhancements to reduce loadings of critical pollutants to the open waters of the Great Lakes as necessary to attain beneficial uses. LaMPs also address pollutants which might impair waters that currently attain beneficial uses.

As part of the Lake Michigan LaMP process, the Lake Michigan States (Wisconsin, Illinois, Indiana, Michigan) are evaluating the beneficial use impairments due to all stressors, including toxics, habitat quantity and quality, exotic species, and human influences. Multi-media pollution prevention projects have recently been completed or are ongoing in greater Chicago, western Michigan, and Milwaukee. Sediment assessment and remediation projects are proceeding in Illinois, Michigan and Indiana. Agricultural "clean sweeps" to properly collect and dispose of unused pesticides are continuing in Indiana, Michigan and Wisconsin, and urban "clean sweeps" are taking place in Northwest Indiana. The Lake Michigan Forum (i.e., the public participation component of the Lake Michigan LaMP), along with the Federal and State governments, also continues to foster public participation. The Forum has finalized an action plan for enhancing public outreach, education, and participation in the LaMP process.

Implementation of the Lake Michigan Enhanced Monitoring and Mass Balance Project is also proceeding in the Lake Michigan basin. This project is a cooperative effort among EPA, the U.S. Geological Survey, U.S. Fish and Wildlife Service, National Oceanic and Atmospheric Administration, National Biological Survey and the four Lake Michigan States, and supports the Lake Michigan LaMP process, GLTRE, and CAAA requirements by determining the relative loadings of several LaMP Critical Pollutants from both air and water sources to the Lake. Modeling these pollutant inputs, and determining their fate and transport, will allow the participating agencies to predict Lake Michigan system responses to various load reduction alternatives as well as to target limited resources to those pollutant sources posing the greatest risk to the health of the Lake's ecosystem, and will provide important basinwide information for use in other Great Lakes efforts. A revised Lake Michigan LaMP will be published in 1995.

On February 15, 1994, EPA published a notice of availability in the Federal Register of the proposed Stage 1 Lake Superior LaMP (50 FR 7252). The draft Lake Superior LaMP puts forward a framework for zero discharge that will further the goals of virtual elimination in the Lake Superior Basin. EPA and the Lake Superior Basin States have developed a Pollution Prevention Strategy that focuses on all sources (i.e., point and nonpoint) of the nine zero discharge pollutants (PCBs, dieldrin, chlordane, DDT and metabolites, mercury, dioxin (2,3,7,8-TCDD), toxaphene, hexachlorobenzene, and octachlorostyrene), and that identifies pollution prevention opportunities, implementation methods, and measures of success. Participating agencies have agreed to develop a Binational Pollution Prevention Strategy, using the EPA's National Pollution Prevention Strategy as a template. A final Lake Superior LaMP will be complete in 1995.

The workplan for the Lake Ontario Lakewide Management Plan for Critical Pollutants was finalized in November 1993. Target dates include the completion of the development of this LaMP in three stages: Stage I is anticipated to be completed in April 1995; Stage II by December 1995; and Stage III will be complete by the end of December 1996. Also, a work group has been formed to develop a Lake Ontario LaMP Public Forum. The Coordination Committee (water division managers from EPA, NYSDEC, Environment Canada and the OMEE) and Secretariat (technical staff from these same agencies) members are discussing options for the LaMP management structure and incorporating other agencies into the LaMP process when dealing with issues beyond Critical Pollutants.

In the spring of 1993, EPA and Environment Canada formed a temporary Binational Implementation Committee to develop a concept paper that would provide a framework for the development of the Lake Erie LaMP, and to organize a LaMP Management Committee to oversee LaMP development. Representatives of the U.S. and Canadian Federal, State, and Provincial governments met in September 1994 to formally convene a binational Management Committee to oversee development of the Lake Erie LaMP. The Management Committee approved the Lake Erie LaMP concept paper, which describes the proposed focus, scope, and management structure of the Lake Erie LaMP. As outlined in the concept paper, the Lake Erie LaMP will address a number of environmental issues above and beyond toxic substances, including habitat destruction, exotics, and nutrient loadings. The Management Committee also charged a staff-level work group to initiate a variety of LaMP activities.

In addition, EPA expects any new loadings data obtained during the LaMP process will be incorporated by the States and Tribes when establishing or revising TMDLs and wasteload allocations (WLAs) in the Great Lakes System. These new TMDLs and WLAs will then be appropriately reflected in subsequent revisions to NPDES permits.

5. Sediments

Contaminated sediments are a significant source of loadings of toxic pollutants at harbors and river mouths throughout the Great Lakes System. To address this source of toxic pollutant loadings, the 1987 CWA Amendments authorized a five-year demonstration program to identify and develop assessment and treatment technologies for contaminated sediments in the Great Lakes basin (CWA section 118(c)(7)). This program, known as the Assessment and Remediation of Contaminated Sediments (ARCS) Program, was designed to evaluate appropriate assessment and treatment methodologies for the cleanup of toxic pollutants in Great Lakes contaminated sediments. The information developed through the ARCS Program will help support implementation of RAPs by providing guidance to effectively address the contaminated sediment problems in designated AOCs.

Contaminated sediments have been identified as environmental problems in 42 of the 43 AOCs. The 1987 CWA Amendments also specified five AOCs for priority consideration in conducting the demonstration projects. These AOCs are Saginaw Bay, Michigan; Sheboygan Harbor, Wisconsin; Grand Calumet River, Indiana; Ashtabula River, Ohio; and Buffalo River, New York. (Id.)

EPA successfully completed the ARCS Program in 1994. Approximately 40 documents will be published by early 1995 which discuss the findings of the sediment assessment work, risk assessment studies, mass balance modeling results, and results of the pilot demonstrations. Three guidance documents on risk assessment, sediment assessment, and treatment technologies have been published. Technology transfer workshops, which covered such topics as sediment assessments, mass balance modeling, and determining contaminant losses from dredging and disposal projects, have been held at a number of locations throughout the Great Lakes basin.

A key component of the ARCS Program was the public outreach and involvement that was maintained throughout the demonstration process. Information on ARCS Program activities has been widely distributed to the public in the form of ARCS Update fact sheets, news releases, a slide show, and public meetings. The ARCS Program has also made all written documentation accessible by setting up repositories for ARCS Program materials in local libraries at the five ARCS priority locations.

The final summary report on ARCS program results was presented to Congress in the fall of 1994 and is available in the docket for the final Guidance. The conclusions contained in the final summary report discuss the state-of-the-art methods the ARCS Program demonstrated for the assessment of contaminated sediments, especially in the area of toxicity testing, and the new ground broken by the ARCS Program in the application of the mass balance modeling approach. The ARCS Program made significant contributions to the knowledge base on contaminated sediment remediation by selecting promising treatment technologies, taking them out into the field, and demonstrating their effectiveness on site.

The major findings of the ARCS Program consisted of the need to perform thorough, integrated sediment assessments; the importance of mass balance modeling in the evaluation of remediation scenarios; the identification and demonstration of several feasible sediment treatment technologies; and the recognition and success of public involvement and active participation in sediment assessment and remediation projects. The field assessment, contaminant fate modeling, risk assessment, and remediation technology techniques demonstrated in the ARCS Program have improved the knowledge base and will enable Federal, State and local officials to make scientifically sound remediation decisions.

The products of the ARCS Program will not, by themselves, eliminate the problems posed by contaminated sediments, nor do they propose one "cure all" treatment technology for their remediation. They do, however, provide guidance for the selection of sediment assessment and treatment technologies as well as recommendations for future full-scale applications. The results and products from the ARCS Program will have far-reaching implications for the remediation of contaminated sediments within the Great Lakes as well as on a nationwide basis.

At the time the proposed Guidance was published, EPA was also preparing to publish for public comment proposed sediment quality criteria for five organic chemicals. EPA's proposed sediment quality criteria are intended to protect benthic organisms from unacceptable effects of chemicals associated with sediments. The proposed sediment quality criteria, however, do not protect against additive, synergistic or antagonistic effects of contaminants, or bioaccumulative effects to aquatic life or humans. Implementation of the final Guidance will complement the proposed sediment quality criteria in these areas.

In January 1994, EPA announced in the Federal Register the availability of the draft sediment quality criteria for three polycyclic hydrocarbons (acenaphthene, fluoranthene and phenanthrene) and two pesticides (endrin and dieldrin). The public comment period for these criteria documents ended in June 1994, and EPA is now in the process of developing final sediment criteria.

At the time of the proposal, EPA was also in the process of developing a proposed National Contaminated Sediment Management Strategy. On August 30, 1994, EPA announced in the Federal Register the availability of the proposed comprehensive, multimedia Strategy. The proposed Strategy describes specific actions that EPA will take to reduce environmental and human health risks associated with contaminated sediments. The Strategy also defines a plan of action to address the National problem of contaminated sediments and to streamline decision-making within and among EPA programs. EPA accepted comments on the Strategy through October 31, 1994, and is currently reviewing the comments. The proposed Strategy is available in the docket for the final Guidance.

Implementation of EPA's National Strategy has been proceeding in the Great Lakes basin, with emphasis on the Great Lakes AOCs. Programs in EPA and the States have been assessing sediment contamination and utilizing a range of regulatory tools to address the most contaminated sites. Some examples of remediation activity are the sediment cleanups that have taken place at Waukegan Harbor in Illinois, the Black River in Ohio, Cedar Creek near Milwaukee, Wisconsin, and in East Chicago, Indiana. Settlements have also been reached in enforcement actions with responsible parties for sediment cleanup for sites in Gary and East Chicago, Indiana. Among the actions being pursued are those for: Manistique River/Harbor in Manistique, Michigan; the River Raisin near Monroe, Michigan; Ashtabula River and Fields Brook near Ashtabula, Ohio; Grand Calumet River in Hammond, Indiana; and Sheboygan River/Harbor near Sheboygan, Wisconsin.

E. Science Advisory Board Review

Information concerning EPA's Science Advisory Board (SAB) and their review of the draft Water Quality Guidance for the Great Lakes System prior to proposal is contained in the preamble to the proposed Guidance (58 FR at 20826). During the process of developing the final Guidance, EPA met with the SAB from April 27-29, 1994, to discuss the development of a National methodology for developing wildlife criteria and bioaccumulation factors. EPA considered and addressed the SAB's comments pertaining to the Great Lakes System in preparing the final Guidance. Some of these comments are discussed in the applicable sections of this document that follow. The final SAB report is also included in the docket for the final Guidance.

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II. REGULATORY REQUIREMENTS

A. Scope and Purpose

Section 118(c)(2) of the Clean Water Act ("CWA") (Pub. L. 92-500 as amended by the Great Lakes Critical Programs Act of 1990, Pub. L. 101-596) requires EPA to publish final water quality guidance on minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System. Part 132, including appendixes A through F, constitutes the Water Quality Guidance for the Great Lakes System required by section 118(c)(2).

The Guidance fulfills the requirements of section 118(c)(2) and is generally organized as follows:

-- Water quality standards: The Guidance contains numerical water quality criteria for 29 pollutants, listed in Tables 1 through 4 of part 132. The Guidance also contains methodologies for the development of water quality criteria and water quality values for the protection of aquatic life, human health, and wildlife, and a methodology for development of bioaccumulation factors, in appendixes A through D. Together, these criteria and methodologies specify minimum numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life, and wildlife.

-- Antidegradation policy: The minimum antidegradation policy, including an antidegradation standard, implementation procedures, demonstration provisions, and decision provisions are contained in appendix E.

-- Implementation procedures: Minimum implementation procedures are contained in appendix F to part 132.

B. Definitions

1. Proposal. Section 132.2 of the proposed Guidance contained definitions of 71 terms that would apply to part 132. EPA proposed the definitions as a partial list of terms which need to be defined for consistent interpretation of the Guidance. Proposed § 132.4(a) provided that Great Lakes States and Tribes were to adopt requirements applicable to waters of the Great Lakes System for the purposes of sections 118, 303, and 402 of the CWA that are consistent with these definitions, or be subject to EPA promulgation under § 132.5. Other definitions, bearing on the individual portions of the Guidance, were contained in proposed appendixes A through F. Generally, where terms were applied in the proposed Guidance in the same manner as in previous National regulations, such as those in 40 CFR 122.2, 130.2, and 131.3, the proposal did not provide a duplicate definition. In some cases, however, the proposal provided a duplicate definition to assist the reader.

2. Comments. Several comments recommended that EPA resolve differences between definitions proposed in § 132.2 and those proposed in various appendixes to part 132.

A number of comments were received on definitions that are discussed elsewhere in this document. These include: the definition of "bioaccumulative chemical of concern," discussed further in section II.C.8 of this document; and the definition of "existing discharger," discussed further in section VIII.I of this document.

One comment recommended deleting the definition of "reasonable potential." EPA agrees. Since the definition of "reasonable potential" is not necessary to implement the Guidance, EPA has deleted the definition.

Technical and editorial comments were also received concerning a number of definitions.

EPA agrees that definitions should be consistent throughout the Guidance. In some cases, as discussed below under the Final Guidance section, definitions have been modified or deleted from § 132.2 to eliminate such inconsistencies.

EPA agrees with the majority of technical and editorial comments received, and has made changes accordingly. Some of these changes are discussed further under the Final Guidance section below. EPA's responses to individual technical and editorial comments on definitions in § 132.2 are included in the docket for this rulemaking.

3. Final Guidance. Section 132.2 of the final Guidance includes 56 definitions, reflecting deletion of 17 proposed definitions, and addition of two new definitions. Thirty six definitions were clarified or modified, and 18 were unchanged.

The following definitions have been deleted from § 132.2 because they are defined adequately in one or more of the appendixes: "acceptable daily exposure (ADE)," "acute toxic unit (TU_a)," "biomagnification," "chronic toxic unit (TU_c)," "depuration," "dilution fraction," "linear multi-stage model," "octanol/water partition coefficient (K_{OW})," "relative source contribution (RSC)," and "slope factor."

The definition of "allowable dilution flow (Q_{ad})" has been deleted from § 132.2. In response to comments, changes have been made to the final procedure 3 of appendix F that made this definition unnecessary. This change is discussed further in section VIII.C of this document.

The definition of "compliance evaluation level (CEL)" has been deleted because the term is no longer used. This change is discussed further in section VIII.H of this document.

The definition of "existing uses" has been deleted to because it duplicates the definition in 40 CFR 131.3.

EPA deleted the proposed definition of "noncarcinogen" because it should be clear that a noncarcinogen is any substance which is not a carcinogen. Furthermore, EPA found that the proposed definition could have been confusing when compared to the definition of "carcinogen."

The definition of "reasonable potential" has been deleted from § 132.2 as discussed in Comments above.

The definitions of "steady-state BAF/BCF" and "superlipophilic chemicals" were deleted, since revisions to the methodology for development of BAFs made the terms unnecessary. These changes are discussed further in section IV of this document.

The definition of "biota-sediment accumulation factor (BSAF)" has been added, and is discussed in section IV of this document.

The definition of "new Great Lakes discharger" has been added, and the definition of "existing discharger" has been modified and redefined as "existing Great Lakes discharger." Together, the two definitions categorize all discharges to waters of the Great Lakes System depending on whether the construction of buildings, structures, facilities, or installations generating the discharge commenced before ("existing") or after ("new") March 23, 1997. Under procedure 3 of appendix F, mixing zones for BCCs are not available to new Great Lakes dischargers after March 23, 1997; for existing Great Lakes dischargers, mixing zones for BCCs are generally not available after March 23, 2007 except under specified circumstances. These provisions are discussed more fully in section VIII.C of this document. Under procedure 9 of appendix F, NPDES permits may allow compliance schedules under certain circumstances to existing Great Lakes dischargers but not to new Great Lakes dischargers. These provisions are discussed more fully in section VIII.J of this document.

The definition of "bioaccumulative chemical of concern (BCC)" has been modified, and is discussed in section II.C of this document.

The definition of "carcinogen" has been clarified to add a reference to a discussion of the classification of carcinogens in section II.A of appendix C to the final Guidance.

The definition of "chronic toxicity" has been clarified to add reference to "delayed adverse effects" to reflect EPA's concern that pollutants such as 2,3,7,8-tetrachlorodibenzo-p-dioxin (2378-TCDD) have been observed to cause delayed adverse effects days, weeks, or even months after exposure. See, for example, "Interim Report on Data and Methods for Assessment of 2378-TCDD Risks to Aquatic Life and Associated Wildlife," EPA, March 1993 (EPA 600/R-93/055), which is available in the docket for this rulemaking.

The definition of "Great Lakes States and Great Lakes Tribes" has been modified to clarify that an Indian Tribe in the Great Lakes basin would be a "Great Lakes Tribe" subject to the provisions of the final Guidance only if EPA has approved water quality standards for the Tribe, or if EPA has authorized the Tribe to administer an NPDES program. This clarification was necessary because the Guidance provisions for water quality standards would be meaningless unless at least a basic set of standards are in place, including designated uses, narrative criteria, and legal authority references. Similarly, the Guidance provisions for NPDES permits would be meaningless unless the Tribe has been authorized to administer an NPDES program. Provisions applicable to Tribes are discussed further in section II.D.3 of this document.

The definition of "Tier II value" has been modified, and is discussed in sections II.C.2 and VI of this document.

The definition of "wet weather point source" has been modified to incorporate the existing definition of point source contained in § 122.2, for the convenience of the reader. Furthermore, in response to comments and to clarify possible ambiguities in the proposal, EPA has modified the definition in the final Guidance to clarify that the definition includes only certain types of discharges, to specify the types of excluded discharges more explicitly, and to delete an unnecessary definition of combined sewer overflow. The exclusion for wet weather point sources is discussed in section II.C.7.

The following definitions were modified to make technical clarifications and corrections: "acute toxicity," "acute-chronic ratio (ACR)," "bioaccumulation," "bioaccumulation factor (BAF)," "bioconcentration," "bioconcentration factor (BCF)," "chronic toxicity," "criterion continuous concentration (CCC)," "criterion maximum concentration (CMC)," "EC50," "endangered or threatened species," "final acute value (FAV)," "final chronic value (FCV)," "final plant value (FPV)," "Great Lakes System," "human cancer value (HCV)," "human noncancer value (HNV)," "LC50," "minimum level (ML)," "no observed adverse effect level (NOAEL)," "no observed effect concentration (NOEC)," "quantification level," "quantitative structure activity relationship (QSAR)," "risk associated dose (RAD)," "species mean acute value (SMAV)," "species mean chronic value (SMCV)," "stream design flow," "uncertainty factor (UF)," "uptake," and "wasteload allocation (WLA)."

The following definitions are the same as proposed, or the same with editorial corrections: "adverse effect," "connecting channels of the Great Lakes," "detection level," "Federal Indian Reservation," "genus mean acute value (GMAV)," "genus mean chronic value (GMCV)," "Great Lakes," "human cancer criterion (HCC)," "human noncancer criterion (HNC)," "Indian Tribe," "load allocation (LA)," "loading capacity," "lowest observed adverse effect level (LOAEL)," "open waters of the Great Lakes," "threshold effect," "Tier I criteria," "total maximum daily load (TMDL)," and "tributaries of the Great Lakes System."

C. Adoption and Application of Criteria, Methodologies, Policies, and Procedures

1. Adoption of Tier I Criteria and Methodologies

a. Proposal. The proposed Guidance included a two-tiered approach, consisting of methodologies to develop water quality criteria (Tier I), and methodologies to calculate water quality values (Tier II) with fewer data than the full minimum data required for a Tier I criterion calculation. The purpose of Tier II methodologies is to provide a uniform approach for evaluating and controlling pollutants when there are insufficient data to develop Tier I criteria. In the absence of State- or Tribal-adopted Tier I criteria for a pollutant, the Tier I and Tier II methodologies provide mechanisms with which to interpret and ensure that the States' and Tribes' narrative criteria prohibiting the discharge of toxic pollutants in toxic amounts are reflected in water quality-based effluent limits. The preamble to the proposed Guidance described the two-tiered approach in more detail (58 FR 20835; April 16, 1993).

Proposed § 132.4(a) provided that Great Lakes States and Tribes were to adopt Tier I methodologies for developing numeric water quality criteria to protect aquatic life, human health, and wildlife consistent with those specified in appendixes A through D, or be subject to EPA promulgation under § 132.5.

Upon State or Tribal adoption or EPA promulgation of the Guidance, proposed § 132.4(b) specified that Great Lakes States or Tribes would have used the Tier I methodologies in appendixes A, C, and D and the methodology in appendix B when adopting or revising numeric water quality criteria. In addition, if a Great Lakes State or Tribe had not adopted a numeric water quality criterion for a pollutant in its water quality standards, but enough data existed to meet Tier I minimum data requirements, proposed § 132.4(c) provided for use of the Tier I methodologies for any development of numerical criteria to implement narrative criteria. Such implementation would include development of water quality-based effluent limits, where appropriate.

The proposed Guidance also included numeric criteria in Tables 1 through 4 of part 132 that were derived using the Tier I methodologies. Proposed § 132.3 would have required Great Lakes States and Tribes to adopt these specific numeric criteria or more stringent criteria into their water quality standards for the Great Lakes System or be subject to EPA promulgation under § 132.5.

b. Comments. EPA received a number of comments on the requirements for adopting additional Tier I criteria beyond those listed in Tables 1 through 4 of part 132, and for revising the criteria in the Tables. Many commenters supported the proposed approach because it would ensure increased consistency among the water quality standards of Great Lakes States and Tribes. Other commenters urged EPA to provide more flexibility to States and Tribes in adopting criteria consistent with the Guidance, including the flexibility to modify the criteria in Tables 1 through 4 to reflect new scientific findings and data. Many commenters argued that the criteria methodologies and the criteria in Tables 1 through 4 should be provided as non-binding guidance.

A large number of comments also suggested that EPA should be responsible for developing any new or revised Tier I criteria as additional data become available and are evaluated. These commenters believe that it is more efficient for EPA to develop criteria than for States or dischargers who may not have the expertise or resources to develop criteria independently. Some of these commenters also suggested that EPA should ensure full public review of such new or revised criteria. Some commenters also urged EPA to amend Tables 1 through 4 in future EPA rulemakings. Additionally, a few commenters were concerned that the Guidance as proposed may not provide sufficient protection to endangered or threatened species from pollutants that may be found to have particularly potent effects.

EPA agrees that it is important for States and Tribes to have the flexibility to modify criteria and values, including the criteria in Tables 1 through 4, in appropriate circumstances when new scientific findings and data become available. EPA has determined that the proposed minimum requirements, together with changes to the procedure for site-specific criteria modifications in the final Guidance, as well as EPA's planned approach to assist States and Tribes in implementing the Guidance, provide adequate flexibility for incorporating new information without sacrificing the improved consistency in Great Lakes water quality standards envisioned in the Great Lakes Critical Programs Act ("CPA").

Site-specific criteria modifications provide a degree of flexibility to incorporate new scientific findings and data as they may affect a specific waterbody. EPA has retained the provisions allowing site-specific modifications to criteria developed under the Guidance, including criteria in Tables 1 through 4, and has expanded the flexibility of the provisions to allow less restrictive site-specific modifications for aquatic life, human health and wildlife criteria under certain conditions using the final procedure 1 of appendix F. These provisions are discussed further in section VIII.A of this document.

Additionally, there are several steps within the criteria methodologies where flexibility is available to reflect new findings and data. For example, although EPA states a preference for using the linearized multistage model when deriving human health criteria, the final Guidance allows the use of different models if the data support their use. In addition, the final Guidance recognizes that the EPA methodology for conducting cancer risk assessments is currently under review and that any changes adopted by EPA can be incorporated by the States and Tribes. Also, the section VIII.A of appendix B provides that BAFs derived in accordance with the BAF methodology in the final Guidance should be modified if changes are justified by available data.

EPA's planned approach for implementing the final Guidance will further facilitate flexibility to incorporate new scientific findings and data. EPA intends to expand the future assistance it provides to Great Lakes States and Tribes over that envisioned at the time of the proposal. EPA's planned implementation is as follows:

-- EPA Region 5, in cooperation with EPA Regions 2 and 3 and Headquarters offices, and the Great Lakes States and Tribes, will establish a Great Lakes Initiative (GLI) Clearinghouse to assist States and Tribes in developing numeric Tier I water quality criteria and Tier II water quality values. Further information about the GLI Clearinghouse is available from the address listed at the beginning of this document. As additional toxicological data and exposure data become available or additional Tier I numeric criteria and Tier II values are calculated by EPA, States, or Tribes, Region 5 will ensure that this information is disseminated to the Great Lakes States and Tribes.

-- EPA Region 5 will work with the States and Tribes, EPA Regions 2 and 3, EPA Headquarters offices, and EPA research laboratories to review new toxicological and exposure data. The review will include consideration of data quality and appropriateness for use with the Guidance methodologies. For pollutants of especially high interest and/or concern, Region 5 and the other

EPA offices identified above intend from time-to-time to use the Clearinghouse information to develop GLI criteria guidance documents similar to those supporting the proposed and final Guidance. EPA will then publish a notice in the Federal Register announcing the availability of such documents and inviting public comment on them. After reviewing the comments, EPA will finalize the GLI criteria guidance documents and make them available as guidance to Great Lakes States and Tribes. The GLI criteria guidance documents would represent EPA's best current information about effects of the pollutants in the Great Lakes System. The GLI criteria guidance documents could address either or both Tier I criteria and Tier II values.

-- Regions 2, 3 and 5, through their review and approval of State water quality standards under section 303 of the CWA, will work with the States to ensure that all Great Lakes States and Tribes maintain a minimum consistent level of protection for aquatic life, human health, and wildlife throughout the Great Lakes System consistent with the methodologies in the final Guidance. EPA will also make a special effort to encourage Great Lakes States and Great Lakes Tribes to adopt criteria based on any newly calculated GLI criteria guidance documents in the next triennial review of water quality standards under section 303. If such efforts are not successful for all States, EPA could evaluate use of section 303(c)(4), if appropriate, to determine that a particular State or Tribe needed new or revised water quality standards reflecting the new criteria, and promulgate Federal criteria if necessary for that State or Tribe to ensure minimum consistent criteria are present in all States and Tribes.

EPA believes the above plans will provide the flexibility to incorporate new data into water quality criteria development. For example, if new data become available that would result in significant changes to criteria in Tables 1 through 4, EPA may use the above process to develop one or more revised GLI criteria guidance documents. EPA would then work with the States and Tribes in their adoption of the revised criteria. If the revised criteria are more stringent than the corresponding criteria in Tables 1 through 4 of part 132, States and Tribes would be able to adopt them without further EPA rulemaking. If the revised criteria are less stringent than the corresponding criteria in Tables 1 through 4 of part 132, EPA would consider initiating a rulemaking action to delete or revise criteria in the Tables if necessary to allow or facilitate State and Tribal adoption of the less stringent criteria.

It is also possible that the new information could be so substantial that it makes some criteria in Tables 1 through 4 scientifically indefensible. In this situation, States or Tribes could utilize the provisions in § 132.4(h) to adopt new criteria even if they were less stringent than criteria in Tables 1 through 4 without further EPA rulemaking. EPA expects that this situation would occur rarely, if at all.

The above plans will also result in an efficient use of resources to develop additional criteria and values where they are most needed. Furthermore, this approach provides more flexibility than the alternative of EPA conducting a rulemaking every time any additional data could support a modification to a criterion in Tables 1 through 4. Finally, the final Guidance retains the existing State and Tribal responsibility to adopt water quality standards as necessary under the CWA without waiting for EPA to develop detailed criteria guidance. At the same time, however, the involvement of EPA in facilitating the review of data, developing GLI criteria guidance documents as appropriate, in conjunction with continued oversight of the section 303 water quality standards programs will contribute to more consistent criteria in the future throughout the Great Lakes System.

EPA considered but rejected the suggestion of some commenters that the criteria methodologies and the numeric criteria in Tables 1 through 4 of part 132 should be provided as guidance but not specified as minimum requirements for State and Tribal adoption. First, EPA does not believe that the suggested approach would satisfy the requirements of section 118(c)(2). That section not only directs EPA to provide guidance to the Great Lakes States on "minimum" water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System, but also requires the States to adopt provisions consistent with the guidance or be subject to EPA promulgation. EPA believes that whether States and Tribes adopt standards, policies, and procedures consistent with the final Guidance, or whether EPA promulgates them, Congress intended that the final Guidance would establish minimum requirements for the Great Lakes System. This issue is discussed further in section II.D.2 of this document.

Second, the suggested approach could result in significant variations between State and Tribal programs submitted under section 118(c)(2)(C). As discussed in the preamble to the proposed Guidance, the establishment of more uniform control of water pollution in the Great Lakes System was one of the most important goals of the CPA, and the 1986 Great Lakes Toxic Substances Control Agreement signed by the eight Great Lakes Governors (58 FR 20820-23, and 20838-39). Progress toward this goal will not be achieved unless the Guidance specifies the "minimum" requirement for the Great Lakes System.

Similarly, EPA considered but rejected an alternative approach that would retain the provisions for States and Tribes to adopt criteria consistent with the criteria in Tables 1 through 4, but would provide the methodologies in appendixes A through D as guidance but not specified as minimum requirements for State and Tribal adoption. EPA believes the criteria in Tables 1 through 4 are necessary to protect human health, wildlife, and aquatic life in the Great Lakes System, but is concerned that these criteria alone would not be sufficient. The pollutants in Tables 1 through 4 are good examples of pollutants in the Great Lakes System, but they are clearly not the only criteria necessary to protect human health, wildlife and aquatic life in the Great Lakes System. For example, in sections I and II of this document EPA identifies BCCs as a category of pollutants of high concern in the System, yet because of the limited time and resources available to develop the proposed and final Guidance, Tables 1 through 4 do not contain criteria for all 22 currently-identified BCCs. Also, in some cases a pollutant that appears in only one of the four Tables would be likely to have a lower criterion in another of the Tables if the other criteria were developed. For these reasons, EPA believes that the final Guidance must also continue to provide for State and Tribal adoption of criteria methodologies consistent with appendixes A though D in order to increase the consistency between water quality criteria and permit limits throughout the Great Lakes System and to satisfy EPA's obligation to specify minimum requirements necessary to protect human health, wildlife, and aquatic life.

EPA also considered but rejected an alternative approach under which States and Tribes could use the Guidance's criteria methodologies to adopt and submit for EPA review criteria less stringent than those in Tables 1 through 4 solely on the basis of new data or information. Such an approach would have two major problems. First, it would be difficult to develop an operational definition for "new" data that would define all factors necessary for concluding that data and information were sufficiently new or significant to justify EPA approval of a submitted criterion less stringent than in Tables 1 through 4. States, Tribes and EPA would also face an additional administrative burden of determining whether particular data sets met the definition.

Second, although this approach would enable new data to be incorporated rapidly, EPA is concerned that it could result in significant departures from the increased uniformity supported by EPA and the States and envisioned in the CPA. For example, one State could use a new toxicological study to develop and adopt less stringent criteria before EPA and other experts participating in the GLI Clearinghouse described above could review the quality and appropriateness of the study. EPA believes such peer review is desirable for all pollutants, but especially for pollutants such as those in Tables 1 through 4 that have benefitted from extensive EPA, State, and public review, and include pollutants of widespread concern and interest in the Great Lakes System. These numeric criteria and methodologies were initially developed by technical experts from EPA, the Great Lakes States, the U.S. Fish and Wildlife Service, and other participants in the Great Lakes Water Quality Initiative, who are familiar with the data form and the unique characteristics of the Great Lakes System. During the development of the Guidance, this cooperative effort to review and process toxicological data also resulted in a high degree of consensus for the numeric criteria in Tables 1 through 4. If EPA and the other participants had unlimited time and resources, it would be desirable to utilize the same process for all pollutants requiring numeric criteria.

EPA believes that the implementation plans discussed above provide a reasonable and systematic way to incorporate the effects of new data into water quality criteria development without the disadvantages of the alternative approach. Additionally, as discussed further below, the Guidance provides adequate flexibility to the States and Tribes to modify the criteria in Tables 1 through 4. This flexibility is provided through § 132.4(i), which preserves State and Tribal authority to adopt more stringent provisions; through § 132.4(h) which provides for more or less stringent modifications based on scientific indefensibility and is discussed in section II.C.6 of this document; and through § 132.3 which provides for more or less stringent site-specific modifications of the criteria in the circumstances specified in procedure 1 of appendix F.

EPA also does not believe that it is necessary or appropriate for EPA to be solely responsible for developing new or revised Tier I criteria, or to make State or Tribal adoption of new or revised criteria contingent on EPA amendment of Tables 1 through 4 of part 132 in future rulemakings. The CWA has always placed the primary responsibility for developing and adopting criteria on the States and Tribes approved to administer water quality standards programs. If the final Guidance were to alter this relationship and make EPA responsible in the future for developing and/or conducting rulemaking for all new or revised criteria, State and Tribal adoption of criteria that might otherwise be necessary to protect aquatic life, human health, or wildlife and for which data were available could be significantly delayed. EPA believes that the provision for States to adopt the methodologies found in appendixes A through D, together with the information exchange and peer review that will occur through the operation of the GLI Clearinghouse, will provide the States and Tribes with an adequate framework for ensuring consistent and timely interpretation of narrative standards. At the same time, EPA recognizes that there are some situations, especially with toxic pollutants of high concern and interest, where additional EPA involvement in criteria development is desirable. Furthermore, EPA's planned involvement in coordinating and disseminating information will maximize efficient use of limited State, Tribal, and Federal resources. For this reason, EPA is prepared to participate actively in operating the GLI Clearinghouse described above, and is committed to working with States and Tribes to develop, review, analyze, and disseminate data, and to develop GLI criteria guidance documents as necessary in accordance with available resources.

EPA also agrees with comments that EPA could help facilitate public review of the adoption of new or revised criteria, and implementation of the criteria in NPDES permits. Under 40 CFR 131.20, States and Tribes are to provide an opportunity for public participation in adoption or revision of water quality standards. Under 40 CFR 123.25, States implementing the NPDES program are to provide an opportunity for public participation during development of discharge permits. EPA believes the GLI Clearinghouse will assist States and Tribes in implementing these responsibilities by providing an additional opportunity for the public to review data that may be used in the development of future water quality standards and NPDES permit limits. Furthermore, EPA intends to provide an opportunity for public review and comment before finalizing any future GLI criteria guidance documents.

Finally, EPA agrees with commenters that it is important to incorporate into regulatory programs any new toxicological data which shows that a threatened or endangered species--or a surrogate for such species--is particularly sensitive to a pollutant. EPA believes the implementation plans described above will ensure that endangered or threatened species are adequately protected. For example, when relevant new data become available, the data will be placed in the GLI Clearinghouse where they will be available to States, Tribes, and other interested persons. EPA will place special emphasis in the Clearinghouse on data relevant to protection of endangered or threatened species, and will alert States and Tribes to data that indicate unusual sensitivity of these species or their surrogates in the Great Lakes basin. EPA and the U.S. Fish and Wildlife Service will also work with States and Tribes to identify sites where special protection may be recommended. States and Tribes must use such data wherever appropriate in their water programs, and EPA will evaluate these actions during the triennial reviews of water quality standards under section 303(c) of the CWA. Before approving State and Tribal water quality standards, EPA will ensure that they are not likely to jeopardize the continued existence of any listed endangered or threatened species, or result in the destruction or adverse modification of such species' critical habitat. EPA could not approve State or Tribal adoption of a criterion that does not adequately protect endangered or threatened species. EPA's implementation of the Endangered Species Act is discussed further in section II.G of this document.

c. Final Guidance. For the reasons above, the proposed minimum requirements regarding Tier I criteria and methodologies generally have been retained in the final Guidance.

In response to issues and comments discussed elsewhere in this document, the minimum required application of the Tier I methodology for development of wildlife criteria has been limited to BCCs. This change is reflected in § 132.4(a)(5), § 132.4(d)(4), and appendix D to part 132, and is discussed further in section VI of this document. The final Guidance retains the proposed provisions to apply the Tier I methodologies for human health and aquatic life to all pollutants except those in Table 5 of part 132.

2. Adoption and Application of Tier II Methodologies

a. Proposal. The proposed Guidance included a mechanism to interpret and ensure that existing narrative prohibitions against the discharge of toxic substances in toxic amounts are reflected in water quality-based effluent limitations in a consistent way throughout the Great Lakes System, even where data are limited. If a State or Tribe has not adopted a numeric water quality criterion for a pollutant and insufficient data exist to meet Tier I minimum data requirements, proposed § 132.4(c) would provide for application of Tier II methodologies to develop Tier II values to implement the narrative criteria. Additionally, if sufficient data to calculate a Tier II value for a pollutant on Table 6 of part 132 do not exist, procedure 5 of the proposed implementation procedures (appendix F to part 132) provided that the permitting authority, under specified circumstances, would generate or require the permittee to generate the data necessary to derive Tier II values.

The above approach is consistent with existing EPA national regulations at 40 CFR 122.44(d)(vi) which require permit authorities to establish effluent limits for individual pollutants or indicator parameters under specified circumstances when the pollutant is present in the effluent at a concentration that causes, has the reasonable potential to cause, or contributes to an excursion above any water quality standard, including numeric and narrative criteria for water quality. This approach is discussed further in section VIII.E of this document.

b. Comments. EPA received many comments objecting to the inclusion of Tier II methodologies in the Guidance. Among the concerns raised were that the Tier II methodologies are not scientifically valid for use in determining water quality-based effluent limits, that it is inappropriate to encourage dischargers to generate data to be used in development of Tier II values, that such data generation is too costly and time-consuming, and that the Tier II methodologies are overly restrictive. A large number of comments singled out the Tier II methodology for aquatic life as a particular concern because it allows use of fewer data than the established national aquatic criteria methodology, because values are adjusted to be more restrictive when fewer data points are available, and because of possible overlap with the implementation procedure for whole effluent toxicity. Many comments singled out the Tier II methodology for wildlife because of concerns about the appropriateness of the scientific approach. Some commenters suggested the use of biological tests such as whole effluent toxicity tests and bioconcentration testing in place of the Tier II methodologies for numerical pollutant-specific values. Some commenters suggested that anti-backsliding and antidegradation requirements would prevent future adjustments in Tier II numbers when more data become available. Some commenters suggested that EPA should have the responsibility to generate Tier II values.

EPA also received a number of comments supporting the proposed use of Tier II methodologies in the Guidance. These comments indicated that it is critical for the waters of the Great Lakes System that toxic substances not remain unregulated simply because adequate data to calculate a Tier I criterion are not available. These commenters also believe that the proposed approach properly places the burden of proof on dischargers to demonstrate that their discharges will not damage the aquatic ecosystem or human health.

With regard to the aquatic life methodology, EPA carefully reviewed the concerns of commenters about potential overlap between Tier II requirements for aquatic life and the appendix F requirements for whole effluent toxicity testing. The final Guidance clarifies and elaborates on the option of using indicator parameter limits under 40 CFR 122.44(d)(1)(vi)(c). A full discussion of the use of the indicator parameter option and its role in the final Guidance appears in section VIII.E of this document. As discussed in that section of the document, the State or Tribe is still required to adopt the Tier II methodology for aquatic life. As described in procedure 5 of the final Guidance, States and Tribes will then be required under this Guidance to implement the Tier II values through water quality-based effluent limitations (WQBEL) based on such values when, under procedure 5, such limits are determined to be required. When deriving limits to meet Tier II values, States and Tribes have the option of using an indicator parameter limit, including use of a WET limit under appropriate conditions, in lieu of a Tier II-based limit. If an indicator parameter is used, the State or Tribe must ensure that the indicator parameter will attain the "applicable water quality standard" (as described in 40 CFR 122.44(d)(1)(vi)(C). The "applicable water quality standard" in this instance would be the State's or Tribe's narrative water quality standard that protects aquatic life, as interpreted using the Tier II methodology.

EPA does not agree, however, with comments that questioned the scientific validity of the proposed aquatic life Tier II methodology. EPA has reviewed commenters' concerns, and concluded that the Tier II approach is scientifically sound and necessary for the Great Lakes System, and is appropriate for development of water quality-based effluent limits. Furthermore, EPA does not agree with comments that the methodology is overly restrictive. For these reasons, the proposed aquatic life Tier II methodology is retained in the final Guidance. Further discussion of this issue is found in section III of this document.

EPA also does not agree with comments that the proposed human health Tier II methodology is not scientifically valid. A full discussion of this issue is found in section V of this document.

EPA does agree with some of the concerns expressed about the applicability of the wildlife methodology for developing wildlife criteria or values beyond the BCCs. As a result, EPA has modified the final Guidance to no longer require Great Lakes States and Tribes to adopt provisions mandating the use of the proposed wildlife Tier II methodology when developing water quality-based effluent limits, nor to require the use of the wildlife Tier I methodology for pollutants other than BCCs. These issues are discussed further in section VI of this document.

EPA also agrees with comments that it is appropriate for dischargers to share the cost of developing data on pollutants for which there are no Tier I criteria and/or Tier II values, and does not agree with comments that it is inappropriate. EPA recognizes that the ultimate statutory responsibility for developing, adopting, and approving water quality standards rests with States, Tribes, and EPA. The CWA, however, also makes dischargers ultimately responsible for the content of their discharges, and gives broad authority to the Administrator and the States for data gathering and reporting concerning such discharges (CWA sections 308, 402). As a matter of public policy, EPA believes it is appropriate to provide incentives to reduce the presence of toxic pollutants in discharges. Procedure 5.C of appendix F of the final Guidance provides such an incentive. Upon adoption or promulgation, it would require NPDES permit authorities to generate toxicological data sufficient to calculate Tier II values in certain circumstances, but would retain their current ability to require permittees to generate such data.

At the same time, EPA does not want to impose an undue burden on dischargers, and has reviewed carefully the comments of those concerned about the cost and time required to generate Tier II data. EPA has concluded that because of the amount of existing data already available for the GLI Clearinghouse, the potential burden to generate required Tier II data in specified circumstances will be relatively insignificant. EPA's analysis is as follows.

Upon adoption or promulgation, the Guidance would provide that dischargers could be required, under conditions and with some exceptions specified in procedure 5.C of appendix F, to generate data to derive Tier II values if sufficient data do not exist for the 138 pollutants selected by the States and EPA for the initial focus of the Initiative (listed in Table 6 of part 132). This means that a permitting authority, when faced with the need to develop an effluent limit for a pollutant for which there is no Tier I criterion or Tier II value, would need to generate or require the permittee to generate data to develop a Tier II value for that pollutant. The conditions and exceptions for this procedure are described further in section VIII.E of this document. For human health, EPA has already developed Tier I criteria for 18 of the 138 pollutants, and has tentatively determined that there is currently enough toxicological information available to calculate at least 101 more Tier I criteria, leaving only 14 pollutants for which there is not enough data to calculate at least a Tier II human health value, and 5 pollutants which are currently under review by EPA. For aquatic life, EPA has developed Tier I criteria for 15 of the 138 pollutants, and in addition has tentatively determined that there is currently enough information available to calculate at least 98 more Tier I criteria or Tier II values. This means that the maximum potential burden for dischargers to generate required data would be for 14 human health values and 25 aquatic life values. For several of the remaining 25 pollutants, however, it is possible that the pollutant is insoluble in water at levels that are acutely toxic to daphnids. In these situations, under the scientific defensibility exclusion of § 132.4(g) there would be no need to conduct the toxicity tests.

This maximum potential burden may never be realized by dischargers for several reasons. First, in operating the GLI Clearinghouse, EPA and the States may identify additional data on the remaining pollutants. Second, EPA may decide to generate the necessary data for one or more of the remaining pollutants. Third, one or more States may decide to generate the data, and not require dischargers to generate the data. Finally, the pollutants may not be in an individual discharger's effluent, and therefore would not trigger the need to generate data under procedure 5 of appendix F. Because of the above mitigating factors, EPA believes the burden to generate required Tier II data is likely to be small.

EPA is also aware that because the Tier II methodologies generally yield more conservative numbers than Tier I, to reflect the greater uncertainty related to the absence of complete data sets, an incentive is created for dischargers to generate additional toxicological data to enable generation of a new Tier II value or a Tier I criterion. To the extent that dischargers choose to conduct studies to generate new data, this is an optional activity and not a requirement of the final Guidance. Additionally, the cost of such testing could be offset by any reduction in treatment costs associated with less stringent permit limits based on Tier I criteria. EPA has therefore not estimated the potential cost if any of this optional activity.

Additionally, in situations where dischargers are required to generate data to derive Tier I criteria or Tier II values, the final Guidance continues to specify that permit authorities may grant a reasonable period of time in which to provide additional studies necessary to develop a Tier I criterion or to modify the Tier II value. These provisions are discussed further in section VIII.H of this document.

EPA also agrees in part with commenters who recommended allowing the use of established biological tests in place of the Tier II methodologies for numerical pollutant-specific values. As described above, when deriving limits to meet Tier II values, States and Tribes have the option of using an indicator parameter limit, including use of a WET limit under appropriate conditions, in lieu of a Tier II-based limit. EPA does not agree, however, with suggestions by commenters that the entire Tier II approach be replaced by reliance on established biological tests. Although whole effluent toxicity testing and permit limits are established procedures that EPA believes are effective in controlling toxicity to aquatic organisms in many circumstances, such testing is not designed to address toxic effects on human health. Furthermore, the whole effluent toxicity approach has some limitations for aquatic life protection as discussed in the section III of this document. Similarly, other ecological testing suggested by commenters, such as rapid bioassessment and biological criteria evaluations, do not address human health concerns. Other suggestions, such as effluent and chemical-specific bioconcentration testing, and fish tissue residue studies of receiving waters, have been adopted into the Guidance as part of the methodology to develop bioaccumulation factors in section IV of appendix B, and as part of procedure 8.F of appendix F. They are measurement methods, however, not regulatory approaches, and therefore should not be used as separate regulatory controls to replace the Tier II approach as suggested by some commenters. Furthermore, they do not directly measure end points of concern in protecting aquatic life, and would likely not be acceptable indicators under existing § 122.44(d)(1)(vi).

Finally, EPA does not agree with the concern of many commenters that the CWA's anti-backsliding provisions will prevent the future adjustment of water quality-based effluent limits based on Tier II values. Application of anti-backsliding provisions of the CWA are discussed in section II.C.3 of this document.

c. <u>Final Guidance.</u> For the reasons above, EPA has made specific modifications and exceptions to the proposed minimum requirements for States and Tribes to adopt and use Tier II methodologies. These changes include:

-- The application of the Tier II methodology for aquatic life has been modified to clarify that States and Tribes have the flexibility to use either Tier II values or indicator parameters including whole effluent toxicity, where appropriate and justified, consistent with the current national NPDES permit program. This change is reflected in changes to procedure 5 of appendix F to part 132, and is discussed further in VIII.E of this document.

-- EPA has eliminated the proposed minimum requirement to use a Tier II methodology for deriving wildlife values in the development of water quality-based effluent limits. This change is reflected by removing the Tier II wildlife methodology from appendix D to part 132, and retitling the appendix; by removing requirements to adopt and use the methodology in §§ 132.4(a)(5), 132.4(c), and 132.4(d)(4); and removing wildlife values from the definition of Tier II value in § 132.2. These changes are discussed further in section VI of this document. Removing these requirements from part 132, however, does not relieve permit authorities from their responsibilities under 40 CFR 122.44(d)(1) to ensure that narrative water quality standards are implemented to protect wildlife.

3. Application of Anti-backsliding Provisions of the Clean Water Act

a. Proposal. The preamble to the proposed Guidance (58 FR 20837) discussed why in most cases the anti-backsliding provisions of the CWA will not prevent adjustments to either Tier I criteria or Tier II values. ("Anti-backsliding requirements" refers to the need to make certain showings to justify making an effluent limitation less stringent.) First, because anti-backsliding requirements do not apply to changes made in an effluent limitation prior to its compliance date, they would not apply where permit limits based on Tier II values are revised as a result of studies performed under a compliance schedule pursuant to proposed procedure 9 of appendix F. Second, even where anti-backsliding requirements do apply (e.g., where effluent limitations based on Tier I criteria or Tier II values change after the compliance date), dischargers may be able to meet the requirements of section 303(d)(4) and therefore be allowed to have less stringent effluent limitations.

b. Comments

Comment: Comments indicated that EPA should exempt Tier II based limits from anti-backsliding requirements regardless of the time period involved, even after the limits become effective.

Response: The statute does not provide the flexibility to exempt Tier II limits from anti-backsliding requirements after the limits become effective. However, as discussed below, even where anti-backsliding requirements do apply, they do not prevent all changes for effluent limitations.

Comment: Some comments asked for the statutory justification for indicating that anti-backsliding requirements do not apply until the compliance date or if a limitation is appealed.

Response: EPA has reviewed the statutory language contained in section 402(o)(1), which contains the general prohibition against backsliding for WQBELs. The statute refers to effluent limitations that have been "established." Restrictions on backsliding do not apply to challenged permit limits which have been stayed pending final agency action as these limitations have not been "established." For example, where a limit is challenged in an evidentiary hearing or administrative appeal, the limit may be made more or less stringent than the initially proposed limit, without the change being subject to the anti-backsliding requirements. EPA has also determined that the anti-backsliding requirements do not apply to limits with a delayed compliance date, until the date of compliance, as the limitation again is not yet "established" until that date. EPA has codified in procedure 9.C of appendix F of the final Guidance its interpretation that a limitation is not established for the purposes of section 402(o) until its effective date.

None of the Great Lakes States has indicated to EPA that they have anti-backsliding requirements that are more stringent than the EPA interpretation.

Comment: Commenters stated that it will be very difficult to satisfy the anti-backsliding requirements.

Response: There is flexibility provided by EPA's interpretation of sections 402(o) and 303(d)(4) to allow relaxation of effluent limitations in many of the circumstances described in the comments. Specifically, EPA does not interpret section 402(o) to require compliance with both sections 402(o)(2) and 303(d)(4), but only with one or the other (as well as 402(o)(3)) in order to establish less stringent limitations.

Comment: Commenters stated that EPA should issue a regulation interpreting the anti-backsliding requirements.

Response: EPA is not issuing a regulation defining national anti-backsliding policy in this rule, since such a regulation would have much broader applicability than the Great Lakes basin. However, EPA is repeating and clarifying its interpretation of the anti-backsliding requirements of sections 402(o) and 303(d)(4) in this document. See the Final Guidance section below for a detailed explanation of EPA's interpretation.

Comment: Commenters stated that backsliding should not be allowed from current effluent limitations and existing conditions.

Response: The statute or existing regulations do not prohibit a change from existing limitations, so long as the exceptions are met and there is compliance with the requirements contained in section 402(o)(3).

Comment: A number of comments dealt with the interaction of anti-backsliding and antidegradation requirements.

Response: Antidegradation requirements do apply to an analysis of the anti-backsliding requirements, as provided under section 402(o)(3). However, this is consistent with the general requirement under the CWA that permits comply with water quality standards including antidegradation. See the NPDES regulations (40 CFR 122.44(b) and (d)) on establishment of WQBELs to ensure compliance with water quality standards, including antidegradation policies. Specific issues concerning compliance with antidegradation in the Great Lakes are addressed in section VII of this document.

Comment: Some commenters expressed concern that the antibacksliding requirements of section 303(d)(4)(A) of the CWA would make it difficult to revise limits based on Tier II values if studies were completed after the compliance date for the limit in question. For example, if future studies resulted in a Tier II value being changed to a less stringent Tier II value or Tier I criterion, after the effective date of an initial Tier II-based limit, the concern is that antibacksliding would prohibit the relaxation of the Tier II-based limit.

Response: Section 303(d)(4)(A) requires that the limit which is to be relaxed have been based on a TMDL or other wasteload allocation established under section 303(d). Since any effluent limit based on a Tier II value will also be based on procedure 3 of appendix F (i.e., on an approved TMDL, WLA in the absence of a TMDL, or assessment and remediation plan), such effluent limitations will satisfy the requirement that they be based on a TMDL or other wasteload allocation established under section 303(d). EPA therefore believes that permittees will be able to satisfy the requirements of section 303(d)(4)(A).

c. Final Guidance. EPA has retained the proposed provisions concerning the application of CWA anti-backsliding requirements to the implementation of the final Guidance. Final procedure 9.C of appendix F states explicitly that anti-backsliding requirements contained in section 402(o) do not apply to changes made in an effluent limitation prior to its compliance date. In addition, there is adequate flexibility contained in EPA's interpretation of the anti-backsliding requirements of the CWA to allow adjustments to either Tier I criteria or Tier II values in many situations.

The approach in the final Guidance regarding the applicability of anti-backsliding requirements will provide the greatest degree of uniformity among the States and Tribes in terms of when Tier II values would become a part of a final permit. In addition, the approach of the final Guidance will likely provide the greatest degree of environmental protection in the short term because there will be a shorter time for completion of the studies and issuance of a permit with final effluent limitations. This approach also is consistent with the language of the CWA itself.

The following discussion clarifies and expands EPA's interpretation of sections 402(o) and 303(d)(4), and explains why the States and Tribes have considerable flexibility to revise WQBELs.

Section 402(o) of the CWA, added by the Water Quality Act of 1987 (WQA), for the first time establishes express statutory language prohibiting the backsliding of permit limits. Section 402(o) consists of three main parts. First, section 402(o)(1) prohibits (subject to exceptions in sections 303(d)(4) and/or 402(o)(2)) backsliding of two types of permit limits: (1) technology-based effluent limitations based on best professional judgment (BPJ) being revised to reflect subsequently promulgated effluent guidelines which are less stringent, and (2) water quality-based effluent limitations established on the basis of sections 301(b)(1)(C) or 303(d) or (e). Second, section 402(o)(2) outlines six specific exceptions to the prohibition contained in section 402(o)(1). Third, section 402(o)(3) outlines a baseline requirement that must be met before any limits can be relaxed, namely that the new limit must ensure compliance with applicable effluent guidelines and water quality standards.

EPA's pre-WQA anti-backsliding regulations were revised on January 4, 1989 (54 FR 246), to reflect the prohibition imposed by section 402(o) for the first situation: revision of existing BPJ-based permit limitations to reflect subsequently issued effluent guidelines (40 CFR 122.44(l)(2)). EPA's current anti-backsliding regulations have not been revised to reflect the 1987 WQA prohibition on the backsliding of the second situation: relaxation of effluent limitations established on the basis of sections 301(b)(1)(C) or 303(d) or (e). However, EPA believes these provisions must be implemented based upon the CWA in the meantime.

All other types of backsliding--for example, backsliding from effluent guideline derived limits, from new source performance standards, from existing BPJ limits to new BPJ limits, or from water quality-related standards or conditions (except for effluent limitations)--remain unaffected by the 1987 WQA amendments and EPA's existing regulations at 40 CFR 122.44(l)(1) will continue to govern them. This is because section 402(o) only prohibits the backsliding of "effluent limits," not other standards or conditions such as monitoring frequency or changes in species or protocol for whole effluent toxicity (WET) testing. In addition, the requirements contained in CWA section 402(o) do not lend themselves to application to changes of such standards and conditions. The relaxation of all other types of standards or conditions contained in a permit are, however, subject to EPA's existing backsliding regulations at 40 CFR 122.41(l)(1). Under these regulations, a permittee must meet a cause for modification in order to allow relaxation.

As indicated in the preamble to the proposed Guidance (58 FR 20837), EPA has consistently interpreted section 402(o) of the CWA to allow relaxation of WQBELs if either the requirements of section 402(o)(2) or section 303(d)(4) are met. These are independent exceptions to the prohibition against relaxation of water quality-based permit limitations. In dealing with anti-backsliding issues under the final Guidance, section 303(d)(4) will, in most cases, provide the flexibility necessary for permitting authorities to issue permits reflecting adjustments to Tier I criteria or II values.

Section 402(o)(1) provides that backsliding from WQBELs is prohibited except in compliance with section 303(d)(4). Section 303(d)(4) has two parts that must be considered, along with an identification requirement: paragraph (A) which applies to "non-attainment waters" and paragraph (B) which applies to "attainment waters."

Section 303(d)(4)(A) allows establishment of a less stringent WQBEL when the receiving water has been identified under section 303(d)(1)(A) and where applicable water quality standards are not being met (i.e., a "non-attainment water"), if the permittee meets two conditions. First, a permittee may seek a less stringent effluent limitation under section 303(d)(4)(A) only if the existing permit limitation was based on a total maximum daily load (TMDL) or other wasteload allocation (WLA) established under section 303. Second, relaxation of a WQBEL is only allowed if attainment of water quality standards is ensured, or if the designated use which is not being attained is removed in accordance with 40 CFR part 131.

Section 303(d)(4)(B) applies to waters where the water quality equals or exceeds levels necessary to protect the designated use, or to otherwise meet applicable water quality standards (i.e., an "attainment water"). Under section 303(d)(4)(B), permit limitations based on a section 303 TMDL/WLA, on any water quality standards established under section 303, or on any other permit standard may be relaxed only where this is consistent with a State's antidegradation policy (see 40 CFR 131.12).

Section 402(o)(2) also outlines exceptions to the general prohibition against backsliding from WQBELs. These exceptions are independent of the section 303(d)(4) exception discussed above and are also applicable to the backsliding of BPJ limits to reflect subsequently promulgated less stringent guidelines.

Regardless of whether any of the backsliding exceptions are applicable and met, section 402(o)(3) acts as a floor and restricts the extent to which WQBELs (and BPJ limits) may be relaxed. Specifically, section 402(o)(3) prohibits the relaxation of such permit limitations below applicable technology-based effluent limitation guidelines in effect at the time the permit is renewed, reissued or modified. In addition, it prohibits the relaxation of limits if such relaxation would result in a violation of applicable water quality standards, which include antidegradation requirements.

EPA is providing four examples of the application of anti-backsliding requirements. (EPA has not provided the analysis of these examples under section 402(o)(2), because section 303(d)(4) in almost all cases is more flexible.)

<u>Example 1</u>

<u>Scenario</u>: A publicly owned treatment works (POTW) seeks to relax its WQBEL for pollutant X. The current permit limitation is based on the TMDL and WLA for the POTW developed in accordance with 40 CFR 130.7. The POTW is in compliance with its existing limitation. The applicable water quality standards for pollutant X is attained. The POTW has developed new models with new river flow information, which indicate that the water quality standards for pollutant X would be maintained with a relaxed permit limitation. The permitting authority can revise the permittee's WLA to allow a larger discharge of pollutant X because another discharger to the TMDL ceased the discharge of pollutant X. May the effluent limitation for pollutant X be relaxed?

<u>Answer</u>: Section 303(d)(4) may justify the requested relaxed permit limitation. Section 303(d)(4)(B) is the applicable provision because the water quality standards for pollutant X is currently attained. Under section 303(d)(4)(B), a permit limitation can be relaxed if antidegradation requirements are met. Finally, the permitting authority may only allow backsliding if the relaxed limitation would not result in violation of any effluent limitations guideline or other water quality standards.

<u>Example 2</u>

<u>Scenario</u>: On June 30, 1991, the State issued a NPDES permit to an industrial permittee which for the first time included a WQBEL for pollutant Y. The limitation for pollutant Y is a delayed effective date limitation which is effective on June 30, 1994. The WQBEL is derived from the State's existing water quality criteria. The State conducted additional water quality studies on pollutant Y during its triennial review in 1993 and relaxed the water quality criterion for pollutant Y. On January 30, 1994, the permittee seeks to modify its permit to relax the effluent limitation for pollutant Y, based upon the new State water quality criterion. Will the anti-backsliding provisions of the CWA and NPDES regulations prevent relaxation of the permit limitation?

<u>Answer</u>: No. In this case, the permittee seeks to revise an effluent limitation which is not yet effective. The anti-backsliding provisions of the CWA and NPDES regulations do not apply to a delayed effective date limitation until it is effective. Prior to relaxing the permit limitation, however, the permitting authority will need to ensure that the action is consistent with antidegradation provisions.

<u>Example 3</u>

<u>Scenario</u>: The State has a narrative water quality criterion of "no toxics in toxic amounts." On the basis of WET testing data or other information, the State finds reasonable potential to exceed the narrative water quality criterion and imposes a WET limitation under 40 CFR 122.44(d)(1)(v). The permittee determines that pollutant Z is the cause of the WET in its discharge. The permittee can demonstrate through sufficient data (including WET testing data) that an effluent limitation for pollutant Z will assure compliance with the narrative water quality standards as well as the State's numeric criteria for pollutant Z as required by 40 CFR 122.44(d)(1)(v). May the State modify the permit to delete the WET limitation and to add the limitation for pollutant Z?

<u>Answer</u>: Section 303(d)(4) may justify this action. The applicable provision of section 303(d)(4) is section 303(d)(4)(B) because the narrative water quality standards is currently attained. (The permittee is currently complying with the existing WET limitation to attain and maintain the State's narrative water quality standards.) Under section 303(d)(4)(B), the permittee may backslide so long as antidegradation requirements will be met, and the relaxed limitation will not cause a violation of any effluent limitations guidelines and water quality standards applicable to the discharge. In this case, this appears likely because the discharger can demonstrate that the new limitation for pollutant Z will assure compliance with applicable narrative as well as numeric water quality standards.

<u>Example 4</u>

<u>Scenario</u>: An industrial permittee seeks to revise its WQBEL of 1000 mg/L for a pollutant to 6000 mg/L, its actual discharge level. The permittee has installed and properly operated and maintained its treatment facilities, but has been unable to achieve the effluent

limitation of 1000 mg/L. The current permit limitation is based upon a TMDL and WLA for the permittee, which were developed in accordance with 40 CFR 130.7. The water quality standards for the pollutant is not being attained. New modeling information shows that the water quality standards for the pollutant will be attained with a permit limitation of 4000 mg/L. The permitting authority is able to revise the discharger's WLA to allow a permit limitation of 4000 mg/L. May the permit limitation be revised from 1000 mg/L to 6000 mg/L?

Answer: No. However, under sections 303(d)(4), the permit limitation may potentially be relaxed to 4000 mg/L. The water quality standards for the pollutant is not currently being attained. Therefore, the applicable 303(d)(4) provision is 303(d)(4)(A). In this case, the permitting authority may allow backsliding to 4000 mg/L under section 303(d)(4)(A) because the existing effluent limitation is based upon a TMDL/WLA and the data shows that attainment of the water quality standards is assured with a permit limitation of 4000 mg/L (but not with a limitation of 6000 mg/L). The permitting authority may also revise the discharger's WLA to allow a discharge limitation of 4000 mg/L. However, before backsliding to a limitation of 4000 mg/L will be allowed in this case, the permitting authority must also find that the relaxed limitation will not result in violation of applicable water quality standards (including antidegradation requirements) and effluent limitations guidelines for the discharge.

4. Basin-wide Application of Criteria and Values

a. Proposal. With exceptions discussed below, the proposed Guidance generally provided for State and Tribal application of the criteria, values and methodologies in the Guidance to all waters of the Great Lakes System regardless of current use designations. This approach was selected in order to provide the integrated Great Lakes ecosystem a consistent approach to pollution control across the entire basin (see 58 FR 20838-40).

The proposal contained four exceptions to this approach: First, Great Lakes States or Tribes could apply more stringent numeric criteria or values to any waters of the Great Lakes System within their borders. Second, Great Lakes States or Tribes could develop less stringent site-specific modifications to the criteria and values for aquatic life for specific waters of the Great Lakes System in certain limited circumstances. Third, Great Lakes States and Tribes would be required to adopt different types of human health criteria depending in part on the designated uses of the waters: "drinking" criteria and values would apply to open waters and connecting channels of the Great Lakes, and to other waters designated for use as public water supplies; "nondrinking" criteria and values would apply to all other waters. Fourth, the Guidance provided general exceptions for 16 pollutants listed in Table 5 of the proposed Guidance; for discharges from wet weather point sources; and for situations where the criteria methodologies are not scientifically defensible.

b. Comments. A few commenters asserted that the application of human health and/or wildlife criteria/values regardless of current use designations throughout the Great Lakes System seems overly restrictive. In particular, these commenters are concerned that this practice is not justified for non-bioaccumulative substances because these pollutants may never reach the lakes, actual drinking water supplies, or appropriate wildlife habitats when discharged into upstream waters. Other commenters stated that Congress did not intend to take away the Great Lakes States' ability to develop use designations and to develop water quality standards protective of those uses. Other commenters stated that the approach fails to recognize the ecological diversity of the Great Lakes ecosystem.

A few comments supported the proposed approach which allows application of site-specific criteria as a more appropriate mechanism for developing criteria and values than through a use-designation mechanism.

EPA carefully considered the concerns expressed about the proposed approach, but continues to believe the proposed approach is appropriate. First, section 118(c) of the CWA requires the Guidance to specify minimum numerical limits on pollutants to protect human health, aquatic life, and wildlife in the Great Lakes System. EPA believes it is a reasonable interpretation of this requirement to develop criteria that are generally applicable to the entire Great Lakes System in order to improve consistency of water quality criteria while providing sufficient flexibility to address site-specific circumstances. (See 58 FR 20837-40.) This interpretation is also reasonable in light of the short statutory deadline established by Congress to complete the Guidance.

Second, the approach was not developed because of an assumption that pollutants move freely throughout the ecosystem, although both bioaccumulative and non-bioaccumulative pollutants can become widely dispersed. Rather, as explained in the preamble to the proposed Guidance, EPA believes that the Great Lakes are an integrated ecosystem necessitating a more consistent approach to pollution control across the entire basin.

Third, following the current National program of differing criteria based on differing use designations could seriously hinder--and perhaps prevent--the attainment of the goals of the CPA. Contrary to the views of the commenter above, EPA believes Congress did intend to restrict some of the current flexibility in the national program in order to achieve more uniform protection of the Great Lakes System through enactment of the special requirements in section 118(c) for this ecosystem.

Fourth, EPA believes that uniform minimum water quality standards can help simplify implementation and avoid costly duplication of research and standard-setting by EPA and the Great Lakes States and Tribes.

Fifth, as a practical matter, designated uses currently do not exhibit wide variation across the basin. For example, use designations for most waters within the Great Lakes System currently include protection of aquatic life and recreational uses. No comments were received in response to EPA's request for comments on any waters within the Great Lakes System that are not currently designated to protect these uses.

Finally, to the extent that there may be unique local situations not amenable to strict application of basin-wide criteria, the final Guidance contains several areas of flexibility, including: the scientific defensibility exclusion in § 132.4(h), discussed further in section II.C.6 of this document; site-specific criteria modifications available through procedure 1 of appendix F, discussed further in section VIII.A of this document; and variances available through procedure 2 of appendix F, discussed further in section VIII.B of this document.

EPA agrees with the comment, however, that the Guidance should recognize the ecological diversity of the Great Lakes ecosystem. It is reasonable to provide differential criteria or flexibility in implementing the criteria to reflect variations due to local physical, chemical, and biological factors. The proposed Guidance provided some different criteria--for example, different aquatic life criteria depending on water hardness, and different human health criteria for open waters of the Great Lakes--to reflect common variations. It also provided flexibility of implementation, including site-specific modifications to criteria to address more specific or localized differences.

The final Guidance also includes additional flexibility in applying criteria and values to further recognize ecological diversity within the Great Lakes basin. Procedure 1 of appendix F now allows site-specific modifications of human health and wildlife criteria and values that can be either more stringent or less stringent to reflect site-specific information on bioaccumulation factors. This change, together with the flexibility already provided in the proposal allowing both more stringent and less stringent site-specific modifications for aquatic life criteria/values, should provide sufficient flexibility to reflect site-specific conditions and the ecological diversity of the Great Lakes basin. Changes to the procedure for site-specific modifications are discussed further in section VIII.A of this document. In addition, changes were made in the definition of high quality waters in the antidegradation policy to exclude certain waters from an antidegradation review depending on their ecological, recreational, or aesthetic significance. Changes to the antidegradation policy are discussed further in section VII of this document.

c. Final Guidance. With one exception, the proposed provisions of § 132.4(d) specifying the applicability of criteria and values have not been changed in the final Guidance. The exception is that § 132.4(d)(4) has been modified to eliminate the requirement for States and Tribes to adopt provisions consistent with the Tier II wildlife methodology, as discussed above and in section VI of this document.

5. Pollutants Subject to Federal, State, and Tribal Requirements

a. Proposal. The proposal left to the discretion of the States and Tribes whether to adopt provisions requiring the use of the Guidance's criteria development methodologies or implementation procedures 1, 2, 3, 4, 5, 7, 8, and 9 in appendix F for a pollutant if it was listed in Table 5 of the proposed Guidance. Proposed Table 5 listed 16 pollutants selected by the Great Lakes States and EPA during the Great Lakes Initiative process: alkalinity, ammonia, bacteria, biochemical oxygen demand, chlorine, color, dissolved oxygen, dissolved solids, hydrogen sulfide, pH, phosphorus, salinity, sulfide, temperature, total and suspended solids, and turbidity. These pollutants would continue to be subject to existing water programs, such as State or Tribal programs implementing 40 CFR part 131 for the development and adoption of water quality standards and criteria, 40 CFR part 122 for development of NPDES permits, and other appropriate requirements and guidance under the CWA or State or Tribal law. They would also be subject to the antidegradation policy in appendix E. The proposal did not need to exempt the Table 5 pollutants from procedure 6, since procedure 6 applies to whole effluent toxicity not to individual pollutants.

As discussed more fully in the preamble to the proposed Guidance (58 FR 20842-43), the Initiative Committees believed that regulatory authorities should retain the flexibility to address these pollutants in their existing water quality programs.

b. Comments. Many commenters supported the proposed listing of pollutants in Table 5 that would only be subject to existing Federal, State, and Tribal requirements. In particular, several commenters supported the proposed listing of chlorine in Table 5, pointing out that States need continuing flexibility in their programs to deal with the special uses of chlorine as a disinfectant in water and wastewater treatment. Other commenters supported the proposed listing of ammonia, citing its role as a nutrient as well as its toxicity.

Other commenters urged EPA to delete ammonia and chlorine from Table 5. These commenters believe that ammonia and chlorine, although regulated by states in the basin, should be controlled more consistently because of their potential adverse effects on aquatic biota. Commenters also argued that the Guidance methodologies and procedures can technically be applied to ammonia and chlorine, and that the States are not consistently regulating these pollutants within the basin.

Various individual commenters suggested: deleting hydrogen sulfide and sulfide from Table 5; deleting salinity from Table 5; adding non-toxic pollutants to Table 5; and adding common inorganic constituents such as chloride, sulfate, sodium, and calcium to Table 5.

EPA agrees with comments that Table 5 should be retained in the final Guidance, because for the pollutants in the final Table 5 it would be scientifically and technically inappropriate to require use of some or all of the Guidance's methodologies and procedures. EPA agrees with comments that the proposed Table 5 should be modified, however, to remove two pollutants--hydrogen sulfide and sulfide. The reasons for listing or removing pollutants in Table 5, together with EPA's response to comments concerning specific pollutants, are as follows.

-- Alkalinity. The Guidance methodologies and implementation procedures are not scientifically and technically appropriate for developing and applying water quality criteria and values for alkalinity. The Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with specific chemicals. Alkalinity is not a specific chemical, but the combined effect of several substances such as carbonates, bicarbonates, hydroxides, borates, silicates, and phosphates. Furthermore, the Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with chemicals that exert an adverse effect as the concentration of the chemical becomes too high, while alkalinity exerts adverse effects on aquatic life if it is too low, and human health--irritation to swimmers by altering the pH of the lacrimal fluid around the eye--if it is too high. Additionally, some components of alkalinity such as carbonate and bicarbonate can have a beneficial effect on water quality by complexing some toxic heavy metals and reducing their toxicity to aquatic life. It has also been noted that some waterfowl habitats are more productive with higher alkalinities. The criteria development methodologies and implementation procedures in the final Guidance do not address these types of issues or end points. The final Guidance also does not address other end points of concern commonly identified for low alkalinity, including adverse impacts on industrial uses such as food and beverage production. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of alkalinity.

-- Ammonia. EPA considered carefully the concerns of some commenters that ammonia be removed from Table 5 and made subject to all provisions of the final Guidance. EPA shares concerns of some commenters that there may be inconsistencies among State water programs addressing ammonia. Nevertheless, EPA found that there would be significant problems in applying the aquatic life criteria methodology and corresponding implementation procedures for ammonia, and that even if these could be overcome, there would likely be no significant improvements in consistency of permit limits for this pollutant throughout the Great Lakes basin.

For reasons described in section II.C.4 of this document, the aquatic life methodology in the final Guidance was developed to provide generally a single set of criteria (or a single equation, in the case of pollutants that are adjusted for a water quality characteristic) to protect aquatic life throughout the basin regardless of the specific species present in different waterbodies. For ammonia, however, EPA's best current information is that a single set of water quality criteria to protect aquatic life is not appropriate. In January 1985 EPA issued a water quality criteria document for ammonia, "Ambient Water Quality Criteria for Ammonia - 1984." The criteria document was supplemented by additional guidance to EPA Regional water quality standards coordinators in July 1992 in a memorandum, "Revised Tables for Determining Average

Freshwater Ammonia Concentrations." These documents are available in the docket for this rulemaking. In these documents, two sets of criteria are presented: one set to protect aquatic life when salmonids or other sensitive coldwater species are present, and one set to protect aquatic life when salmonids or other sensitive coldwater species are absent. Both sets include separate chronic and acute criteria for temperatures ranging from 0° C to 30° C. The two sets of chronic criteria differ from each other by factors of approximately 1.4 at temperatures above 15° C, and are the same at temperatures 15° C or below. The two sets of acute criteria differ from each other by factors of approximately 1.4 at temperatures above 20° C, and are the same at temperatures 20° C or below.

Furthermore, EPA has determined that even if ammonia were removed from Table 5, there would likely be no significant change in consistency among States and Tribes in implementing the criteria. The EPA 1984 ammonia criteria document provides general recommendations on implementation which emphasizes consideration of site-specific factors. The document recommends including site-specific factors when conducting wasteload allocation modeling in those situations, including consideration of effluent variability, and the selection of different design flows for steady-state wasteload allocation modeling depending on whether the systems are stressed or unstressed. Accordingly, States and Tribes would likely develop site-specific criteria modifications and/or site-specific adaptations of wasteload allocation models for the majority of waters throughout the basin.

Because the implementation procedures in the final Guidance are designed to be applicable to a wide range of pollutants, they do not provide details that would assist States and Tribes in making site-specific modifications and adaptations in the specific case of ammonia. For example, appendix F of the final Guidance: provides no direction concerning what site-specific information should be developed for wasteload allocation modeling in the above situation or how the information should be used; does not include direction on how to evaluate whether systems are stressed or unstressed; and does not describe how design flows should be selected in stressed or unstressed systems. Therefore, in the absence of such direction, States and Tribes would simply be implementing current laws and national program guidance.

EPA considered the possibility of developing more detailed guidance concerning the site-specific modifications and adaptations recommended for ammonia. EPA also considered developing site-specific numeric criteria and/or site-specific wasteload allocation modeling parameters for ammonia for all waters in the entire basin. Neither approach would be possible or administratively feasible within the time EPA had available to complete the final Guidance.

Another problem raised by commenters is that ammonia not only produces toxic effects in aquatic life but also is a nutrient that with other forms of nitrogen can contribute to accelerated eutrophication of lakes and other waters. EPA agrees that ammonia can contribute to eutrophication problems, although if it is controlled to prevent toxic effects, its contribution to eutrophication will be less. Nevertheless ammonia needs to be considered because of its interaction with other forms of nitrogen when performing total maximum daily loads and wasteload allocations to address eutrophication problems. The Guidance methodologies and procedures do not reflect eutrophication as an end point.

For these reasons, EPA decided to retain ammonia as a pollutant listed in Table 5 to part 132. Nevertheless, because of inconsistencies among State programs in the Great Lakes basin in addressing ammonia, EPA will take additional steps to review such programs. These steps are discussed below under the Final Guidance section.

EPA notes that under § 132.4(e)(2), discharges that contain pollutants on Table 5 such as ammonia are still subject to the whole effluent toxicity provisions contained in procedure 6 of appendix F of the final Guidance. These provisions are discussed further under the Final Guidance section below and in section VIII.F of this document.

-- Bacteria. The methodologies in appendixes B and C and the implementation procedures in appendix F are not scientifically and technically appropriate for developing and applying criteria and values for bacteria. First, the concept of bioaccumulation in appendix B cannot be applied in the case of bacteria. Second, the human health methodology in appendix C is based on toxicological analysis of dose-response relationships, while the criteria for bacteria are based on upper limits for densities of indicator bacteria in waters that have been associated with acceptable health risks for swimmers. Finally, the implementation procedures for individual pollutants in appendix F are generally designed for chemicals whose effects are related to their concentration in the water column, whereas the effects of bacteria are generally related to the density of bacterial colonies measured after several days of culturing in the laboratory. Neither steady state nor dynamic water quality modeling used in appendix F has been found to be applicable to developing total maximum daily loads, water quality-based effluent limits, or loading limits for bacteria. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of bacteria.

-- Biochemical oxygen demand. The Guidance methodologies and implementation procedures are not scientifically and technically appropriate for developing and applying water quality criteria and values for biochemical oxygen demand (BOD). First, the Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with specific chemicals or related congeners. BOD is not a specific chemical, but the combined effect of many chemicals which lead to the depletion of oxygen as they are degraded by aquatic organisms. Second, BOD exerts no measurable toxic effect itself on aquatic life, human health, or wildlife, but rather is a precursor together with other factors of an adverse effect on aquatic life, the lowering of dissolved oxygen. Third, the water quality modeling needed to develop total maximum daily loads and water quality-based effluent limits for BOD requires different data inputs and different mathematical calculations than the modeling generally required in appendix F for pollutants that exert a measurable toxic effect. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of BOD.

-- Chlorine. EPA does not agree with comments that chlorine should be removed from Table 5. Key portions of the Guidance implementation procedures are not scientifically and technically appropriate for applying water quality criteria and values for chlorine. First, chlorine exerts acute toxicity effects, but is chemically highly reactive and degrades in receiving waters much more rapidly than most other pollutants. The half life of total residual chlorine can range from 1 to 3 hours, which is far shorter than most other pollutants. Procedures 3.C.4 and 3.D.3 of appendix F provide that wasteload allocations to protect aquatic life from acute effects shall not exceed the Final Acute Value (FAV) for the pollutant in order to provide an adequate margin of safety, as a default assumption in the absence of site-specific data. The FAV cap may be exceeded; however, if a site-specific mixing zone demonstration is conducted and approved pursuant to procedure 3 of appendix F. EPA is concerned that because of chlorine's unique characteristics, the above procedures, together with related elements of procedure 5, have the potential to result in overly stringent controls on discharges of chlorine in the Great Lakes basin. Because the Initiative Committees excluded chlorine when developing the draft Guidance, State and EPA technical staff did not consider chlorine's unique characteristics when developing procedures 3.C.4 and 3.D.3. Because of these concerns, EPA does not believe it would be appropriate scientifically and technically to apply the Guidance implementation procedures without modifications to take into account chlorine's unique properties. EPA considered the possibility of reviewing procedures 3.C.4 and 3.D.3 to evaluate and address these concerns, but concluded this approach would not be possible or administratively feasible within the time EPA had available to complete the final Guidance.

Second, in the Great Lakes basin there are a number of dischargers who practice deliberate, controlled, repetitive, intermittent chlorination in order to control undesirable organisms in their production or treatment processes. Under these scenarios, the total time chlorine is discharged is often limited to several hours, and the concentration of chlorine discharged over that time period is quite variable, such that the peak concentration may be experienced for only a limited period of time during those few hours. The Guidance implementation procedures may not be scientifically and technically appropriate for applying water quality criteria in waters affected by such discharges. Furthermore, the restrictions in procedures 3.C.4 and 3.D.4 concerning wasteload allocations based on acute aquatic life criteria were not designed for such situations, and if applied as specified in the final Guidance could result in wasteload allocations that may not be scientifically and technically appropriate. Therefore, EPA believes it would be inappropriate to require States and Tribes to apply the aquatic life methodology and corresponding implementation procedures to chlorine. EPA considered the possibility of developing more appropriate implementation procedures for chlorine under these circumstances. EPA concluded that the effort to develop such procedures would not be possible or administratively feasible within the time EPA had available to complete the final Guidance.

For these reasons, EPA decided to retain chlorine as a pollutant listed in Table 5 to part 132. Nevertheless, because of inconsistencies among State programs in the Great Lakes basin in addressing chlorine, EPA will take steps to review such programs. These steps are discussed below under the <u>Final Guidance</u> section.

EPA notes that under § 132.4(e)(2), discharges that contain pollutants on Table 5 such as chlorine are still subject to the whole effluent toxicity provisions contained in procedure 6 of appendix F of the final Guidance. These provisions are discussed further under the <u>Final Guidance</u> section below and in section VIII.F of this document.

-- <u>Color.</u> The Guidance methodologies and implementation procedures are not scientifically and technically appropriate for developing and applying water quality criteria and values for color. First, the Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with specific chemicals or related congeners. Color is not a specific chemical, but the result of degradation processes in the natural environment. There is no agreement as to the chemical composition of color, and in fact the composition may vary chemically from place to place. Second, the aquatic life methodology is designed to protect aquatic life from adverse toxicological effects, while the effects of color in water on aquatic life principally are to reduce light penetration and thereby generally reduce photosynthesis by phytoplankton and to restrict the zone for aquatic vascular plant growth. The criteria development methodologies in the final Guidance do not address these end points. Third, the water quality modeling needed to develop total maximum daily loads and water quality-based effluent limits for color would require different data inputs and different mathematical calculations from the water quality models generally required to implement the total maximum daily load procedures in the final Guidance. EPA is not aware of any water quality modeling that is generally available to support development of total maximum daily loads for color. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of color.

-- Dissolved oxygen. The Guidance methodologies and implementation procedures are not scientifically and technically appropriate for developing and applying water quality criteria and values for dissolved oxygen. First, the Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with chemicals that exert an adverse effect as the concentration of the chemical becomes too high, while dissolved oxygen exerts adverse effects on aquatic life if it is either too low or too high. The Guidance methodology to develop aquatic life criteria and values, and implementation procedures such as those for total maximum daily loads and loading limits would require significant revision to accommodate such a pollutant. Second, the Guidance implementation procedures are generally designed to develop water quality-based effluent limits for the same pollutant that has reasonable potential to exceed water quality standards, while to achieve a dissolved oxygen level that is not too low requires water quality-based effluent limits on different pollutants, primarily biochemical oxygen demand. The Guidance's implementation procedures would require significant revision to accommodate these situations. Third, to achieve a dissolved oxygen level that is not too high generally requires addressing eutrophication problems, which are not addressed by the Guidance, or ensuring that a dam or other hydrologic modification does not induce oxygen supersaturation through turbulent mixing, which may or may not involve development of water quality-based effluent limits for dissolved oxygen. The Guidance's implementation procedures would require significant revision to accommodate these situations. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of dissolved oxygen.

EPA considered the possibility of developing more appropriate criteria development methodologies and implementation procedures for dissolved oxygen. EPA concluded that the effort to develop such methodologies and procedures would not be possible or administratively feasible within the time EPA had available to complete the final guidance.

-- Dissolved solids and salinity. The Guidance methodologies and implementation procedures are not scientifically and technically appropriate for developing and applying water quality criteria and values for dissolved solids and salinity. First, the Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with specific chemicals or related congeners. Dissolved solids and salinity are not specific chemicals, but the combined effect of several unrelated substances. Second, the methodologies and implementation procedures are designed to be used with chemicals that exert an adverse effect as the concentration of the chemical becomes too high. Although dissolved solids and salinity can produce adverse effects at high levels, they can also produce more subtle effects at lower concentrations that affect the ecological balance of an ecosystem. For example, increased dissolved solids and salinity can favor aquatic species that are not native to an ecosystem and can disrupt the community structure. The Guidance methodologies and implementation procedures do not address these types of end points. Third, the establishment of water quality criteria for dissolved solids and salinity often involves site-specific considerations that are not addressed by the final Guidance. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of dissolved solids and salinity.

-- Hydrogen sulfide and sulfide. EPA agrees with comments that the Guidance methodologies and procedures are scientifically appropriate for developing and implementing criteria and values for hydrogen sulfide and sulfide, and has therefore removed hydrogen sulfide and sulfide from Table 5 in the final Guidance. These pollutants were originally listed by the Initiative Committees because they were believed to have only organoleptic effects. In response to comments, EPA reviewed the available scientific information, including EPA's Quality Criteria for Water, July 1976, and found that the pollutants have adverse effects that can be addressed by the Guidance methodologies and procedures. EPA is therefore removing them from Table 5.

-- pH. The Guidance methodologies and implementation procedures are not scientifically and technically appropriate for developing and applying water quality criteria and values for pH. First, the Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with chemicals that exert an adverse effect as the concentration of the chemical becomes too high, while pH exerts adverse effects on aquatic life if it is either too low or too high. The Guidance methodology to develop aquatic life criteria and values, and implementation procedures such as those for total maximum daily loads and loading limits do not accommodate such a pollutant. Second, the implementation procedures in the final Guidance, including the procedures for total maximum daily loads, reasonable potential, and loading limits, are generally designed to develop water quality-based effluent limits for the same pollutant that has reasonable potential to exceed water quality standards. Achieving a pH level that is not too low or too high, however, might require water quality-based effluent limits on different pollutants, such as specific acids, bases, or buffering compounds that affect the overall pH of the effluent and receiving water. The Guidance's implementation procedures do not accommodate these situations. Third, the implementation procedures for total maximum daily loads are designed for pollutants that are expressed as an ordinary concentration, while pH is expressed as the negative logarithm of the hydrogen ion concentration. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of pH.

EPA considered the possibility of developing more appropriate criteria development methodologies and implementation procedures for pH. EPA concluded that the effort to develop such methodologies and procedures would not be possible or administratively feasible within the time EPA had available to complete the final Guidance.

By listing pH among the pollutants in Table 5, EPA does not intend to exclude pH as a water quality factor in calculating criteria and values for other pollutants. Where appropriate, pH should continue to be used as such a factor.

-- Phosphorus. The Guidance methodologies and implementation procedures are not scientifically and technically appropriate for developing and applying water quality criteria and values for phosphorus. The Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with chemicals that exert an adverse effect, while the primary environmental concern with phosphorus is its role as a nutrient in accelerating eutrophication of lakes and other waterbodies. The Guidance methodologies and procedures do not reflect eutrophication as an end point. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of phosphorus.

-- Temperature. The Guidance methodologies and implementation procedures are not scientifically and technically appropriate for developing and applying water quality criteria and values for temperature. The Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with chemicals that exert an adverse effect as the concentration of the chemical becomes too high, while both high and low temperatures can have both beneficial and adverse effects, depending on aquatic species, stage of life cycle, and other chemical and physical factors. Furthermore, adverse effects from temperature often arise from abrupt spatial and temporal differences in temperature, rather than from temperature extremes. The Guidance methodologies and implementation procedures do not take these types of factors into account. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of temperature.

By listing temperature among the pollutants in Table 5, EPA does not intend to exclude temperature as a water quality factor in determining criteria and values for other pollutants. Where appropriate, temperature should continue to be used as such a factor.

-- Total and suspended solids, and turbidity. The Guidance methodologies and implementation procedures are not scientifically and technically appropriate for developing and applying water quality criteria and values for total and suspended solids, and turbidity. First, the Guidance methodologies for numeric criteria and values and the corresponding implementation procedures are designed to be used with specific chemicals or related congeners. Total and suspended solids, and turbidity are not specific chemicals, but the combined effect of several unrelated substances. Second, the aquatic life methodology and corresponding implementation procedures are designed to be used with chemicals that exert a direct adverse effect on aquatic life, while these pollutants exert their adverse effects through both direct and indirect means. For example, turbidity not only directly clogs gills, mats eyes, and impairs respiration, but also indirectly affects aquatic life by impairing visibility necessary for finding food, altering water temperature, and reducing primary productivity that serves as the base of the aquatic food chain. Total and suspended solids produce many of the same effects as turbidity, and also affect reproduction of some aquatic life by blanketing spawning areas and smothering eggs in stream beds. The Guidance's aquatic life methodology and implementation procedures do not reflect the indirect effects described above. Third, the Guidance implementation procedures are generally designed to develop water quality-based effluent limits for the same pollutant that has reasonable potential to exceed water quality standards, while to achieve a turbidity level that protects aquatic life will require water quality-based effluent limits on different pollutants, such as total or suspended solids. Therefore, EPA believes it is not appropriate to apply the Guidance methodologies and implementation procedures in the case of total and suspended solids and turbidity.

EPA does not agree with the comments to add additional pollutants to Table 5. Some comments suggested adding "non-toxic" pollutants, including common inorganic constituents such as chloride, sulfate, sodium, and calcium. EPA has decided not to add such pollutants. First, it would likely be difficult to develop an operational definition of "non-toxic." For example, each of the inorganic constituents suggested by commenters has some degree of adverse effects. Furthermore, the effect of a pollutant is a function of both toxicity and exposure, not toxicity alone. Listing a pollutant in Table 5 solely on the basis of low toxicity, however defined, would not be appropriate, because even pollutants with relatively low toxicity could have adverse effects in the environment if present in high concentrations. Second, EPA believes that the final Guidance's criteria development methodologies and implementation procedures are designed to develop appropriate criteria, total maximum daily loads, and water quality-based effluent limits over a wide range of toxicities, including pollutants with lower toxicities. For example, under procedure 5 of appendix F, a discharge containing relatively small amounts of a pollutant with low toxicity might not have reasonable potential to exceed water quality standards, and therefore would not require water quality-based effluent limits. If the pollutants did have reasonable potential to exceed water quality standards, the Guidance methodologies and implementation procedures would be used to develop water quality-based effluent limits. If a pollutant identified in the future has unique "non-toxic" features making one or more of the Guidance methodologies or procedures scientifically indefensible in a particular situation, then § 132.4(h) of the final Guidance could be used generally to exempt that pollutant from selected provisions of the Guidance. Therefore, for all these reasons, it is neither appropriate nor necessary to add "non-toxic" pollutants to Table 5.

The scientific defensibility exclusion discussed in section II.C.6 of this document is designed to achieve a purpose similar to although more limited than Table 5. EPA believes both provisions are useful and appropriate in different circumstances. The scientific defensibility exclusion is available for a pollutant for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible. It enables Great Lakes States and Tribes to apply an alternative methodology or procedure acceptable under 40 CFR part 131 when developing water quality criteria or implementing narrative criteria, or to apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws. This provision would be used to provide exclusions for reasons which are currently unidentified, or not broadly applicable. The Table 5 exclusions, in contrast, are useful for the 14 pollutants where valid scientific and technical reasons for not regulating them under such provisions are already available and broadly applicable as discussed above. The use of the Table 5 exclusion in § 132.4(g) promotes administrative efficiency and conserves resources of States, Tribes, and dischargers by not repeating the analysis of scientific defensibility for each occurrence or discharge of these pollutants.

c. <u>Final Guidance.</u> The final Guidance retains the proposed Table 5 of part 132. Table 5 has been renamed "Pollutants Subject to Federal, State, and Tribal Requirements" to provide a more accurate description.

The final Guidance also retains the proposed provisions for excluding these pollutants from certain specified provisions of part 132, but not from all requirements in Federal, State, or Tribal water quality programs. Sections 132.4(b), 132.4(c), and 132.4(h)(1) of the final Guidance provide that States and Tribes do not need to apply the methodologies for development of criteria and values in appendixes A through D for pollutants in Table 5, but instead must apply any methodologies and procedures acceptable under 40 CFR part 131 when developing water quality criteria or implementing narrative criteria for these pollutants. Sections 4(e)(2) and 132.4(h)(2) of the final Guidance provide that States and Tribes do not need to apply implementation procedures 1, 2, 3, 4, 5, 7, 8, and 9 of appendix F of part 132 for pollutants in Table 5, but any alternative procedures used instead must be consistent with all applicable Federal, State, and Tribal laws.

EPA recognizes that some of the methodologies or implementation procedures of the final Guidance could technically be applied in establishing controls on the discharge of some or all of the pollutants listed in Table 5. For example, procedure 2 (Variances from Water Quality Standards) could be applied in determining whether to grant a variance from water quality standards to a point source discharger of any pollutant. Great Lakes States and Tribes may apply such methodologies or implementation procedures in establishing water quality criteria or controls on the discharge of any pollutant in Table 5 of the proposed Guidance.

In applying alternative methodologies and procedures in the above situations, States and Tribes are encouraged to apply technical guidance that EPA has issued where appropriate to assist in developing and implementing consistent water quality-based controls for these pollutants.

Section 132.4(f) provides no exclusion for Table 5 pollutants from the antidegradation provisions of the Guidance. The antidegradation policy in appendix E, however, provides for different requirements for BCCs than for non-BCCs. The antidegradation policy is discussed in section VII of this document.

For reasons discussed above, hydrogen sulfide and sulfide have been removed from Table 5. The other 14 pollutants listed in the proposal have been retained. No new pollutants have been added.

As discussed in the Comments section above, EPA is concerned about the possibility of inconsistencies among State programs in the Great Lakes basin in addressing ammonia and chlorine. For example, there are differences in numeric criteria adopted by different States for these two pollutants, especially for ammonia. There has not been a systematic evaluation, however, of the implementation procedures used in applying the criteria in the Great Lakes States, nor has there been an evaluation of resulting water quality-based effluent limits in NPDES permits. In part this is because of the complexity of comparing implementation procedures and effluent limits from State to State where States have flexibility in implementation of water quality programs, including the authority to be more stringent than the CWA and implementing regulations.

In order to determine whether significant inconsistency exists in the level of protection of aquatic life from adverse effects of ammonia and chlorine, and to take corrective action if warranted, EPA will work with the States in reviewing water quality standards and implementation of those standards for ammonia and chlorine in the Great Lakes basin as part of EPA's responsibilities under section 303(c) of the CWA. Under section 303(c), States and Tribes must review and revise their water quality standards every three years, and EPA must review and approve or disapprove such standards. For the next two triennial review cycles, EPA will give special attention to working with the States with respect to standards and implementation procedures affecting ammonia and chlorine in the Great Lakes basin to ensure that any inconsistencies are addressed. The review will include the following steps:

- EPA will coordinate with the States and Tribes in reviewing whether water quality criteria for ammonia and chlorine have been adopted in all appropriate waters. Under 40 CFR part 131, States and Tribes must adopt criteria necessary to protect designated uses.

- EPA will place existing toxicological data on ammonia and chlorine in the GLI Clearinghouse, including the EPA criteria documents and supplementary information issued in 1984 and 1992 for ammonia, and in 1985 for chlorine, under section 304(a) of the CWA. It will include any new data or additional valid data that is not be reflected in the above documents.

- To assist the States in ensuring that all States adopt adequate and consistent criteria, EPA will review numeric criteria adopted by the States and Tribes for ammonia and chlorine to determine whether the criteria meet all applicable requirements and are based on consideration of current available scientific information, including data in the GLI Clearinghouse. The review will include consideration of any site-specific modification procedures used by the States and Tribes.

- EPA will also assist the States by reviewing implementation procedures in use by States and Tribes to develop total maximum daily loads, wasteload allocations, and water quality-based effluent limits for these two pollutants as part of EPA's ongoing review of TMDLs and NPDES programs and permits. To assist in this review, State and Tribal procedures will be compared with existing national policies and guidance.

- EPA will use the results of the review in fulfilling its responsibilities to review the triennial submissions of State and Tribal water quality standards. If a State or Tribe does not adopt and submit appropriate criteria for these pollutants, EPA will take appropriate steps including disapproval of the water quality standards, and promulgation of Federal standards for affected waters to ensure consistent and adequate standards for all the Great Lakes System.

The above review steps differ from triennial reviews normally conducted by EPA in five ways. First, they specify two pollutants for in-depth evaluation. That is, EPA plans to evaluate more detailed supporting information concerning State and Tribal standards for these pollutants. Second, EPA will give special attention to identifying and evaluating differences among State and Tribal programs for these pollutants. Third, EPA will coordinate reviews of procedures used in developing total maximum daily loads and water quality-based effluent limits with the triennial reviews, even though they are not a part of the review and approval process of 40 CFR part 131. Fourth, EPA will assist State and Tribal development of water quality standards by providing information through the GLI Clearinghouse. Fifth, the review will be specific to one drainage basin, the Great Lakes basin. Because of differences in the timing of different States' and Tribes' review cycles, and because of the complexities of the interstate comparisons, EPA expects the full review of ammonia and chlorine standards to require up to two triennial review cycles. EPA will make every effort to complete the review no later than 2003.

As part of the consultation with the U.S. Fish and Wildlife Service (FWS) under section 7 of the Endangered Species Act concerning the Guidance, the FWS raised concerns that inconsistencies in standards and how they are applied for ammonia and chlorine may be adversely affecting endangered or threatened species in the Great Lakes basin. In implementing the above review, EPA will consult with the FWS concerning EPA's approval of State and Tribal water quality standards under section 303(c) of the CWA. In addition, EPA will invite and encourage the States and Tribes to participate actively in the consultations. EPA and the FWS believe that the review described above, together with the involvement of FWS in consultations with EPA and the States and Tribes, will serve on an expedited basis to minimize inconsistencies in controls for ammonia and chlorine.

6. <u>Scientific Defensibility Exclusion</u>

a. <u>Proposal.</u> The proposed Guidance at § 132.4(g) provides that the Great Lakes States and Tribes need not apply the proposed criteria methodologies and implementation procedures to any pollutant for which the regulatory authority demonstrates that one or more procedures in the Guidance are not scientifically defensible. The reason for this exclusion is that there may be pollutants identified in the future for which some of the methodologies or procedures in the final Guidance may not be technically appropriate.

EPA specifically invited comment on whether the final Guidance should specify minimum requirements for use of this exclusion, demonstration elements, or procedures for EPA review of these submissions.

b. Comments. Some commenters recommended removal of the language in § 132.4(g) allowing pollutants to be excluded from Guidance procedures and State adoption based simply on a State demonstration, preferring that EPA formally add such pollutants to Table 5.

Several commenters suggested that no minimum requirement should be specified for an exclusion demonstration, and that the Guidance should strive to maintain the flexibility needed for consideration of all site-specific possibilities.

EPA has determined that the scientific defensibility exclusion proposed in § 132.4(g) is necessary and appropriate to include in the final Guidance. Based on long experience in implementing the CWA, EPA has found that no matter how carefully a regulatory requirement is planned, there is no way to anticipate all possibilities. In the water quality standards program in particular, new scientific information inevitably arises that cannot always be accommodated within existing program structures. Eliminating the exclusion would likely require future rulemaking by EPA, States, and Tribes to adjust to new scientific information. Because rulemaking is often a long process, eliminating the exclusion would make it very difficult to adapt quickly to new information when necessary.

EPA believes that the exclusion will be implemented in a way that will maintain a reasonable consistency in State and Tribal programs. As explained in the preamble to the proposed Guidance (58 FR 20843), EPA Regional Offices will work with the States and review State demonstrations during water quality standards submissions, TMDL approvals, and NPDES program implementation. Through this process, the Regional Offices and States will ensure that the scientific defensibility exclusions, if approved, will be consistent with the Guidance, other EPA regulations, and current EPA policy and guidance.

EPA agrees with comments that implementation of the exclusion should proceed without further detailed guidance on minimum requirements, demonstration elements, or review procedures. Since the nature of the exclusions cannot be predicted in detail, such guidance would need to be highly speculative and likely could not anticipate all the circumstances. EPA anticipates that the States and EPA Regions will be able to address most situations in a reasonable way using professional judgment.

c. Final Guidance. For the reasons above, EPA has retained the exclusion for scientific defensibility in the final Guidance.

During its review, EPA discovered that there may have been ambiguity concerning the scope of the exclusion. EPA intended that the exclusion be limited to each specific element of the Guidance that was demonstrated to be inappropriate if applied to a specific situation, and not to all other elements. For example, EPA intended that a pollutant for which a State demonstrated that the Guidance's methodology for development of aquatic life criteria could not be applied should still be subject to other provisions of the Guidance adopted into State or Tribal law, such as other criteria methodologies, site-specific modification procedures, implementation procedures, and antidegradation policies. Accordingly, in order to improve the clarity of the scientific defensibility exclusion, EPA has created a new § 132.4(h) with clarified wording, and deleted the corresponding text from § 132.4(g). The new wording, similar to the proposal, is intended to allow States or Tribes to use an alternative methodology or procedure that corresponds to the methodology or procedure found to be scientifically indefensible.

7. Wet Weather Exclusion

a. Proposal. The proposed Guidance allowed, where appropriate, but did not require, the Great Lakes States and Tribes to adopt provisions consistent with any of the proposed implementation procedures for establishing controls on wet weather point source discharges. Proposed § 132.4(e)(1) provided that "any procedures applied in lieu of these implementation procedures shall be consistent with all applicable Federal, State, and Tribal requirements." Accordingly, even though permitting authorities would not be required to apply State or Tribal requirements consistent with the part 132 implementation procedures in establishing controls on wet-weather point source discharges, all permits would still be required to contain any limitations and conditions necessary to ensure compliance with the CWA and implementing Federal and State regulations. The proposed wet weather exclusion did not apply to the development of water quality criteria and values, since water quality criteria and values apply to waters of the Great Lakes System regardless of the source of the pollutant.

EPA proposed this exclusion from the Guidance implementation procedures because they do not address the significant differences that can exist between wet weather point source discharges and dry-weather point source discharges. The preamble to the proposed Guidance discussed these differences, including the significant variability that exists during and immediately following wet weather events in rates, durations, and composition of wet weather flows (58 FR 20840-42).

b. Comments. Several comments were received supporting retaining the wet weather exclusion in the final Guidance, including comments that application of stringent provisions in the Guidance would in essence prohibit all combined sewer overflows.

A few comments, while not opposing the exclusion on a temporary basis, urged EPA to develop a mechanism for addressing pollution during wet weather point source discharges, since commenters believe that wet weather discharges contribute significant loadings of toxic pollutants to the Great Lakes System and must be stemmed.

No comments on the definition of "wet weather point source" itself were received, although some comments expressed concerns about whether specific types of discharges were or were not excluded from the Guidance implementation procedures.

EPA agrees with the comments that the exclusion should be retained, for the reasons given in the preamble to the proposal (58 FR 20840-42). EPA also agrees that mechanisms are needed for addressing pollution during wet-weather events. Accordingly, procedure 3.B.8 of appendix F has been clarified to provide that States and Tribes must consider pollution resulting from wet weather events, where appropriate, when developing TMDLs. States and Tribes retain flexibility, however, in determining how to account for such discharges and are free to choose the specific procedures they deem most appropriate.

EPA recognizes that the proposed definition of "wet weather point source" should be clarified. As a result, the technical modifications to the definition have been made to clarify which types of discharges are included in the definition, to clarify which types of discharges are excluded, and to delete an unnecessary definition of combined sewer overflow. The definition has also been modified to use terminology from the existing definition of point source contained in § 122.2, for the convenience of the reader.

c. Final Guidance. Section 132.4(e) of the final Guidance retains the proposed wet weather exclusion.

The exclusion applies to "wet weather point sources" as defined in § 132.2. For the reasons above, the definition in the final Guidance has been modified to read as follows:

> Wet weather point source means any discernible, confined and discrete conveyance from which pollutants are, or may be, discharged as the result of a wet weather event. Discharges from wet weather point

sources shall include only: discharges of storm water from a municipal separate storm sewer as defined at 40 CFR 122.26(b)(8); storm water discharge associated with industrial activity as defined at 40 CFR 122.26(b)(14); discharges of storm water and sanitary wastewaters (domestic, commercial, and industrial) from a combined sewer overflow; or any other stormwater discharge for which a permit is required under section 402(p) of the CWA. A storm water discharge associated with industrial activity which is mixed with process wastewater shall not be considered a wet weather point source.

A combined sewer overflow (CSO) is the discharge from a combined sewer system (CSS) at a point prior to the headworks of a publicly owned treatment works (POTW) treatment plant. A CSS is a wastewater collection system owned by a State or municipality (as defined by section 502(4) of the CWA) which conveys sanitary wastewaters (domestic, commercial and industrial wastewaters) and storm water through a single-pipe system to a POTW treatment plant (as defined in 40 CFR 403.3(p). CSOs consist of mixtures of domestic sewage, industrial and commercial wastewaters, and storm water runoff. CSOs are point sources subject to NPDES permit requirements including both technology-based and water quality-based requirements of the CWA. The NPDES permit requirements for CSOs are explained in EPA's Combined Sewer Overflow Control Policy (59 FR 18688, April 19, 1994).

EPA would like to clarify that although Great Lakes States and Tribes are not required to apply Guidance procedures in establishing controls on the discharge of pollutants by wet weather point sources (except for procedure 3.B.8 of appendix F which provides that TMDLs must consider discharges from wet weather events, where appropriate), they may nevertheless choose to do so. Furthermore, the use of such procedures as variances and compliance schedules are available under existing State programs pursuant to parts 122 and 131.

8. Bioaccumulative Chemicals of Concern

a. Proposal. The proposed Guidance identified a class of highly bioaccumulative pollutants, termed BCCs, for special attention. The Great Lakes Initiative Steering Committee believed that every reasonable effort should be made to reduce loadings of all BCCs, because these pollutants tend to persist throughout the Great Lakes ecosystem and have a propensity to bioaccumulate in the food chain, and have been associated with serious and systemwide impacts.

The BCCs were defined in general as those chemicals which bioaccumulate in aquatic organisms by a human health bioaccumulation factor (BAF) greater than 1000, in accordance with the BAF methodology proposed in appendix B to part 132. BCCs would include, but not be limited to the pollutants identified as BCCs in Table 6.

In the proposed Guidance, a pollutant found to be a BCC would be subject to the following special provisions upon State or Tribal adoption or EPA promulgation:

- Under the methodology for deriving non-cancer human health criteria, the proposed Guidance assumed a relative source contribution (RSC) from surface water pathways (water and fish) of 80 percent for BCCs, to at least partially account for exposures through other pathways. For non-BCCs, the RSC assumption was 100 percent. Accordingly, the proposed methodology for deriving the human health non-cancer criteria would be 20 percent more conservative for BCCs than for non-BCCs.

- Under the antidegradation procedures of the proposed Guidance, any action by a discharger that results in an increase in the baseline rate of mass loading of a BCC would be considered a significant lowering of water quality, and thereby trigger an antidegradation review.

- The proposed Guidance provided, in general, that mixing zones for existing discharges of BCCs would be eliminated within 10 years after publication of the final Guidance. For new sources of BCCs, mixing zones would not be allowed beginning on the date of publication of the final Guidance.

- The proposed Guidance provided that for BCCs, permit authorities must generate or cause the discharger to generate the data necessary to derive Tier II values to protect aquatic life in certain circumstances that would not apply to non-BCCs.

- The proposed Guidance would establish a specific process to regulate the discharge of any pollutant for which the water quality based effluent limit was below a level that could be analytically quantified. If the pollutant were a BCC, the discharger would also have to determine if the BCC were bioconcentrating or bioaccumulating in fish exposed to the effluent. If such monitoring revealed unacceptable accumulation in fish tissue, additional actions would be required of the discharger.

b. Comments. EPA received a number of comments suggesting that establishing special provisions for BCCs is not warranted because bioaccumulation of pollutants is already taken into account in the proposed methodologies for developing criteria fully protective of the Great Lakes basin. EPA also received comments supporting the BCC provisions, stating that such provisions are necessary because of the long retention times of the Great Lakes, and because of the widespread adverse effects to human health and wildlife from these types of pollutants.

A number of comments recommended that if special provisions were to be established for BCCs, the BCCs should be limited to substances that have been shown through environmental monitoring, including sampling of fish tissues, to be present at concentrations of concern. Other comments stated that such an approach would be overly simplistic, and would not provide a preventive approach for these pollutants.

A large number of comments questioned various aspects of the definition of BCCs. Many were concerned that the definition did not include the concepts of toxicity and persistence. Of these, some comments recommended deleting pollutants from the BCC list that are not strongly toxic or do not persist for long periods even if they are highly bioaccumulative, while others supported adding pollutants that are persistent even if they are not highly bioaccumulative. Many comments were received concerning the proposed BAF cutoff level of 1000 for defining BCCs: many stated that the proposed level was arbitrarily selected, or based on inadequate scientific analysis; some felt the proposed cutoff was too low; some felt it was too high; and some supported the proposed level. Some comments recommended that only field-measured BAFs, not predicted BAFs, should be used in determining BCCs; others supported the proposed use of both field-measured and predicted BAFs. Some comments recommended considering the sediment route of exposure in establishing BCCs.

Some comments recommended that additional chemicals should not be subject to the special provisions for BCCs until after formal public comment in the Federal Register including review of the BAF.

After careful consideration of the comments, EPA continues to believe that the special provisions for BCCs are warranted. EPA's continued support of the special emphasis on BCCs parallels the position of the Great Lakes States as initially expressed by State representatives on the Initiative Committees. EPA believes that these special provisions for BCCs are a reasonable approach to address the issue of persistent bioaccumulative pollutants in the Great Lakes System, for the following reasons. First, persistence of toxic pollutants is a major concern in an aquatic system like the Great Lakes, for the reasons discussed in the preamble to the proposed

Guidance (58 FR 20820-23, 58 FR 20844-45), and in section I.B of this document. Persistence is especially problematic for chemicals that are highly bioaccumulative, because the most important exposure pathway for these chemicals for humans and wildlife in the Great Lakes System is consumption of fish and other aquatic organisms. Persistent bioaccumulative chemicals will result in high exposures to humans and wildlife for a long time to come.

Second, proposed procedures 3A and 3B in appendix F for development of total maximum daily loads (TMDLs) envisioned predominant use of a simple, steady-state mass balance approach for both bioaccumulative and non-bioaccumulative pollutants. Although the final Guidance would allow use of other approaches for developing TMDLs, EPA expects that the steady-state mass balance approach will be the approach used in a majority of waters within the Great Lakes System because of its ease of implementation. The steady-state mass balance approach is a method used to approximate the mass of pollutants within a water body. This approach assumes that the input of mass into the system (e.g., through point and nonpoint source loadings, atmospheric deposition, groundwater seepage) equals the loss of mass from the system plus any losses due to transformation of mass within the system. In other words, the approach assumes that no mass accumulates in the system. This method provides a first approximation of allowable loading allocations.

For persistent bioaccumulative pollutants, however, approximation based on a steady-state mass balance approach will likely not be accurate. As discussed in section I.A of the preamble to the proposed Guidance (58 FR 20822), there are significant interactive physical, chemical, and biological processes that affect the long-term behavior of persistent bioaccumulative pollutants in the Great Lakes System, resulting in fairly common occurrences where such pollutants do accumulate in the system. Additionally, although the phased approach to TMDLs discussed in section VIII.C of this document recommends subsequent monitoring to identify any shortcomings in the chosen control approach, this approach may present a significant risk of allowing persistent bioaccumulative pollutants to concentrate in the ecosystem above ambient criteria levels before the control approach can be evaluated and revised as necessary. EPA believes the costs of future remediation actions to address BCCs would be significantly more expensive than efforts to control the BCCs before they enter the environment. Accordingly, additional controls intended to prevent concentrations of persistent bioaccumulative pollutants from increasing to the level of criteria concentrations in Great Lakes waters are reasonable.

In the proposal, EPA requested comment on issues concerning the details of the proposed special provisions for BCCs. After analyzing those issues and the comments received, EPA has modified several of the provisions in ways that may in some cases reduce costs for the regulated community without significantly increasing the risk from BCCs. EPA believes that with these modifications the provisions for BCCs will continue to address the concerns of the Initiative Committees for controlling the discharges of BCCs. These modifications include:

-- Modifying the methodology for deriving non-cancer human health criteria to assume a relative source contribution (RSC) from surface water pathways of 80 percent for all pollutants, not just BCCs. Therefore, the 80 percent RSC still applies to BCCs, but is no longer a "special" provision for BCCs. The reasons for this change are discussed in section V.C.5 of this document.

-- Changing the antidegradation provisions to replace numeric existing effluent quality-based ("EEQ") limits as a means of implementing antidegradation for BCCs with a narrative description of the types of activities that will trigger an antidegradation review, and to provide greater flexibility in the implementation, demonstration and decision components. These modifications are discussed further in section VII.A of this document.

-- Providing an opportunity for dischargers to retain a limited mixing zone for a BCC under certain limited circumstances if the discharger is complying with all applicable technology-based and water quality-based requirements and has reduced its discharge of the BCC to the maximum extent possible, but is unable to meet water quality standards in the absence of a mixing zone. This modification is discussed further in section VIII.C.4 of this document.

-- Deleting the provision for dischargers to determine if BCCs were bioconcentrating or bioaccumulating in fish exposed to the effluent in situations where the water quality-based effluent limit was below a level that could be analytically quantified. This modification is discussed further in section VIII.H.4 of this document.

EPA could not accept the concept put forth by commenters that pollutants should not be regulated as BCCs until they are shown to be present at concentrations of concern in the Great Lakes System. As discussed above, EPA is concerned about preventing concentrations of BCCs from increasing to the level of criteria concentrations in Great Lakes waters. The regulatory approach, suggested by some commenters, that would not trigger preventive action until some measurable concentration resulting in adverse conditions is reached in the environment would not be effective in addressing this concern, particularly because of the difficulties of measuring these pollutants at levels of concern in the environment. As discussed further in sections VII.B and VIII.C.4 of this document, the special provisions for BCCs in the final Guidance will take full effect over the next twelve years (two years for State/Tribal adoption or promulgation, plus ten year phase-in period). A program requiring systematic environmental monitoring followed by a regulatory process to designate BCCs could significantly delay implementation of these provisions and allow build-up of new persistent, bioaccumulative pollutants in the Great Lakes System. The risks to the Great Lakes ecosystem of such a delay are too great to warrant such an approach.

EPA agrees with comments that toxicity and persistence should be included in the definition of BCC. As discussed in the preamble to the proposed Guidance (58 FR 20807, 58 FR 20820), toxic pollutants that are persistent and bioaccumulate are of particular concern in the Great Lakes System. With regard to toxicity, EPA has amended the definition of BCC in the final Guidance to provide that a chemical must also have "the potential to cause adverse effects" in order to be a BCC. Under this revised definition, if data become available showing that a chemical that otherwise meets the BCC definition does not have the potential to cause an adverse effect, State or Tribal authorities would not have to apply any adopted or promulgated provisions for BCCs to that chemical. EPA expects that very few pollutants, if any, would be excluded as BCCs in this way, since most substances have potential adverse effects at some level of concentration. Nevertheless, if scientifically valid experimental evidence is provided which demonstrates that a chemical has no potential for producing adverse effects, then a State or Tribe could find that the special provisions for BCCs need not be applied for that pollutant.

EPA has also made changes to the final definition of BCCs with regard to persistence. As discussed in the preamble to the proposed Guidance (58 FR 20821), the proposed definition of BCC was based principally on the concept of bioaccumulation. EPA and the Initiative Committees had considered including persistence in the definition, but found that data were not systematically available concerning persistence. That is, systematic data were not found concerning the cumulative effect of relevant fate and effect processes for the full range of specific pollutants in the Great Lakes System under field conditions, or under laboratory conditions which had been field correlated and verified. Upon review of comments received, and after reevaluation of available data, EPA believes that it is possible, though unlikely, that very specific data might become available showing that a toxic, bioaccumulative pollutant is very short-lived in the aquatic environment. For example, the pollutant may be highly volatile and escape to the atmosphere. In this situation, it would not be necessary to have a full range of data on the cumulative effect of relevant fate and effect pathways for comparison with other pollutants. Rather, the specific data could be used to determine that the pollutant is not persistent. For this reason, EPA has amended the definition of BCC in the final Guidance to include the qualification that "chemicals with half-lives of less than eight weeks in the water column, sediment, and biota are not BCCs." The definition conforms with the Great Lakes Water Quality Agreement, which defines persistent toxic substances as any substance with a half life in water greater than eight weeks.

EPA does not agree with comments that highly persistent pollutants should be subject to the special provisions developed for BCCs even if they are not highly bioaccumulative. First, as discussed above, the special provisions for BCCs in the final Guidance are designed to ensure that exposure to humans and wildlife from BCCs is minimized. The most likely fate for many persistent but not highly bioaccumulative pollutants is to be deposited in sediments, where they will likely remain for long periods. The potential for exposure to humans and wildlife while possible is diminished because the contaminants do not bioaccumulate and in many cases are buried in the sediments.

Second, the threat these pollutants pose to benthic and other aquatic organisms that come in direct contact with the sediment is being addressed through other approaches. Benthic organisms are represented in the methodology for development of criteria to protect aquatic life. In addition, the potential toxicity to benthic organisms from desorption of pollutants from sediment is addressed in existing State programs on a case-by-case basis through implementation of narrative criteria. EPA has also developed a methodology which, when finalized, will be available to assist States and Tribes in addressing the potential toxicity to benthic organisms more systematically. In January 1994 EPA published a notice announcing the availability of proposed national sediment quality criteria for the protection of benthic organisms, guidelines for deriving these criteria on a site-specific basis, and the technical basis for deriving the criteria (59 FR 2652, January 18, 1994). EPA is analyzing the comments received in response to the notice, and will be developing final sediment quality criteria based on the analysis. When the methodology is finalized, it will be available for EPA, States, and Tribes to develop sediment quality criteria for the protection of benthic organisms. This approach is scientifically more appropriate for the control of persistent but not highly bioaccumulative pollutants than the special provisions developed for BCCs in the final Guidance. The BCC provisions were designed to reduce loadings, not to specifically achieve protective levels of contaminants in sediments.

Third, it is reasonable to limit application of the special BCC provisions to highly bioaccumulative pollutants. The special provisions for BCCs and the methodology for defining these pollutants were developed by the senior water program managers in the eight Great Lakes States and three EPA Regional Offices. These managers selected this approach based on their many years of regulating pollutants, including direct experience in the Great Lakes basin.

EPA agrees with comments that recommended considering the sediment route of exposure in predicting BAFs, and partially agrees with comments that recommended that only field-measured BAFs, not predicted BAFs, should be used in determining BCCs. As a result, EPA has added the field-measured biota-sediment accumulation factor (BSAF), which considers the sediment route of exposure, to the hierarchy of methods for deriving BAFs; has selected a new BAF model that better accounts for chemical uptake through sediments; and has modified the Tier I minimum data requirements for human health and wildlife criteria to specify minimum bioaccumulation data. The definition of BCCs has also been revised to be consistent with the above changes. The final Guidance now specifies that the minimum BAF information needed to define an organic chemical as a BCC is either a field-measured BAF or a BAF derived using the BSAF methodology, and that the minimum BAF information needed to define an inorganic chemical, including an organometal, as a BCC is either a field-measured BAF or a laboratory-measured BCF. The reasons for these changes as well as other changes affecting the derivation of BAFs are discussed in section IV.B.2 of this document.

In response to a number of comments on the BAF cutoff level for defining a BCC, EPA has reviewed all of the information and policy considerations in selecting the cutoff level. As a result, EPA has made the risk management decision to retain the proposed BAF cutoff level of 1000 for defining BCCs.

EPA does not agree with the comments that the selection of a BAF cutoff level of 1000 for defining BCCs is arbitrary. EPA believes that this comment may have resulted from a confusion about the nature of risk management decisions. As EPA explained in the preamble to the proposal (58 FR 20844), the selection of a BAF cutoff level is a risk management decision that involves weighing information and policy considerations, rather than a risk assessment assumption that results solely from a scientific analysis. It is not possible, therefore, to specify a mathematical formula or systematic algorithm employing environmental data to select a cutoff level.

EPA weighed a wide range of information and policy considerations in this decision. These include the following considerations:

-- The cutoff level for a BAF should include pollutants that are "highly bioaccumulative" based on exercise of reasonable best professional scientific judgment. EPA believes that a BAF of over two or three orders of magnitude (100 or 1000) would meet this definition.

-- The cutoff level should be high enough that it includes most pollutants for which the fish consumption pathway is the most important route of exposure for humans and wildlife. To select a lower level would cause a scientist using reasonable best professional judgment to question whether the pollutant was "highly bioaccumulative."

-- The cutoff level should be low enough to include those persistent, bioaccumulative pollutants already found to be causing significant contamination, including 2,3,7,8-TCDD (dioxin), mercury, and PCBs.

-- The cutoff level should be low enough to provide adequate assurance that other chemicals that could potentially contaminate the food web of the Great Lakes ecosystem in the future are subject to the special provisions for BCCs.

-- The cutoff level should not be set so low that the regulatory and administrative structure in place in the Great Lakes States and Tribes for control of discharges to waters would be overwhelmed.

-- The cutoff level should be developed after consideration of the scientific, policy, administrative, and technical input from stakeholders in the Great Lakes basin--State regulators, regulated community, and public interest groups.

EPA has determined that the cutoff level of 1000 initially selected by the GLI Steering Committee meets all of the above considerations. As explained in the preamble to the proposal, a pollutant with a BAF greater than 1000 was believed by the Steering Committee to have a high potential to be found in aquatic organisms of the Great Lakes System and therefore to have the potential to cause a significant risk to the health of the aquatic life and consumers of the aquatic life such as wildlife and humans inhabiting the Great Lakes basin. The Steering Committee made its recommendation on the basis of information available to them as managers of water quality programs.

EPA recognizes that other numbers meeting the above considerations could have been selected as a cutoff. For example, several commenters suggested lowering the cutoff to 250. Others suggested a cutoff of 100, and others suggested including all pollutants in Table 6 regardless of BAF. None of these commenters, however, provided reasons other than increasing the number of pollutants to be treated as BCCs as high as possible to avoid as much risk as possible. In other words, none of these commenters provided a rationale that would prefer one "low" cutoff over any other.

On the other hand, a few commenters suggested raising the cutoff to 10,000 or 100,000. They appear to believe the cutoff should be as high as possible without exceeding the BAF of the least bioaccumulative pollutant currently known to cause problems in the basin. EPA believes there are currently known "problem" BCCs, such as lindane, with BAFs lower than 10,000. EPA believes that it is reasonable and appropriate to retain the proposed cutoff of 1000 not only to avoid excluding such pollutants, but also to prevent adverse inputs from additional bioaccumulative chemicals in the future. Past discharges of highly bioaccumulative pollutants have resulted in contamination of the Great Lakes System that is taking decades to subside. EPA believes it is reasonable and appropriate to prevent this from happening with other chemicals in the future.

EPA does not agree with comments that EPA should solicit formal public comment before States or Tribes treat any additional chemicals as BCCs in the future. EPA believes that the States and Tribes should have the ability to designate additional chemicals for BCC controls based on information available to them without waiting for EPA to act. As discussed above, EPA will operate the GLI Clearinghouse as a means to share pollutant information, including BAFs, as quickly as possible. If new information becomes available showing an organic chemical to have a field-measured BAF of over 1000, for example, this information would be reviewed by EPA and other Clearinghouse participants and placed in the Clearinghouse, where States and Tribes would be alerted. States and Tribes would be able to apply the special BCC provisions to the pollutant after following their applicable State or Tribal public review procedures for revisions to water quality standards or for permit development. For example, the State or Tribe could include a description of the special BCC provisions in the public notice for a NPDES permit. EPA believes this would be a more efficient approach than relying in all cases on EPA to sponsor a public review and comment process, which has often taken several years for similar types of actions.

EPA has some concern that inconsistencies could arise among States and Tribes concerning future identification of BCCs under the above approach. EPA believes operation of the Clearinghouse will minimize this possibility. Nevertheless, if serious inconsistencies arise, EPA may from time to time publish available BAF data for a pollutant and solicit public comments. EPA could then issue final technical assistance and recommendations concerning the pollutant to assist State and Tribal revisions to water programs.

c. Final Guidance. EPA has revised the definition of a BCC in § 132.2 of the final Guidance to exclude chemicals that do not have the potential to cause adverse effects. EPA has also modified the proposed definition to exclude chemicals with half-lives of less than eight weeks in the water column, sediment, and biota. Finally, the definition specifies that the human health BAF for non-metals must be derived from a field-measured BAF or a field-measured BSAF. EPA has retained all other features of the proposed definition, including the BAF cutoff level of 1000. The revised definition reads:

> BCC is any chemical that has the potential to cause adverse effects which, upon entering the surface waters, by itself or as its toxic transformation product, accumulates in aquatic organisms by a human health bioaccumulation factor greater than 1000, after considering metabolism and other physicochemical properties that might enhance or

inhibit bioaccumulation, in accordance with the methodology in appendix B of this part. Chemicals with half-lives of less than eight weeks in the water column, sediment, and biota are not BCCs. The minimum BAF information needed to define an organic chemical as a BCC is either a field-measured BAF or a BAF derived using the BSAF methodology. The minimum BAF information needed to define an inorganic chemical, including an organometal, as a BCC is either a field-measured BAF or a laboratory-measured BCF. BCCs include, but are not limited to, the pollutants identified as BCCs in section A of Table 6 of this part.

EPA has applied the above changes in the definition to calculate BAFs for individual pollutants listed in Table 6. The results are included in the Great Lakes Water Quality Initiative Bioaccumulation Factor Technical Support Document, which is available in the docket for this rulemaking. These calculations have resulted in the deletion of six chemicals from the proposed list of pollutants in Table 6A: aldrin, 4-bromophenyl phenyl ether, endrin, heptachlor, heptachlor epoxide, and methoxychlor. For these six chemicals there were insufficient data to develop a field-measured BAF or a BAF predicted from a field-measured BSAF. BAFs based on laboratory-measured BCFs are available for endrin, heptachlor, heptachlor epoxide, and methoxychlor; BAFs based on a laboratory-predicted BCF are available for aldrin and 4-bromophenyl phenyl ether.

As a result, the final Guidance lists 22 BCCs in Table 6A to part 132. They represent EPA's best scientific judgment at this time concerning which pollutants on Table 6 meet the final definition of BCCs. States and Tribes may determine, however, that additional pollutants meet the definition or should be subject to the special provisions for BCCs. If so, they should take appropriate regulatory action as discussed above to treat the chemicals as BCCs in their water quality standards and NPDES permit programs, including the special provisions for BCCs contained in the final Guidance.

EPA has underway field testing programs to develop field-measured BAFs and field-measured BSAFs for additional pollutants, including the six chemicals deleted from the proposed list of BCCs. It is possible that some of this testing may result in identification of additional pollutants that meet the definition of BCC. When this testing is complete and BAFs have been calculated, EPA will place the results in the GLI Clearinghouse where they will be available for States to use in making their determinations.

9. Potential Bioaccumulative Chemicals of Concern

a. Proposal. The proposal listed ten chemicals as potential BCCs in section B of the proposed Table 6. Although the ten chemicals had BAFs of greater than 1000 based on predicted BCFs (eight chemicals) and on laboratory-measured BCFs (two chemicals), other available information described in the proposal to the preamble raised serious doubts that the actual BAFs for these chemicals exceeded 1000. For this reason, EPA proposed that the special provisions for BCCs would not apply to these ten pollutants. EPA invited comment on whether any or all of the potential BCCs should be listed as BCCs and any additional data relevant to these determinations.

b. Comments. Many comments recommended that EPA delete the list of potential BCCs and not apply the special BCC provisions to these chemicals. These commenters asserted that the ten potential BCCs are readily metabolized and do not bioaccumulate at high rates.

Some comments recommended that several polynuclear aromatic hydrocarbons (PAHs) on the list of potential BCCs should be treated as BCCs, asserting that these chemicals have relatively high BAFs when measured in lower trophic level species, and therefore pose a risk to wildlife or people eating those species, even though they are metabolized by higher trophic level species and therefore have relatively low human health BAFs.

EPA agrees that the potential BCCs should not be treated as BCCs, and should be deleted from the final Guidance. For the reasons discussed above in section II.C.8 of this document, EPA has modified the definition of BCC in the final Guidance to use only the two methods of developing BAFs for non-metals that take into account metabolism. None of the ten potential BCCs have BAFs available using these two methods, and therefore they are not listed as BCCs in Table 6. Furthermore, as discussed in the preamble to the proposed Guidance, there are indications that the ten chemicals would likely not have BAFs exceeding 1000 if metabolism were taken into account. If reliable data were to become available in the future showing a BAF of over 1000 for any of these ten chemicals or other chemicals based on a field-measured BAF or BSAF, then States and Tribes would need to apply the special BCC provisions to these chemicals.

EPA does not agree that the PAHs with high BAFs at low trophic levels should be treated as BCCs at this time. The special provisions for BCCs are designed to address pollutants that accumulate in the food web of the Great Lakes ecosystem. Pollutants that accumulate in lower trophic levels but which are metabolized at higher levels are not as likely to affect the food web as a whole as those that continue to accumulate at higher trophic levels. The definition of a BCC in the final Guidance therefore does not include any special procedures that would classify such a pollutant as a BCC. Such a pollutant would, however, become a BCC if data were to become available in the future resulting in a human health BAF of over 1000.

EPA established the category of "potential BCC" in the proposed Guidance primarily to obtain comment on whether such pollutants met the definition of BCCs and should, accordingly, be subject to the special provisions for that class of pollutants. Since EPA has now completed its analysis of comments and determined that potential BCCs do not appear to satisfy the final definition of BCC, and since no special provisions in the Guidance apply to potential BCCs that do not apply to other pollutants, there is no further purpose for retaining the list of potential BCCs in the final Guidance. Therefore, the proposed list of potential BCCs has been deleted.

c. Final Guidance. For the reasons discussed above, the proposed list of potential BCCs in section B of Table 6 of part 132 has been deleted. Section C of Table 6 has been redesignated as section B, Pollutants That Are Not BCCs.

10. Pollutants of Initial Focus

a. Proposal. As described in the preamble to the proposed Guidance (58 FR 20843-44), 138 pollutants were identified by the Great Lakes Initiative Steering Committee and listed in Table 6 of the proposed Guidance as the pollutants of initial focus in the Great Lakes Water Quality Initiative. The 138 pollutants in proposed Table 6 included: (a) the 126 pollutants identified by EPA as priority toxic pollutants in appendix A of 40 CFR 423; (b) selected pollutants listed in the Great Lakes Water Quality Agreement of 1978 (as amended by the Protocol signed November 18, 1987); (c) certain pollutants categorized under the Lake Ontario Toxics Management Plan and the Niagara River Toxics Management Plan; and (d) three pollutants included on a case-by-case basis.

The primary purpose of the Initiative Committees in specifying pollutants in Table 6 was to provide an initial focus for criteria development and the calculation of bioaccumulation factors in the Great Lakes System. The pollutants included in Table 6 were not intended to be a comprehensive inventory of all pollutants present, used, manufactured, or stored in the Great Lakes System, but were thought to represent pollutants which may be of concern in the Great Lakes, and for which adequate effluent, ambient, and toxicity data would be available to assess the impact of the various options considered in developing the Guidance.

The proposed Guidance provided an initial focus on the Table 6 pollutants in the following three ways: First, the pollutants for which EPA and the States applied the proposed criteria methodologies to derive numeric water quality criteria--that is, the pollutants in Tables 1 through 4--were selected from the list of pollutants in Table 6. Second, EPA and the Great Lakes States calculated bioaccumulation factors (BAFs) for the Table 6 pollutants to assist EPA and the States in developing criteria and values to protect human health and wildlife. Third, the Table 6 list of pollutants is one factor used in determining when States, Tribes, and/or permittees need to generate data necessary to calculate Tier II values used in developing water quality-based effluent limits. Comments on the use of Table 6 in the data generation provisions of procedure 5 of appendix F are discussed in section VIII.E of this document.

b. Comments. Some comments suggested additional pollutants to be added to Table 6, including: pollutants listed in the Great Lakes Water Quality Agreement, Annex 10, Appendix 1 (Hazardous Polluting Substances) or Appendix 2 (Potentially Hazardous Polluting Substances); high-use pesticides; persistent pollutants that do not bioaccumulate; all drinking water contaminants as listed in the 1986 amendments to the Safe Drinking Water Act; pollutants categorized as ID or IE in the Categorization of Toxics in Lake Ontario or in the Categorization of Toxic Substances in the Niagara River; all the dioxins, furans and PCBs that are known to operate via the Ah receptor in any animal species; as well as a number of specific pollutants listed by commenters.

Some comments suggested that Table 6 should be limited to chemicals which are causing demonstrated impacts to water quality in the Great Lakes System. Other comments suggest limiting Table 6 to pollutants which pose water quality concerns unique to the Great Lake system, such as the list of critical pollutants being developed by Lakewide Management Plans. Other comments recommended that in the interest of establishing reasonable priorities for the Great Lakes States, EPA should eliminate non-BCCs from Table 6. Other comments recommended removing specific pollutants from Table 6, such as asbestos, fluoride, methylene chloride, phenol, phthalate esters, and silver.

Some comments expressed concern that the proposed Guidance did not include clear procedures on how additional toxic pollutants that are introduced or discovered in the Great Lakes Ecosystem will be added to Table 6, or be regulated prior to formal revision of the Guidance.

EPA does not agree that additional pollutants should be added to Table 6. EPA believes it would be counterproductive to expand the pollutants of initial focus to a significantly larger set of pollutants. Table 6 has already been used successfully during the development of the proposed and final Guidance to focus development of data needed to implement the final Guidance. As a result of EPA and State efforts, many of the data gaps that existed for these pollutants at the start of the Great Lakes Water Quality Initiative have been filled. Applying limited EPA, State, Tribal, and discharger resources at this time to address a broader list of pollutants in the ways described under the Proposal section above would divert resources away from other important actions, such as developing a richer data base concerning effects of pollutants in the proposed Table 6 on endangered or threatened species.

EPA also does not agree with comments that the list of 138 should be reduced. All of the 138 pollutants have been identified as either priority pollutants under the CWA or as pollutants of specific concern in the Great Lakes basin. EPA also does not agree that Table 6 should be limited to BCCs. BCCs are not the only types of pollutants currently or potentially affecting the Great Lakes ecosystem. For the same reasons, EPA does not agree with comments that specific pollutants be removed from the list.

EPA recognizes that the final Guidance does not include procedures for adding additional pollutants to Table 6. EPA believes that the GLI Clearinghouse can be used as a forum for determining additional needs for BAF calculations, and for sharing of BAF results. If it should become apparent in the future that adding pollutants to Table 6 would assist in reducing disparities between data generation approaches of the States and Tribes under procedure 5.C of appendix F, EPA would consider recommending that States and Tribes expand the Table 6 lists that they have adopted into their programs to be consistent with the final Guidance. This could be done during the triennial review of water quality standards programs under section 303 of the CWA.

c. Final Guidance. The final Guidance retains Table 6 as proposed.

EPA would like to clarify that the methodologies and procedures in the final Guidance generally apply to all pollutants, except for the pollutants in Table 5. The Table 6 list of pollutants is one factor used in determining when States, Tribes, and/or permittees need to generate data necessary to calculate Tier II values used in developing water quality-based effluent limits.

D. Procedures for Adoption and EPA Review

1. Adoption Procedures

a. Proposal. Proposed § 132.5(a) required the Great Lakes States and Tribes to adopt and submit for EPA review and approval the criteria, methodologies, policies and procedures developed pursuant to part 132 by a date no later than 18 months from the date of final publication of the part 132 requirements. EPA proposed the 18-month deadline in order to allow the full time available under the statute for EPA review and approval of submissions and for States and Tribes to correct any identified deficiencies, and still allow EPA to meet the section 118(c)(2)(C) requirement for review, approval or disapproval and promulgation by EPA, if necessary, within two years after the final publication of the Guidance. Proposed § 132.5(d) also provided a 30-day public comment period on the submissions.

If a Great Lakes State or Tribe failed to submit criteria, methodologies, policies, and procedures to EPA for review, or if EPA disapproved portions of all of a State or Tribal submission because it was inconsistent with part 132, proposed § 132.5 provided that the requirements of part 132 would apply to discharges within the State or Federal Indian Reservation upon EPA's publication of a final rule in the Federal Register indicating the effective date of the part 132 requirements in the identified jurisdictions.

b. Comments. A few commenters recommended that the Guidance be adopted as soon as possible because they believe it is a major step forward in efforts to protect the Great Lakes and fulfill promises of the U.S.-Canada Great Lakes Water Quality Agreement and the Great Lakes Governors' Toxic Substances Control Agreement.

Some commenters indicated that the two-year adoption period was too short. Other commenters recommended that EPA eliminate the 18-month deadline for State submittals, or allow extensions to the deadline on a case-by-case basis as long as the State and EPA agree on a schedule that will meet the statutory deadline. Several commenters stated that the public comment requirements during EPA's review of State submittals may not be necessary, and are inconsistent with the current national program.

EPA agrees that States and Tribes should adopt provisions consistent with the Guidance as soon as possible. EPA has reviewed the steps States, Tribes, and EPA must take to develop, adopt, approve, and if necessary disapprove and promulgate the Guidance, however, and has concluded that it would not be possible nor practical to complete these steps in less time than the two years specified in section 118(c)(2)(C) of the CWA. EPA has therefore not shortened the deadline in the final § 132.5(a). EPA encourages States and Tribes to accelerate their adoption and submission processes as much as possible, and as discussed further below, EPA Regional Offices will work with States and Tribes to facilitate early adoption and approval where possible.

EPA recognizes that the two-year deadline specified by the Congress may be extremely ambitious. EPA's experience in reviewing State water quality standards adopted under section 303(c) indicates that many of the Great Lakes States have had difficulties adopting even routine water quality standards revisions within three years as specified for triennial reviews in the CWA. Nevertheless, EPA believes the States, Tribes, and EPA Regional Offices can work together to meet the deadline, especially since the majority of provisions of the final Guidance were developed by the States themselves as part of the Great Lakes Water Quality Initiative and many are currently in effect in one or more of the States. Furthermore, the two-year deadline is established explicitly by section 118(c)(2)(C) of the CWA. Therefore, the final Guidance retains the two-year deadline for final approval or promulgation.

EPA agrees with comments, however, that flexibility may be appropriate in some cases concerning the eighteen-month deadline for State and Tribal submissions to EPA under § 132.5. There may be situations where the EPA Regional Office has worked closely with the State or Tribe during their development and adoption of provisions consistent with the Guidance and believes that the full six month period for EPA review of the submission will be unnecessary. For example, a State may decide to adopt the provisions of the Guidance with only minor modifications, and may have early indications that the public supports this approach. In this situation, EPA believes that an extension to the eighteen-month deadline would be reasonable because EPA would have a high degree of assurance that it would still be able to review and approve the submission within the two-year statutory deadline. Therefore, EPA has added § 132.5(c) that allows the EPA Regional Administrator to extend the deadline for a State or Tribal submission beyond 18 months if the Regional Administrator believes that the submission will be consistent with the requirements of the final Guidance and can be reviewed and approved within the two-year deadline. In these cases, EPA expects that the Regional Administrator will need to reach early agreement with the State or Tribal director on a joint schedule for specific steps that the State or Tribe and EPA will take over the two-year period to meet the requirements of § 132.5. To ensure success, the EPA Regional Offices will likely need to provide technical guidance and assistance to the States or Tribes early in the adoption process, and will need to begin analyzing drafts of the State or Tribal submission even before it is formally submitted to determine whether provisions are consistent with the final Guidance.

EPA also agrees in part with comments that the proposed requirement for a 30-day comment period was unnecessary and should be revised. The proposed provision for public comment was patterned in general on existing minimum public comment requirements for proposed modifications to State NPDES programs under 40 CFR 123.62(b) and State water quality standards programs under part 131. Section 123.62(b) requires a public comment period on State NPDES submissions only if the proposed program modification is substantial. Furthermore, section 303 of the CWA and part 131 do not require EPA to provide public review and comment on EPA approvals of State water quality standards submissions. <u>City of Albuquerque v. Browner</u>, 38 ERC 2062 (DNM 1993). EPA believes that it is not necessary or appropriate to impose more extensive public notice-and-comment requirements for submissions under part 132 than for the submissions in the underlying NPDES and water quality standards programs affected by part 132. EPA also believes that EPA Regional Offices will be able to determine whether a specific provision in the submission constitutes a substantial modification to the underlying State program without great difficulty because of their familiarity with the existing State programs.

Therefore, EPA has modified proposed § 132.5(d), now redesignated § 132.5(e), to conform with the minimum public notice and comment requirements of parts 123 and 131.

One commenter urged that phase-in periods for implementing certain provisions (e.g., the ban on mixing zones for BCCs) be dated from the time of final federal publication of the Guidance, not the date of State and Tribal final adoptions. EPA does not agree with this comment. Section 118(c)(2)(C) requires States to adopt provisions consistent with the final Guidance by no later than two years from date of publication, or be subject to EPA promulgation within that two-year period. Because the provisions will not be effective until they are promulgated by a State, Tribe, or Federal agency, EPA believes that it is reasonable to delay the computation of any phase-in period until the statutory deadline for such promulgation. Accordingly, all phase-in periods and similar provisions that distinguish between activities occurring before or after a specified date (e.g., the definition of "new Great Lakes discharger") are calculated from the date two years after publication of this final Guidance.

c. Final Guidance. Section 132.5(a) of the final Guidance retains the general deadline of eighteen months after publication of the final Guidance, or September 23, 1996, for States and Tribes to submit criteria, methodologies, policies, and procedures developed pursuant to the Guidance.

The final Guidance has been modified to add new § 132.5(c) which allows the Regional Administrator to extend the deadline for the submission required in § 132.5(a) if the Regional Administrator believes that the submission will be consistent with the requirements of the final Guidance and can be reviewed and approved no later than March 23, 1997. As discussed under the Comments section above, EPA expects that before granting an extension the Regional Administrator will reach agreement with the State or Tribal director on a joint schedule for specific steps to meet the requirements of § 132.5. The joint schedule should include opportunities for EPA to review drafts of State or Tribal provisions in order to facilitate EPA review and approval. In these cases, EPA intends to provide technical guidance and assistance to the State or Tribe throughout the adoption process, beginning as soon as possible. Conforming provisions have been added to § 132.5(a), and proposed § 132.5(c) has been redesignated as § 132.5(d).

The provisions for public notice and comment in proposed § 132.5(d) have been redesignated as § 132.5(e) and modified to provide for public notice and at least 30 days' public comment only in situations where the State submits substantial modifications to its NPDES program.

The provisions for EPA approval and disapproval in proposed § 132.5(d) have been moved to new § 132.5(f).

In reviewing proposed § 132.5, EPA noted that it would be administratively impossible for EPA to provide the 30-day comment period on State submissions and still issue a notice of approval of a State or Tribe's submission within 60 days of receipt of the submission as proposed in § 132.5(d)(1). The proposed 60-day deadline was based on the similar deadline in section 303(c) of the CWA for approving State water quality standards. The section 303(c) approach does not include a requirement for public notice and comment, however. Since the final Guidance includes a minimum of 30 days for such a requirement in cases where a State submits a substantial modification to its NPDES program, EPA has modified the final Guidance to add 30 days to the deadline for EPA approval. Final § 132.5(f)(1) now requires EPA to issue a notice of approval of a State or Tribe's submission within 90 days of receipt of the submission.

Proposed § 132.5(e) has been redesignated as § 132.5(g).

A new § 132.5(h) has been added concerning results of consultation under the Endangered Species Act. It is discussed further in section II.G of this document.

Proposed § 132.5(f) has been redesignated as § 132.5(i).

2. Interpretation of "Consistent With"

a. Proposal. Section 118(c)(2)(C) of the CWA requires Great Lakes States to adopt water quality standards, antidegradation policies, and implementation procedures consistent with the final Guidance, or EPA is required to promulgate for the States. Section 132.5(e) of the proposed Guidance specified the conditions under a State or Tribe submission is consistent with the requirements of part 132. Generally, the proposed Guidance provided that submitted criteria, methodologies, policies and procedures would be consistent with part 132 if they are "equal to or more restrictive than" the provisions in the final Guidance. Proposed § 132.5(e)(3) clarified EPA's intention to evaluate the State and Tribal submissions on a provision-by-provision basis by providing that if States or Tribes adopt provisions more restrictive than the final Guidance, the more restrictive provision may not be offset by relaxation of other specific elements of the final Guidance.

b. Comments. Many comments urged EPA to strictly interpret the "consistent with" requirements, and to require States and Tribes to justify deviations from the Guidance, in order to achieve the desired standardization of programs basin-wide. Several comments urged EPA to require explicitly that all State and Tribal procedures and criteria be consistent with and no less stringent than Guidance procedures and criteria. A few comments said States should be directed to retain existing numeric water quality criteria and procedures where they are more stringent than the final Guidance, in order to maintain continual progress toward zero discharge as outlined in the Great Lakes Water Quality Agreement and the CWA.

Some commenters interpreted the CPA as directing EPA to publish guidance to the states, rather than a fixed rule, and therefore urge EPA to give the States a measure of latitude in implementing the Guidance. Some commenters argued that EPA should not reduce State flexibility currently available in States' implementation of section 303(c) of the CWA.

Some commenters believed that State flexibility is needed to enable cost-effective implementation of the Guidance, to maintain State primacy as provided in the CWA, to minimize the administrative burden on the States, to reflect the innovative nature of the Guidance, and because States are more familiar with the environmental conditions in local areas and are better able to work effectively with dischargers to address problems. Some commenters urged additional state flexibility to ensure that future improvements in science are readily incorporated into the Guidance. Some comments stated that more flexibility is needed to reflect ecological differences between areas in the Great Lakes basin which require different regulatory responses. Some commenters recommended that since many real-world permitting situations probably exist which preclude a straightforward application of the proposed implementation procedures, EPA should to the maximum extent possible structure the final Guidance to function truly as "guidance" for the States.

Some comments recommended that where the overall outcome is the same, EPA should allow a state to be less stringent in one area of the methodology if it is more stringent in another. Some commenters suggested that EPA should interpret "consistent with" as meaning "substantially equivalent to" so that States and Tribes may adopt criteria and procedures tailored to their own circumstances so long as the overall impact of the program is to treat substantially similar sources in a substantially equivalent manner.

EPA does not agree that the amendments to section 118(c)(2) of the CWA directed EPA simply to publish non-binding guidance. This section not only directs EPA to provide guidance to the Great Lakes States on minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System, but also requires the States to adopt water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System which are consistent with such guidance or be subject to EPA promulgation (section 118(c)(2)(C)). EPA believes that whether States and Tribes adopt minimum standards, policies, and procedures consistent with the final Guidance, or whether EPA promulgates them, the Congress intended that the final Guidance would establish minimum, and ultimately, enforceable requirements for the Great Lakes System.

This interpretation of section 118(c)is supported by the primary authors of the Critical Programs Act. In a June 9, 1994, letter to Governor Cuomo discussing this issue, Senators Levin, Glenn, and Kohl emphasized the need to provide enforceable requirements through a federal regulation in order to improve consistency in State water quality programs in the Great Lakes System.

> ...While flexibility is built into the law, the Great Lakes Guidance is nevertheless intended to be an enforceable federal regulation....Guidelines without enforceability cannot achieve the overarching goal of the Great Lakes Initiative to ensure consistent Great Lakes water quality protections throughout the basin.
>
> In light of the differences among our state water quality programs, the Great Lakes Guidance will no doubt require adjustments in each of our states. But our states knew that when they launched the Initiative and committed themselves to developing a single set of rules for everyone to live by in the Great Lakes Basin. In fact, reducing state disparities was a driving force behind the Initiative....

This interpretation of section 118(c) is also supported by the extremely short time frame specified in the statute for EPA promulgation of the Guidance in the absence of State adoption. As discussed above, provisions consistent with the final Guidance must ultimately be adopted by Great Lakes States and Tribes or be promulgated by EPA within two years. This statutory deadline for State adoption and EPA approval or promulgation of the Guidance does not allow sufficient time for EPA to take additional steps, such as publishing the proposed and final Guidance first, followed by proposing and finalizing a separate rule governing EPA approval and promulgation. Rather, the rule that was proposed and is now being finalized contains both the substance of the Guidance, including the criteria in Tables 1 through 4 and the methodologies, policies, and procedures in appendixes A through F, as well as the approval and promulgation procedures that EPA will use for review of State and Tribal submissions.

EPA also does not agree that the CPA intended to afford States the same flexibility currently available under section 303(c) of the CWA. Section 303(c) requires that States adopt and implement water quality standards to help restore and maintain the chemical, physical, and biological integrity of the Nation's waters. EPA has periodically provided guidance to States in implementing these requirements, including water quality criteria published pursuant to section 304(a) of the CWA. States have the flexibility to use section 304(a) guidance or other scientifically defensible approaches in adopting and implementing water quality standards. As discussed in the preamble to the proposed Guidance (58 FR 20835), however, the Initiative Committees believed this level of flexibility over the years had resulted in significant differences in State adopted water quality standards, antidegradation policies, and implementation procedures, as well as inconsistencies in regulatory approaches and individual permit decisions in the Great Lakes basin. The Congress was aware of these inconsistencies and of the efforts of the Initiative Committees to develop the Guidance when it enacted the CPA. The requirements in section 118(c)(2) described above represent the direction of the Congress to adopt or promulgate minimum water quality standards, antidegradation policies, and implementation procedures for the entire Great Lakes System. In order to have any meaning, implementation of these specific requirements for the Great Lakes System will necessarily result in some reduction in the flexibility of the Great Lakes States.

EPA agrees with comments that the final Guidance should require State and Tribal submissions to be at least as protective as the final Guidance in order to achieve the increased consistency and minimum threshold levels of control intended by the Congress. For this reason, EPA has retained the proposed § 132.5(e) with clarifying amendments, now redesignated as § 132.5(g), under which submitted criteria, methodologies, policies and procedures will be considered consistent with part 132 if they are "as protective as" the provisions in the final Guidance. EPA believes that specifying "as protective as" will ensure that provisions adopted by the States and Tribes will be equivalent to or more protective than the final Guidance. Further, EPA believes that this is a reasonable and appropriate mechanism for implementing EPA's duty to define the "minimum" requirements for water programs in the basin.

EPA also agrees with comments, however, that it is appropriate to provide reasonable flexibility to States and Tribes, to the extent that this can be done and still meet the requirements and purpose of the CWA. In overseeing States' implementation of the CWA, EPA has found that reasonable flexibility is not only necessary to accommodate unforeseen circumstances, but is also appropriate to enable innovation and progress as new approaches and information become available. To address the need for flexibility, EPA made several changes to the proposed Guidance.

First, EPA reviewed all sections of the proposed Guidance and all comments to determine the appropriate level of flexibility. Based on this review, the final Guidance provides increased flexibility for State and Tribal adoption and implementation of these provisions in many areas, including antidegradation, TMDLs, intake credits, site-specific modifications, variances, compliance schedules, elimination of mixing zones for BCCs, and the scientific defensibility exclusion. The final Guidance also provides reduced detail of provisions in many areas, and provisions for the exercise of best professional judgment by the Great Lakes States and Tribes when implementing many individual provisions. This increased flexibility is discussed further in section I of this document.

Second, EPA clarified how "offsets" will be considered between elements of State and Tribal programs. See discussion below.

Third, EPA added §132.1(b) in the final Guidance to clarify that verbatim adoption of the Guidance is not required. EPA believes that State and Tribal programs do not need to be identical to the Guidance to result in equally protective criteria, methodologies, policies, and procedures. States and Tribes instead have flexibility to adopt alternative provisions as long as they are as protective of human health, wildlife, and aquatic life in the Great Lakes System as the Guidance.

EPA believes that the flexibility available in the final Guidance will satisfy many of the specific concerns of commenters. For example, based on their familiarity with environmental conditions in local areas, States and Tribes may use the site-specific modification procedures to adjust criteria and values in order to reflect ecological differences from site to site. States and Tribes also have flexibility to adjust criteria, methodologies, or procedures to reflect future improvements in scientific understanding. For example, States and Tribes may use the scientific defensibility exclusion in §132.4(h) to apply a new, alternative methodology or implementation procedure (see section II.C.6 of this document), or they may adjust elements within a Guidance provision as long as the provision as a whole is consistent with the final Guidance (see discussion of "offsets" below in this section).

Additionally, as discussed in section II.C.1 of this document, there are several steps within the criteria methodologies where some flexibility is available to reflect new findings and data.

EPA understands that the science of risk assessment utilized in environmental protection, including criteria methodologies, is rapidly evolving and improving. Therefore, to ensure that the scientific basis for the methodologies in appendices A through D is always current and peer reviewed, EPA will review the methodologies and revise them as appropriate every three years.

The final Guidance is not, by itself, enforceable. Provisions consistent with the Guidance will become enforceable only when adopted by a State or Tribe as part of its NPDES or water quality standards programs, promulgated by EPA in the absence of State or Tribal action, or when included in a NPDES permit.

EPA does not agree with comments that States should be directed to retain existing numeric water quality criteria that are more stringent than the final Guidance. Although under § 132.4(i) States may choose to retain more stringent criteria, the final Guidance does not require them to do so. The CPA requires the Guidance criteria to protect human health, aquatic life, and wildlife. EPA and the Initiative Committees have designed the criteria methodologies to meet this requirement. Therefore, while the development of more stringent provisions may be necessary because of site-specific conditions within their jurisdiction and is also available as an option for States and Tribes under any circumstances, automatic retention of existing more stringent criteria is not required by the CPA. For this reason, the final Guidance generally requires only that the States and Tribes adopt and use criteria and values that are as protective as those produced by the Guidance methodologies.

EPA also does not agree with recommendations that the decision whether State or Tribal submissions are "consistent with" the final Guidance should be based only on the overall outcome of applying all of the Guidance provisions. Such an approach, which would allow "offsets" between separate provisions, would be technically and administratively unworkable for the following reasons. Because of the differing nature of each methodology and procedure and differences in the site-specific characteristics of each discharge and discharge location, it would be administratively difficult, if not impossible, to quantify and compare numerically the effects of allowing more stringent changes in one methodology or procedure, for example, to "offset" less stringent changes in different methodologies or procedures. The only potential way to make a valid comparison would be to apply the full set of Guidance methodologies and procedures to specific cases, such as developing water quality-based effluent limits for a range of NPDES discharges to a range of receiving waters, and comparing those limits with limits derived using alternative State or Tribal procedures for the same dischargers. Based on its experience, EPA does not believe such analyses can produce useful results within a reasonable time or with available resources. Additionally, EPA does not believe that it could undertake this lengthy and complex analysis within the short time period specified by Congress in section 118(c)(2)(C) for review and approval or disapproval and promulgation of the Guidance provisions in the eight Great Lakes States. Finally, allowing offsets between provisions (e.g., between the human health criteria methodology and the aquatic life criteria methodology, or between the TMDL procedure and the mixing zones provisions), would not ensure appropriate levels of protection for human health, wildlife, and aquatic life in the Great Lakes System. For these reasons, EPA has retained the prohibition against offsetting changes between different provisions, but has made editorial changes to clarify that variations or offsets of elements within a particular provision are acceptable as long as the submitted provision is consistent with the Guidance.

c. <u>Final Guidance.</u> The final Guidance generally retains the proposed conditions in § 132.5(e), redesignated as § 132.5(g), under which EPA will determine that the criteria, methodologies, policies, and procedures in a State or Tribal submission are consistent with the requirements of the final Guidance.

EPA corrected the header for § 132.5(g)(2) to refer to "pollutants other than those listed in Tables 1, 2, 3, 4, and 5." In the proposal, reference to Table 5 was omitted by error.

EPA modified § 132.5(g)(2)(ii)(A) to refer to "numeric criteria adopted by the State into State water quality standards and approved by EPA prior to March 23, 1997." EPA added the reference to EPA approval, and changed the date to reflect the two years allowed for State adoption of the final Guidance. EPA found that these technical changes were needed to clarify the intent of this section.

For the reasons discussed in the Comments section above, EPA made editorial changes to clarify the general prohibition in § 132.5(g)(3) against offsets between provisions. The final Guidance states that "adoption of a more protective element in one provision is not justification for adoption of a less protective element in another provision of this part." States and Tribes are not precluded, however, from offsetting elements within a particular provision as long as the adopted provision is consistent with the final Guidance. For example, a State could not use a more protective element in the human health cancer methodology to offset a less protective element in either the human health non-cancer methodology or the aquatic life methodology. In contrast, a State could use a more protective element within the human health cancer methodology (e.g., cancer risk level assumption) to offset a less stringent element within the same methodology (e.g., fish consumption value) as long as the resulting methodology and criteria were as protective as the final Guidance.

When determining whether criteria adopted by the State or Tribe comply with § 132.5(g)(1), EPA will consider not only whether the State or Tribal criteria are numerically as protective as the criteria in Tables 1 through 4, but also whether all other provisions of the Guidance pertaining to the criteria have been fully incorporated. For example, EPA will consider under procedure 1 of appendix F whether more stringent criteria are needed to protect a threatened or endangered species. Additionally, if a State or Tribe submits site-specific criteria less stringent than the criteria in Tables 1 through 4, then the State or Tribe should submit documentation as required by § 132.5(b)(4) showing how procedure 1 has been used to develop the less stringent site-specific modifications. If a State or Tribe uses the scientific defensibility exclusion in § 132.4(h) to develop less stringent criteria, then the State or Tribe should likewise submit full documentation of its demonstration that the corresponding Guidance criteria methodology is scientifically indefensible for the particular situation. It is expected that § 132.4(h) will only be invoked for data which become available after this publication of the final Guidance. That is, § 132.4(h) will generally not serve as the basis to reconsider data already available and considered by EPA prior to this publication.

Similarly, in reviewing criteria and values for pollutants other than those in Tables 1 through 5, EPA will consider whether all relevant requirements of the Guidance have been fully incorporated into State or Tribal programs. For example, States and Tribes should provide documentation on their use of § 132.5(g)(2)(i) or § 132.5(g)(2)(ii) to develop numeric water quality criteria; all data supporting any site-specific modifications; and whether provisions regarding endangered or threatened species have been fulfilled. Similarly, if the State or Tribe has adopted § 132.5(g)(2)(ii), they should include documentation supporting adoption and implementation of the required procedure for developing water quality-based effluent limits and total maximum daily loads.

Finally, supporting documentation will also be necessary to assist EPA in determining whether adopted methodologies, policies, and procedures comply with § 132.5(g)(3). That section describes how EPA will evaluate whether State or Tribal methodologies, policies, and procedures are consistent with the Guidance. For example, the documentation might simply state that the State or Tribe has adopted provisions verbatim from the Guidance, or with only conforming changes. If provisions were adopted with modifications, the supporting documentation should identify the modifications, and should demonstrate that the resulting methodology, policy, or procedure is expected to produce results that are as protective as the corresponding Guidance methodology, policy, or procedure.

EPA would like to clarify that EPA intends to apply the general factors in § 132.5(g) when approving or disapproving State or Tribal water quality standards under § 131.21(b) and modifications to NPDES programs under part 123. That is, future submissions or revisions to water quality standards and NPDES programs for the Great Lakes System must continue to be consistent with the Guidance even after EPA has approved or promulgated standards under § 132.5.

3. Indian Tribes

a. Proposal. The CPA requires Great Lakes States to adopt, or EPA to promulgate, water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance. In the proposal, EPA expanded the requirement to "Great Lakes States and Great Lakes Tribes." "Great Lakes Tribes" are defined as any Indian Tribe whose reservation lies in whole or in part within the drainage basin of the Great Lakes, and for which EPA has approved water quality standards under section 303 of the CWA or which EPA has authorized to administer an NPDES program under section 402 of the CWA. "Indian Tribe" is further defined as any Indian Tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a Federal Indian reservation. EPA believes that inclusion of Great Lakes Tribes in this way is necessary and appropriate to be consistent with section 518 of the CWA. The reasons for EPA's proposal are discussed further in the preamble to the proposed Guidance (58 FR 20834).

b. Comments. Several comments supported the inclusion of Great Lakes Tribes in the proposal, asserting that all land that is part of the Great Lakes ecosystem should be subject to the Guidance.

No comments were received rejecting the proposed approach. Some comments urged EPA to clarify that time frames for Tribes to adopt the final Guidance should not start until the date a Tribe is authorized to administer the program. Another urged EPA to clarify that the proposed 18-month adoption deadline "in no way limits any Tribe's rights or time limits to seek qualification" for treatment as a State.

EPA agrees that Great Lakes Tribes should be subject to the final Guidance for reasons described in the preamble to the proposed Guidance (58 FR 20834). EPA has therefore retained the proposed approach that generally includes Great Lakes Tribes in the provisions of part 132 that otherwise apply to Great Lakes States.

EPA also agrees that any time deadlines for Tribes to adopt the final Guidance should not start until the date a Tribe has a water quality standards or NPDES program in place. For water quality standards, this means the date on which EPA has approved water quality standards for the Tribe, including such basic elements as designated uses, narrative criteria, numeric criteria for at least some pollutants necessary to protect designated uses, and legal authorities. Without such basic elements, the water quality standards provisions in the final Guidance could not be implemented. For NPDES programs, this means the date on which EPA has authorized the Tribe to administer an NPDES program under section 402 of the CWA.

If any Tribe had received either water quality standards approval or NPDES program authorization prior to this publication of the final Guidance (that is, March 23, 1995), then the Tribe would be subject to all provisions of the final Guidance, including the submission requirements contained in § 132.5. No Tribes in the Great Lakes basin have yet received such approval or authorization.

If any Great Lakes Tribe seeks to receive such approval or authorization after March 23, 1995, then the Tribes will be subject to all provisions of the Guidance except the submission requirements in § 132.5. For example, in order for a Tribe to receive approval of its water quality standards, assuming it has been approved to administer a water quality standards program under section 303, the Tribe will need to adopt and submit to EPA water quality standards that meet all requirements of part 131, including § 131.5(a)(5), which requires water quality standards to be consistent with the Guidance in part 132. The requirements for submission and EPA review for such standards are specified in part 131. Additionally, as discussed further in section II.D.2 of this document, EPA will apply the general factors in § 132.5(g) for determining consistency with the final Guidance, as well as all other applicable requirements of part 131, when approving or disapproving Tribal water quality standards under § 131.21(b).

EPA also agrees with comments that the provisions of part 132, including the submission deadlines in § 132.5, in no way limit any Tribe's rights or time limits to seek qualification to administer water quality standards or NPDES programs.

Upon request, EPA will provide technical guidance and assistance concerning both basic water quality provisions, and provisions consistent with the Guidance, to Tribes that have applied or wish to apply for approval to implement water quality standards or NPDES permit programs.

c. Final Guidance. The final Guidance retains provisions for Great Lakes Tribes to adopt water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance. The definition of Great Lakes Tribe has been modified to clarify that this includes only those Indian Tribes for which EPA has approved water quality standards under section 303 of the CWA or which EPA has authorized to administer an NPDES program under section 402 of the CWA.

E. Amendments to NPDES and Water Quality Standards Program Regulations

1. Proposal. The proposal included conforming amendments to the NPDES and water quality standards regulations in 40 CFR parts 122, 123, and 131 to insert references to the provisions of part 132 applicable to Great Lakes States and Tribes. These amendments ensure that future actions under NPDES and water quality standards programs in the Great Lakes basin will be consistent with the Guidance.

2. Final Guidance. No specific comments were received concerning these amendments. The final Guidance retains the proposed amendments to §§ 122.4, 123.25, 123.44, 123.62, 123.63, 131.1, 131.5, and 131.21. The amendments to §§ 122.4, 123.44, and 123.63 were modified to clarify that they apply only after provisions consistent with the final Guidance have been promulgated by the State, Tribe, or EPA. The amendment to § 123.63 was further modified to clarify that the criteria for withdrawal of a Great Lakes State or Tribal NPDES program include failure to adequately incorporate the NPDES implementation procedures in 40 CFR part 132 into individual permits.

F. Precedential Effects of Elements of the Guidance

1. Proposal. The requirements in the proposed Guidance were expressly applicable only to the waters of the Great Lakes System. EPA requested comments on whether EPA should issue National guidance or propose any modifications to 40 CFR parts 122 - 124, 130 and 131 in the future to correspond with specific elements of the proposed Guidance.

2. Comments. Some comments favored broader application, recommending that either the entire final Guidance or all non-Great Lakes-specific aspects of the Guidance be applied nationally to help enhance national consistency.

Many commenters opposed broader application of the Guidance because they believe the Guidance was developed for the unique characteristics of the Great Lakes basin, or because they believe the scientific basis of the Guidance is unproven or its implementation untried. Some commenters recommended developing a national regulation instead of the Great Lakes-specific Guidance, either because they believe the Guidance will reduce the competitiveness of the Great Lakes region, or because it will be counterproductive to have two different NPDES programs within Great Lakes States having waters both inside and outside of the basin. Other commenters recommended having States outside the basin adopt existing nationwide EPA guidance and policy to help alleviate some of the concern that the GLI will cause a competitive disadvantage for the Great Lakes basin.

There are many provisions of the Guidance that might be beneficially applied in other jurisdictions to improve the national program and foster consistency. For example, EPA believes many of the concepts in the *methodology for development of bioaccumulation factors and its use in* developing criteria to protect human health and wildlife could be applied elsewhere. At the same time, EPA would not consider applying specific Guidance elements outside the basin in situations where they are not scientifically or technically defensible. For example, the special provisions for BCCs may not be appropriate in systems not having the long retention times and other chemical, biological, and physical characteristics of the Great Lakes System described in sections I.A and I.B of this document.

During the normal course of developing and improving national water quality programs, EPA will consider incorporating any elements of the final Guidance that appear to be scientifically and technically appropriate. Such changes could be implemented, for example, as internal guidelines for EPA staff in developing criteria guidance under section 304(a), as guidance to States and Tribes in adopting criteria or implementation procedures into their programs, or as Federal rulemaking. Any significant proposed changes affecting national programs would be announced in advance in order to solicit comment from the scientific and technical community, as well as the public at large. In addition, EPA will seek peer review in accordance with EPA policy, which states that major scientifically and technically based work products related to EPA decisions normally should be peer reviewed. EPA will solicit external peer review for those work products that are intended to support the most important decisions or that have special importance in their own right.

EPA is currently considering broader application of concepts in the Guidance methodologies for development of bioaccumulation factors and wildlife criteria. In April 1994, EPA staff presented some of these concepts to the EPA Science Advisory Board for review. In addition, EPA is in the process of reviewing and revising the 1980 National Guidelines which would apply to development of EPA National human health water quality criteria under section 304(a) of the CWA. If EPA decides to proceed with any of these concepts nationally, it will announce its proposal in the Federal Register.

EPA does not agree that the scientific basis for the final Guidance is unproven. The scientific basis for the final Guidance is discussed further in sections I and III through VIII of this document. EPA agrees, however, that the experience of EPA, Great Lakes States, and Great Lakes Tribes in implementing the final Guidance will be useful in deciding how elements of the Guidance can be appropriately applied in other jurisdictions.

EPA does not agree that the Guidance would lead to two different NPDES programs within a State. States are already accustomed to developing different permit conditions and limitations depending on water quality conditions in different parts of the State. The Guidance would simply ensure that consistent approaches are used for waters of the Great Lakes System.

EPA also does not agree with comments recommending a national regulation in place of the proposed Guidance. First, the CPA required EPA to issue water quality guidance for the Great Lakes System, not for the nation. Therefore, EPA did not generally provide opportunity for States, Tribes, or members of the public and regulated community outside the Great Lakes basin to participate in developing the Guidance. Second, the short statutory and judicial deadlines for producing and implementing the Guidance did not allow time for considering broader application beyond the Great Lakes System or obtaining appropriate public comment. Third, EPA does not believe there will be significant detrimental effects to the economy of the Great Lakes region that would place the region at a competitive disadvantage to other parts of the country. As discussed further in section IX.1 of this document, a study conducted for the Council of Great Lakes Governors showed that such effects are expected to be minimal.

EPA agrees that it would be useful to increase the consistency of water quality programs applied nationally. EPA will continue to work toward this goal in implementing water quality standards and NPDES permit programs throughout the country.

3. <u>Final Guidance.</u> The final Guidance contains no mandatory requirements for discharges outside the Great Lakes System.

EPA would like to reemphasize that the provisions in the proposed and final Guidance are expressly applicable only to the waters of the Great Lakes System. EPA has initiated no rulemaking action to extend any Guidance provisions beyond the Great Lakes System. EPA's request for comments in the proposal was soliciting views only on whether any future national guidance or rulemaking affecting water programs beyond the Great Lakes System should include any concepts contained in the final Guidance.

States or Tribes with waters outside the Great Lakes System, in whole or in part, are encouraged to implement any of the Guidance methodologies or procedures that are scientifically and technically appropriate for their situations. This would include any Great Lakes States or Tribes that may choose to apply some or all of the Guidance in portions of their jurisdictions outside the Great Lakes System. Some Great Lakes States indicated their intention to do so in their written comments on the proposed Guidance.

G. <u>Implementation of Endangered Species Act</u>

1. <u>Proposal.</u> The proposed Guidance contained no specific provisions concerning the protection of endangered or threatened species under the Endangered Species Act (ESA). EPA invited comment on several possible approaches that EPA was considering including in the Guidance to reflect EPA's responsibilities under the ESA (58 FR 20848-20849). Under section 7(a)(2) of the ESA, each Federal agency shall, in consultation with the U.S. Fish and Wildlife Service (FWS), or the National Marine Fisheries Service for species under its jurisdiction, ensure that actions authorized, funded or carried out by the Federal agency are not likely to jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA, or result in the destruction or adverse modification of such species' critical habitat (i.e., are not likely to "cause jeopardy" to "listed species").

(There are no species under the jurisdiction of the National Marine Fisheries Service in the Great Lakes basin.)

2. Consultation with the U.S. Fish and Wildlife Service. Procedural requirements for the consultation envisioned in section 7(a)(2) of the ESA are found in 50 CFR part 402. These regulations provide for two types of consultation: formal and informal. Formal consultation procedures are required in situations where a Federal action may affect listed species or critical habitat. The formal procedures include requirements for the Federal agency to provide available information to the FWS, and for the FWS to develop a Biological Opinion discussing the effects of the Federal action on the listed species. Informal consultation is an optional procedure that includes discussions and correspondence between the FWS and the Federal agency to determine whether an action is likely to adversely affect a listed species. If the Federal agency finds, and the FWS concurs in writing, that the action is not likely to adversely affect listed species, consultation is concluded and formal consultation is not necessary.

In January 1993 EPA and the FWS initiated informal consultation under section 7 of the ESA concerning the issuance of the final Guidance. The two agencies identified several specific issues for detailed consultation. In September 1994, EPA initiated formal consultation with the FWS on two of the issues: adequacy of the Guidance's aquatic life criteria methodologies and related implementation procedures to protect endangered mussel species in the Great Lakes basin, and the appropriateness of the Guidance's methodology to develop wildlife criteria. On February 21, 1995, the FWS provided EPA with a written Biological Opinion. The Opinion is available in the docket for this rulemaking. The results of the formal and informal consultation are as follows:

a. Protection of Endangered Mussel Species

EPA and the FWS were concerned about the effects of water quality resulting from implementation of the final Guidance on three listed endangered freshwater mussel species in the Great Lakes System: Pleurobema clava (Clubshell), Epioblasma torulosa rangiana (Northern riffleshell), and E. obliquata perobliqua (White cat's paw pearly mussel). The agencies were concerned that since there is very limited aquatic toxicity information for these species or their surrogates, it is difficult to assess whether the aquatic life criteria methodology in the final Guidance produces criteria that are stringent enough to protect the endangered species.

EPA and the FWS undertook a formal consultation to address this issue. EPA provided information about the proposed Guidance and its expected effects on mussel species to the FWS, including the best scientific and commercial data available. The FWS then carried out a review and evaluation that resulted in the February 21, 1995, Biological Opinion.

The Biological Opinion concluded that the water quality resulting from implementation of the final Guidance is not likely to jeopardize the continued existence of the mussel species. The FWS identified possible concerns, however, that the aquatic life methodologies in the final Guidance may not be stringent enough to avoid adverse effects to listed mussels in all cases. The FWS conducted risk assessment analyses using existing toxicity studies on freshwater mussels. Although such studies are limited in number, and were not used by EPA either because they were not available in time for inclusion or because they did not meet EPA data requirements, the FWS believes that freshwater mussel data would provide a better indication of the sensitivity of the listed mussels than data based on less closely related test organisms. In situations such as this, where information on listed species is limited, the policy of the FWS is to provide the "benefit of the doubt" to the species concerned (51 FR 19952, June 3, 1986; H.R. Conf. Rep. No. 697, 96th Cong., 2d Sess. at 12 (1979)). The FWS assessment resulted in effects concentrations lower than the Guidance aquatic life criteria for some contaminants. Based on these results, the FWS concluded that the water quality resulting from implementation of the aquatic life criteria and values in the final Guidance may result in "incidental take" of an unquantified number of endangered freshwater mussels in the Great Lakes basin.

Section 9 of the ESA prohibits "take" of listed species of fish or wildlife--that is, harassing, harming, pursuing, hunting, shooting, wounding, killing, trapping, capturing or collecting such species, or attempting to engage in any such conduct--unless the take is exempted from this provision as discussed below. FWS policies further define "harm" to include significant habitat modification or degradation that results in death or injury to listed species by significantly impairing behavioral patterns such as breeding, feeding, or sheltering (50 CFR 17.3). Under the terms of section 7(b)(4) and 7(o)(2) of the ESA, taking that is "incidental" to and not intended as part of the Federal agency's action is not considered a prohibited taking provided that such taking is in compliance with requirements in the Biological Opinion specifying reasonable and prudent measures necessary and appropriate to minimize the incidental take, and specifying mandatory terms and conditions to be followed.

To minimize the amount or extent of any incidental take resulting from implementation of the final Guidance, the FWS consulted closely with EPA to develop a coordinated approach. The final Biological Opinion specified reasonable and prudent measures that the FWS considers necessary or appropriate to minimize such impact as the aquatic life criteria, methodologies, and related implementation procedures are implemented in the Great Lakes System as specified in the final Guidance. These measures are as follows:

-- During the next two years, EPA will undertake a screening analysis consisting of acute toxicity testing of freshwater mussels for a limited number of pollutants. During the same period, to enable successful completion of the measures, FWS will develop and analyze life history information on the endangered mussels. The life history information is particularly important in identifying surrogate species, developing test protocols, and culturing test organisms, and further determining what other environmental parameters may be contributing to the decline of the species.

-- EPA and FWS will review the results from the above efforts. The purpose of the review is to compare the sensitivity of the surrogate mussel species with the sensitivity of other species used in developing acute criteria under the final Guidance. The review will also help determine the types of testing needed to conduct a screening analysis for chronic effects.

-- During a subsequent period of approximately four years, EPA and FWS will conduct a screening analysis consisting of selected chronic toxicity testing of freshwater mussels for a limited number of pollutants. The scope and design of this testing will depend heavily on the results of the efforts of the first two years described above.

-- Based on the combined results of the acute and chronic screening analyses, EPA and FWS will assess whether there is evidence that the three endangered mussels or their surrogate species are more sensitive to aquatic pollutants than other species assessed as part of EPA and State criteria development efforts under the final Guidance. If so, then the agencies will develop a joint approach for developing the necessary information to adjust criteria as necessary to protect the species.

-- EPA and the FWS will develop a protocol that can be used to monitor any populations of listed mussels downstream from new discharges permitted under the final Guidance. EPA will then seek through its oversight of State water quality programs to ensure that monitoring of such populations takes place in accordance with the protocol to identify whether any incidental take occurs that is likely to cause jeopardy to the species.

EPA believes that the methodologies and procedures in the final Guidance will be protective of endangered or threatened aquatic species in the Great Lakes System. EPA acknowledges that it is possible that data collected in the future, however, could identify an unusual sensitivity of mussels to a particular pollutant that is not reflected in the methodologies and procedures. Based on experience in implementing water quality criteria under the CWA, EPA believes that this possibility is small, and that the degree of any adverse effects would likely be limited. Nevertheless, EPA agrees that it would be desirable to obtain additional data on freshwater mussels to confirm its belief that mussels will not be adversely affected by water quality resulting from implementation of the final Guidance. For this reason, EPA has agreed to implement the reasonable and prudent measures described above.

b. Wildlife Criteria Methodology

EPA and the FWS were concerned about the effects of water quality resulting from implementation of the final Guidance on five wildlife species listed as endangered or threatened in the Great Lakes basin: Canis lupus (Gray wolf), Myotis sodalis (Indiana bat), Haliaeetus leucocephalus (Bald eagle), Falco peregrinus (Peregrine falcon), and Charadrius melodus (Piping plover). Of these, the primary concern was the bald eagle because of its relatively greater dependence on food sources found at higher levels of the aquatic food chain.

EPA and the FWS undertook a formal consultation to address this issue. EPA provided information to the FWS about the wildlife methodology and its predicted effects on bald eagles. The FWS then carried out a review and evaluation that was included in the February 21, 1995, Biological Opinion.

The Biological Opinion concluded that the final Guidance is not likely to jeopardize the continued existence of the bald eagle, peregrine falcon, or piping plover. The FWS identified possible concerns, however, that the wildlife methodology in the final Guidance may not be stringent enough to protect endangered or threatened species in all cases. In their risk assessment, the FWS used assumptions and assessment approaches that differ from those developed by the Initiative Committees, whose approach was reviewed by the EPA Science Advisory Board and used in the proposed and final Guidance. The model developed by the FWS is based on the dose to the target tissue (the egg), rather than the dose received in the diet. The FWS assessment also considers the protection of individuals as opposed to populations, and emphasizes the need for toxic equivalency factors to account for additive or synergistic effects of complex mixtures of bioaccumulative compounds to wildlife. Based on the results of their assessment, which gives the "benefit of the doubt" to the species in accordance with FWS policy as discussed above, the FWS concluded that the water quality resulting from implementation of the final Guidance may result in "incidental take" of an unquantified number of bald eagles, peregrine falcons, and piping plovers in the Great Lakes basin due to detrimental effects resulting from chronic toxicity.

To minimize the amount or extent of any incidental take resulting from implementation of the final Guidance, the FWS consulted closely with EPA to develop a coordinated approach. The Biological Opinion specified reasonable and prudent measures that the FWS considers necessary or appropriate to minimize such impact as the wildlife criteria, methodologies, and related implementation procedures are implemented in the Great Lakes basin as specified in the final Guidance. These measures are as follows:

-- During the nine years following publication of the final Guidance, EPA will gather information concerning the impacts on endangered or threatened species in the Great Lakes basin from the four chemicals with numeric wildlife criteria in the final Guidance. If at any time new information indicates that water quality after full implementation of the wildlife components of the Guidance may adversely affect endangered or threatened species, EPA will immediately reinitiate consultation.

-- EPA will establish and begin implementing a data-gathering plan, in cooperation with FWS and the States or Tribes, to determine progress in reducing the concentrations of the four chemicals in the Great Lakes aquatic ecosystem, and to help improve understanding of the sensitivities of the listed species to the chemicals if possible.

-- EPA will during the next five years reevaluate and better define loadings of BCCs to the Great Lakes System that might affect listed wildlife species, including a report describing ongoing activities (e.g., Lakewide Management Plans and Remedial Action Plans) that are designed to reduce current levels of contamination in the basin.

-- EPA and FWS will cooperatively plan and host one or more workshops to explore the utility of additivity models in developing wildlife criteria, to consider the scientific basis for use of toxicity equivalency factors (TEFs) when establishing total maximum daily loads or water quality-based effluent limits to implement wildlife criteria, and to discuss research and data needs. The findings of these workshops will be used to develop approaches for utilizing TEFs if appropriate in the development and implementation of wildlife criteria. These approaches will be presented to the EPA SAB for review and comment.

EPA believes that the wildlife criteria methodology in the final Guidance, including the procedures for site-specific criteria modifications, will be protective of endangered or threatened wildlife species in the Great Lakes basin. Nevertheless, EPA believes it will be useful to conduct the type of review described above to confirm that water quality resulting from implementation of the final Guidance is not likely to adversely affect endangered or threatened wildlife species. For these reasons, EPA has agreed to implement the reasonable and prudent measures described above.

c. Other Issues

As a result of informal consultation, and after considering comments (discussed below), EPA decided to include certain additional provisions in the final Guidance to ensure protection of endangered or threatened species consistent with EPA's responsibilities under section 7. These provisions are discussed below. They generally reflect the types of provisions discussed in the preamble to the proposed Guidance (58 FR 20848-49).

EPA and the FWS consulted informally on specific regulatory provisions to ensure that aquatic life and wildlife criteria will be developed or modified on a site-specific basis to protect endangered or threatened species in the Great Lakes System. The two agencies agreed that procedure 1 of appendix F should be modified to provide that Great Lakes States and Tribes must develop more stringent site-specific modifications of criteria and values to protect listed and proposed species, where such modifications are necessary to ensure that water quality is not likely to cause jeopardy to the species. Because efforts to protect and promote recovery of listed and proposed species generally focus on management of specific ecosystems, it is appropriate that States, Tribes, and EPA utilize the procedure for site-specific modifications of criteria and values to address conditions in those ecosystems.

In the above provisions, EPA has included proposed as well as listed species. EPA believes that prevention of water quality conditions that would be likely to jeopardize the continued existence of any species is inherent in the CWA's requirement for EPA to provide guidance on minimum water quality standards to protect aquatic life and wildlife in the Great Lakes basin (CWA section 118(c)(2)), as well as the fundamental principle that water quality criteria must protect designated uses (CWA section 303(c)(2)(A); 40 CFR 131.11(a)(2)). Obviously, if impaired water quality will likely cause the extinction of a species, such water quality would not meet the Act's requirements. In a sense, then, mandating that States adopt site-specific criteria to avoid causing jeopardy to any species is simply an explicit statement of a principle that EPA believes is inherent in the CWA.

The two agencies also agreed that States and Tribes should be encouraged to adopt more stringent site-specific modifications of criteria or values where necessary to protect candidate "C1" species being considered by the FWS for listing under section 4 of the ESA. The "C1" category refers to species for which the FWS has enough substantial information to support proposals to list as endangered or threatened under section 4 of the ESA. The new provisions of procedure 1 of appendix F to part 132 are discussed under the Final Guidance section below.

EPA and the FWS also consulted informally on concerns about whether the final Guidance should apply to ammonia and chlorine. The two agencies agreed that EPA will undertake a review of water quality standards and implementation of those standards for ammonia and chlorine in the Great Lakes basin as part of EPA's responsibilities under section 303(c) of the CWA. This review is discussed further in section II.C.5.c of this document.

The two agencies also consulted informally concerning the adequacy of the Guidance methodologies for developing criteria and values to protect wildlife from certain pollutants that are metabolized by higher trophic level aquatic organisms but not by lower trophic aquatic organisms. Such pollutants include, for example, polynuclear aromatic hydrocarbons (PAHs) which, because of metabolism by fishes, have relatively high BAFs when measured in lower trophic level species, even though they have relatively low BAFs in higher trophic level fish. The methodology for development of BAFs for organic chemicals in appendix B includes procedures for calculating field-measured and/or predicted BAFs for all trophic levels, and allows, on a case-specific basis, wildlife BAFs to be weighted to reflect the proportion of plants, invertebrates, and fish in the diet of the species to be protected.

If a listed wildlife species in the Great Lakes basin were found to be more highly exposed to a bioaccumulative pollutant because of its diet than the representative species used in the wildlife criteria methodology, then procedure 1.A of appendix F would specify that a site-specific modification is needed to protect such species. The site-specific modification could utilize the method described above to weight the BAFs based on the diet of the listed species.

The two agencies agreed that the final methodology for the development of bioaccumulation factors in appendix B, and procedure 1 of appendix F for site-specific modifications, provide adequate protection for listed wildlife species that may consume highly contaminated prey at lower trophic levels.

The two agencies also agreed that the final Guidance should clarify EPA's responsibilities for protecting endangered or threatened species when reviewing and approving State and Tribal submissions under § 132.5. Section 132.5(h) has been added to the final Guidance to require States and Tribes to include in their part 132 submissions any provisions that EPA determines, based on EPA's authorities under the CWA and the results of consultation under section 7 of the ESA, are necessary to ensure that water quality is not likely to cause jeopardy to listed species. This provision is discussed under the Final Guidance section below.

Finally, the two agencies discussed and have agreed upon the procedures the two agencies will use to conduct section 7 consultations where necessary on future EPA actions. These actions include EPA approval or disapproval of submissions by Great Lakes States and Tribes under § 132.5, and EPA approval actions for State and Tribal water quality standards, criteria modifications, and variances under 40 CFR part 131. The procedures are summarized under the Final Guidance section below.

With the issuance of the FWS' Biological Opinion, formal consultation on the issues concerning freshwater mussels and wildlife criteria has been completed. For the remaining issues, as a result of the informal consultation described above, the FWS concurs with EPA that the final Guidance is not likely to adversely affect endangered or threatened species in the Great Lakes basin ecosystem. Therefore, consultation concerning EPA's publication of the final Guidance has been completed.

3. Comments. Some comments asserted that specific ESA provisions in the final Guidance would be an unnecessary additional burden on the States, since most States have a state program for the protection of endangered or threatened species which deals directly with the FWS. Several commenters supported using site-specific modifications to provide protection for endangered or threatened species. Many of these commenters preferred that such a provision be guidance. Other comments asserted that full consultation by EPA with the FWS on administration of all elements of the final Guidance is necessary, and that consultation procedures should be clarified.

EPA does not agree that regulatory provisions regarding ESA are unnecessary in the final Guidance. The ESA imposes specific responsibilities on Federal agencies to protect endangered or threatened species in actions the agencies carry out. EPA believes that the final Guidance should articulate the conditions that EPA, based on its consultation with the Service, believes are necessary to include in State and Tribal submissions to provide the protection for endangered or threatened species envisioned in section 7(a)(2) of the ESA. For example, procedure 1.A of appendix F clarifies the role of site-specific modifications to water quality criteria in protecting endangered or threatened species, and § 132.5(h) of the final Guidance clarifies that EPA will make a determination based on EPA's authorities under the CWA and the results of section 7 consultation concerning the adequacy of State or Tribal provisions for protecting listed species contained in submissions under part 132. EPA believes these clarifications will be helpful in ensuring an orderly approach to protect listed species. Furthermore, although individual States may have State-imposed responsibilities to protect endangered or threatened species, these responsibilities may not coincide in detail with applicable Federal standards. For example, a State's endangered species program may address a list of species that could be different from the species listed under section 4 of the ESA. The clarifications in part 132 concerning the Federal requirements therefore will be helpful in reducing confusion on such matters.

EPA agrees for the reasons discussed under section II.G.2 above that site-specific modifications to criteria and values should be required to protect endangered or threatened species. EPA also agrees that the final Guidance should provide States and Tribes flexibility in achieving such protection, and therefore provides a choice of methods for adopting site-specific modifications. This flexibility in adopting site-specific modifications to protect endangered or threatened aquatic and wildlife species is discussed further in section VIII.A of this document.

4. Final Guidance. As a result of consultation with the FWS, and in response to comments, EPA has made the following changes in the final Guidance:

EPA has added § 132.5(h) to the final Guidance which provides that Great Lakes States and Tribes will need to include provisions that EPA determines, based on the results of consultation under section 7 of the ESA, are necessary to ensure that water quality is not likely to jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

To carry out the ESA, relevant EPA Regional Offices will initiate consultation with the FWS as soon as possible concerning EPA's approval actions under part 132 for each of the Great Lakes States and Tribes. Such consultations will be facilitated if States and Tribes have already consulted with the FWS under State and Tribal arrangements with FWS where such arrangements exist. Initiating consultations early in the process of the States' and Tribes' development of their part 132 submissions is appropriate and necessary because under section 118(c)(2)(C) of the CWA and § 132.5, the States and Tribes must complete their part 132 submissions to EPA generally by September 23, 1996, and EPA must approve such submissions, or promulgate EPA requirements, by March 23, 1997. EPA believes the consultations can and should occur simultaneously with the States' and Tribes' efforts to develop their part 132 submissions.

As a result of the consultation that has taken place with the FWS concerning the final Guidance, EPA believes that consultations can be concluded rapidly and routinely concerning part 132 submissions from States or Tribes that are consistent with the final Guidance. EPA will make every effort to expedite exchange of information and consultation between FWS staff members, State or Tribal representatives, and EPA Regional Office staff members to help determine whether any additional modifications to a particular submission are necessary, such as site-specific modifications. If such situations occur, EPA will notify the State or Tribe as soon as possible.

EPA has consulted with the FWS regarding the methodologies for development of criteria and values in the final Guidance. Based upon available data and information, EPA and the FWS have concluded that criteria and values consistent with the final Guidance generally will result in water quality that is not likely to jeopardize the continued existence of listed species or destroy or adversely modify critical habitat. Thus, in the absence of a need for a site-specific modification, discussed below, States and Tribes adopting criteria and values, methodologies, policies, and implementation procedures consistent with the final Guidance will be approvable by EPA as consistent with the ESA.

EPA recognizes that information may become available--either prior to or subsequent to approval of State and Tribal submissions under part 132--indicating that more stringent criteria/values may be necessary to protect certain species. Therefore, EPA has modified procedure 1.A of appendix F of the final Guidance to provide that Great Lakes States and Tribes need to develop more stringent site-specific modifications of criteria and values to protect listed or proposed species, where such modifications are necessary to ensure that water quality is not likely to cause jeopardy to listed species. As discussed above, this provision is necessary to clarify the role of site-specific modifications in protecting endangered or threatened species listed or proposed under the ESA. Procedure 1.A also encourages States and Tribes to adopt more stringent site-specific modifications of criteria or values where necessary to protect candidate (C1) species.

Procedure 1.A of appendix F provides that such site-specific modifications be made where they are necessary to ensure water quality is not likely to cause jeopardy to listed or proposed species. EPA interprets the phrase "where necessary" to include geographic sites where the species may be affected, and where critical habitat has been designated. Procedure 1 of appendix F allows flexibility in interpreting the geographic extent of "sites." Therefore, States, Tribes, and EPA in consultation with the FWS, should establish the geographic extent of the site-specific modifications to be large enough to provide adequate protection to the species, including survival and recovery. For example, a site-specific modification could be for an area as small as a local stream reach where a listed species currently resides, or as large as the entire portion of the State located within the Great Lakes basin, depending on the needs of the species.

EPA also interprets the phrase "where necessary" to mean where available data indicate that listed or proposed species are especially vulnerable to specific pollutants, such as being more sensitive than the species used to develop existing criteria, or being more exposed than assumed in the Guidance methodologies.

The GLI Clearinghouse, discussed in section II.C.1 of this document, will facilitate the incorporation of new data on listed, proposed, or candidate (C1) species under the ESA, or surrogates for such species, into State and Tribal programs. Any such data will be placed in the EPA-operated Clearinghouse, where they will be available to States, Tribes, and other interested persons. EPA will place special emphasis in the Clearinghouse on data relevant to protection of such species. EPA will alert States and Tribes to data that indicate unusual sensitivity of such species in the Great Lakes basin. EPA and the FWS will also work with States and Tribes to identify sites where special protection may be recommended.

EPA will also work with States and Tribes to disseminate any new data that become available in future years showing that a site-specific modification to criteria is appropriate because a listed or proposed species is especially sensitive to aquatic pollutants. For example, if data relevant to a listed aquatic species become available concerning a SMAV that is less than the calculated FAV, or that would yield a lower criterion or value using the EPA recalculation procedure or resident species procedure, a site-specific modification would be necessary for waters where the species is found. If the State or Tribe already had numeric water quality criteria for the pollutant, the State or Tribe would need to adopt a site-specific modification and submit it to EPA for approval as currently specified in § 131.20. EPA would then consult with the FWS concerning the approval of this submitted revision to the water quality criteria. If the State or Tribe did not submit such a modification, or did not adopt criteria protective of the listed species, and did not demonstrate to EPA why such modifications are not necessary, EPA would have the authority under section 303(c) of the CWA to disapprove the State criteria for relevant areas and take necessary actions. Under section 303(c), EPA would then be required to propose Federal criteria in place of the State or Tribal criteria.

If the State or Tribe had not adopted criteria for the pollutant of concern, it would nevertheless need to utilize the new data in developing criteria or values to be used as appropriate in establishing water quality-based effluent limits for the pollutant, in accordance with § 122.44(d), § 132.4, and adopted State or Tribal provisions consistent with the implementation procedures in appendix F of the final Guidance.

EPA has added provisions to final procedures 1.A.1 and 1.A.2 of appendix F to clarify ways that the site-specific modifications required in procedure 1.A may be accomplished. For aquatic life, procedure 1.A.1(c) describes two ways criteria may be modified to reflect endangered or threatened species that are particularly sensitive to a pollutant. For example, the Species Mean Acute Value (SMAV) for the listed or surrogate species may be found to be lower than the calculated Final Acute Value (FAV) developed using the Tier I methodology in appendix A. In this situation, the lower SMAV would be substituted for the calculated FAV in developing the aquatic life acute criterion. Alternatively, the State or Tribe may lower the criterion using EPA's recalculation procedure or resident species procedure as provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition (August 1994). Procedures 1.A.1 and 1.A.2 are discussed further in section VIII.A of this document. During the consultation process EPA will solicit the views of the FWS concerning the choice of method for criteria modification.

For wildlife, procedure 1.A.2 describes a recommended approach for modifying wildlife criteria to protect endangered or threatened species. Procedure 1.A.2 is discussed further in section VIII.A of this document.

EPA has added provisions to appendix E and to procedures 2 and 3 of appendix F of the final Guidance that restrict certain actions States and Tribes may take to allow lowering of water quality in high quality waters, to grant variances, and to allow mixing zones. Section I.A of appendix E specifies that any lowering of water quality in high quality waters shall be prohibited if such lowering of water quality will be likely to cause jeopardy to listed species. It is discussed further in section VII of this document. Procedure 2.A of appendix F specifies that a variance to a water quality standard may not be granted that would result in water quality likely to cause jeopardy to listed species. It is discussed further in section VIII.B of this document. Procedure 3 of appendix F includes provisions that mixing zones in or outside the context of a TMDL may be allowed, at a minimum, only to the extent that water quality would not likely cause jeopardy to listed species. these provisions are discussed further in section VIII.C of this document.

EPA has determined that each of these restrictions is necessary to clarify how the requirements of the ESA affect decisions regarding implementation of water quality standards. EPA believes including these provisions in the final Guidance will be helpful to States, Tribes, and dischargers to understand the provisions that EPA believes will need to be included in part 132 submissions to meet ESA requirements.

Under section 7 of the ESA, EPA is obligated to consult with the FWS concerning actions carried out, authorized, or funded by EPA that may affect listed species. As discussed above, EPA will consult with the FWS concerning EPA's actions to approve State and Tribal submissions under § 132.5. EPA also intends to consult on approval actions under 40 CFR part 131 for water quality standards in the Great Lakes basin, including criteria modifications and water quality standards variances, that may affect listed species, submitted as revisions to a State's or Tribe's water quality standards. The FWS and EPA recognize that to accomplish timely implementation of standards that may affect listed species, early involvement and technical assistance by the FWS is needed. For example, EPA and the FWS will meet during the triennial period for reviews of water quality standards under section 303(c) of the CWA, preferably during the period when EPA and a State or Tribe discuss the extent of an upcoming review. EPA and FWS agree that meetings, discussions, and exchanges of information throughout the process--from State and Tribal development, adoption, submission of standards, through EPA final action--will facilitate the consultations required by the ESA. EPA will also invite and encourage the States and Tribes to participate actively in the consultations.

III. AQUATIC LIFE

A. Summary of Final Rule

The final Guidance is identical to the Guidance proposed on April 16, 1993, except for the following changes:

-- States and Tribes are permitted to use either the averaging period and frequency of exceedance specified for the proposed Tier I criteria concentrations, or some other scientifically acceptable averaging period and/or frequency of exceedance. If EPA determines that it is necessary to promulgate criteria for a State or Tribe, it will promulgate averaging periods of one hour (Criterion Maximum Concentration) and four days (Criterion Continuous Concentration) and a frequency not to exceed the criteria of more than once-in-three-years (both CMC and CCC).

-- Aquatic life criteria for the nine metals proposed in Tables 1 and 2 of part 132 are expressed as dissolved concentrations and total recoverable concentrations. Conversion factors for the proposed total recoverable metals criteria were derived and publicly noticed on August 30, 1994 (59 FR 44678). EPA adjusted these conversion factors and used them in the calculations to convert the proposed criteria from total recoverable concentrations to dissolved concentrations for the final Guidance. If a State or Tribe fails to adopt aquatic life criteria for metals, EPA will promulgate dissolved criteria.

-- The final Guidance clarifies and elaborates on the option of using indicator parameter limits under 40 CFR 122.44(d)(1)(vi)(C). A full discussion of the use of the indicator parameter option and its role in the final Guidance appears in section VIII.E.2.f of this document (Reasonable Potential Procedure). As discussed in that section of this document the States or Tribes are still required to adopt provisions consistent with the Tier II methodology for aquatic life consistent with the methodology in appendix A. As described in procedure 5 of appendix F to part 132, States and Tribes will then be required under the final Guidance to implement the Tier II values through water quality-based effluent limitations (WQBEL) based on such values when, under procedure 5 of appendix F to part 132, such limits are determined to be required. When deriving limits to meet Tier II values, States and Tribes have the option of using an indicator parameter limit in lieu of a Tier II-based limit. If an indicator parameter is used, the State or Tribe must ensure that the indicator parameter will attain the "applicable water quality standard" (as described in 40 CFR 122.44(d)(1)(vi)(C)). The "applicable water quality standard" in this instance would be the State's or Tribe's narrative water quality criteria that protects aquatic life, as interpreted using the Tier II methodology.

B. Final Tier I Methodology

The final Guidance includes methodologies for deriving Tier I criteria and Tier II values for the protection of aquatic life in the Great Lakes System. The Aquatic Life Tier I methodology is an adaptation of the "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (U.S. EPA, 1985) (1985 National Guidelines), developed under section 304(a) of the Clean Water Act (CWA). A copy of the 1985 National Guidelines is available in the administrative record for this rulemaking. The 1985 National Guidelines can also be obtained through the National Technical Information Service (PB 85-227049). Provisions consistent with the final Tier I methodology must be used when deriving Great Lakes aquatic life criteria for use in State and Tribal water quality standards. The final Guidance also contains Tier I criteria for

16 pollutants that are based on the latest scientific knowledge and derived using an extensive aquatic toxicological data base.

As stated above, the proposed Tier I methodology was an adaptation of the 1985 National Guidelines which has previously undergone scientific peer review and public review and comment, and had been revised where appropriate. EPA stated in the proposal that issues already addressed by EPA in response to previous comments on the 1985 National Guidelines would not be addressed in this proceeding (58FR20852). Therefore, the following discussion focuses on those portions of the Tier I methodology which differ from the 1985 National Guidelines.

1. Required Data

a. Proposal: In the proposed Guidance, two ambient criteria concentrations to protect aquatic life for any given pollutant are derived (the Criterion Maximum Concentration (CMC) and the Criterion Continuous Concentration (CCC)). In order to derive a CMC for a pollutant, it is necessary that acceptable acute toxicity tests exist for aquatic animals in at least eight families which represent differing habitats and taxonomic groups. The CCC is the lowest of the Final Chronic Value (FCV) or the Final Plant Value (FPV) (see appendix A for a complete description of how to derive a CCC or CMC). The aquatic life methodologies to derive both Tier I criteria and Tier II values did allow the use of some data for freshwater species that do not reside in the Great Lakes System.

b. Comments: Several commenters recommended that the proposed Guidance derive different criteria for coldwater versus warmwater assemblages of aquatic species, and possibly for other receiving water categories (based on inclusion or exclusion of different species in the underlying data set). Several commenters also recommended limiting the toxicity data set to species residing in the Great Lakes basin.

EPA recognizes the potential differences between coldwater versus warmwater aquatic species and that there are varied aquatic species assemblages across the Great Lakes System. Because of this, EPA has included provisions in the final Guidance to calculate site-specific modifications to criteria to adjust for site-specific differences in water quality characteristics, species, etc. EPA believes it is better to derive site-specific criteria where necessary than to try to define and protect generic assemblages of aquatic species (such as warmwater, coldwater, etc.). Site-specific criteria can be developed to protect the types of species at each site and, therefore, are more precise. If a State or Tribe wishes to modify the criteria on a site-specific basis to account for a different species assemblage at the site, the recalculation procedure as described in appendix L of the U.S. EPA Water Quality Standards Handbook, Second Edition - Revised (U.S. EPA, 1994) may be used. The 1994 Water Quality Standards Handbook is available in the administrative record for this rulemaking and can also be obtained through the Water Resource Center, 401 M. Street, SW (RC4100), Washington, DC 20460 or by calling (202) 260-7786.

EPA disagrees that toxicity data should be limited to those species residing in the Great Lakes System. EPA believes that species nonresident to the Great Lakes System can represent untested resident species and may used as surrogates for those resident species not yet tested. This approach is consistent with the 1985 National Guidelines.

c. Final Guidance: The data requirements in the final Guidance for deriving Tier I criteria are the same as the proposed Guidance. EPA would like to clarify that all data used in the derivation of Tier I criteria or Tier II values must be from species which are resident to North America.

2. Commercially and Recreationally Important Species

a. Proposal: The 1985 National Guidelines stated that the Final Acute Value (FAV) must be set equal to the lower 95th percentile value, or the Species Mean Acute Value for a species of commercial or recreational importance. The proposed Tier I methodology differed from the 1985 National Guidelines by specifying that the FAV should be lowered only for a species that is recreationally or commercially important to the Great Lakes System. For example, the proposed CMC for cadmium was lowered from 2.3 μg/L to 2.1 μg/L to protect the chinook salmon.

b. Comments: Several commenters noted that the commercially and recreationally important species used to lower some of the criteria do not reside in all receiving waters of the Great Lakes System. Those commenters suggested that the criteria should be lowered to protect such species where they reside, and should not be lowered where they do not reside.

EPA agrees that some of the recreational and commercially important species used to lower criteria do not reside in all receiving waters of the Great Lakes Basin. However, many of these species are located over a large area of the Basin and migrate throughout the lakes and tributaries. EPA believes it is reasonable to adjust the criteria for these species System-wide instead of site-specifically as advocated by the commenters. The current National program and the final Guidance allow States and Tribes to modify the aquatic life criteria on a site-specific basis to account for the situation where the species does not reside at a particular site. To accomplish this, a State or Tribe may choose to modify the criteria using the recalculation procedure described above for those waters where the commercially or recreationally important species does not "occur at the site."

c. Final Guidance: The final Guidance requires the lowering of the FAV for commercially or recreationally important species to the Great Lakes System for the reasons stated above.

3. Ecologically Important Species

a. Proposal: In the proposal, EPA invited comment on whether the Tier I methodology should define "ecologically important" species and include provisions to lower the FAV for such species. EPA also invited comment on whether "ecologically important" species were adequately protected by the proposed Guidance without adding additional provisions.

b. Comments: Many commenters expressed a preference not to include a provision to lower the FAV to protect "ecologically important" species because they believed that a reasonable definition could not be developed. A few commenters favored lowering the FAV to protect "ecologically important" species. A few commenters favored treating all species as "ecologically important," but no commenter offered any other definition of "ecologically important" species.. Some commenters also recommended adding the concept of "culturally important." Many of these commenters named certain species as "culturally" or "ecologically important;" however, these suggestions did not identify any new species meriting protection since the named species are also recognized as commercially or recreationally important species. Several commenters suggested that a provision for "ecologically important" species could be used to provide protection for threatened and endangered species.

EPA agrees with commenters that it is not necessary to include a provision for lowering the FAV for "ecologically important" species. EPA believes that the Tier I methodology as proposed, utilizing all available data, adequately protects "ecologically important" and "culturally important" species. Further, EPA is unable to develop meaningful and workable definitions for these terms that would distinguish ecologically or culturally important species from other species.

EPA agrees that threatened and endangered species should be protected, but does not believe the use of "ecologically important" species is the best mechanism. Instead, EPA has added a provision to procedure 1 of appendix F to part 132 specifying that States and Tribes must adopt site-specific criteria modifications to protect threatened and endangered species that are listed or proposed under the Federal Endangered Species Act. This provision is discussed further in sections II.G. and VIII.A. of this document. EPA has determined that site-specific modifications to ensure protection to threatened or endangered species are more appropriate than modifying the State-wide or Tribal aquatic life criteria or values as done for commercially or recreationally important species, since threatened or endangered aquatic species tend to be isolated to specific sites. States, Tribes, and EPA in consultation with the FWS, should establish the geographic extent of the site-specific modifications to be large enough to provide adequate protection to the listed species. If a threatened or endangered species listed under the Federal Endangered Species Act is found throughout the State's or Tribe's waters, then it may be more prudent to adopt a State-wide or Tribal criteria or value rather than develop numerous site-specific modifications.

c. Final Guidance: For the reasons stated above, the final Guidance does not include a provision for lowering the FAV for "ecologically important" species nor provides a definition for "ecologically important." However, under CWA section 132.4(i) which allows States and Tribes to adopt more stringent provisions, a State or Tribe may independently choose to lower the FAV to protect "ecologically important," "culturally important," or any other group of species that it defines.

4. Elimination of Final Residue Value

a. Proposal: For chronic exposures, EPA proposed to modify the 1985 National Guidelines approach by deleting the option of using the Final Residue Value (FRV) in deriving the Criterion Continuous Concentration (CCC). The CCC was proposed as the lower of the Final Chronic Value (FCV) or the Final Plant Value (FPV).

b. Comments: Many commenters supported eliminating the FRV. A few commenters advocated retaining the FRV because it yields lower criteria.

EPA agrees with the comments that the FRV should not be utilized in the calculation of the CCC. As explained in the proposal (58FR20851), the FRV is intended to prevent concentrations of pollutants in aquatic species from affecting the marketability of those species or affecting the wildlife that consume aquatic life. Consequently, EPA believes use of the FRV is redundant with the methodologies for human health and wildlife criteria contained within the final Guidance. EPA believes that those methodologies will yield more appropriate criteria to protect humans and wildlife. Furthermore, the human health and wildlife criteria derived for dieldrin, endrin, and mercury are more stringent than the National aquatic life criteria found in Table III-4.

c. Final Guidance: The final Guidance does not require the use of the FRV in the derivation of the CCC for the reasons stated above.

5. Acute-Chronic Ratios

a. Proposal: The Acute-Chronic Ratio (ACR) is a method of relating acute and chronic toxicities. To derive an ACR, comparable acute and chronic toxicity studies which have been conducted under similar conditions for a given species are used. From comparable measurements of acute and chronic values, an ACR is calculated by dividing the measured acute value by the measured chronic value. EPA proposed to follow the 1985 National Guidelines by requiring ACRs for at least three families of aquatic animals. The Final Acute-Chronic Ratio (FACR) must be either the geometric mean of some or all of the species ACRs or another value appropriate for sensitive species.

The proposal expressed a preference for the use of freshwater ACRs when deriving a Final Chronic Value (FCV), but allowed the use of ACRs for saltwater species in the derivation of the FCV when the data set for deriving a FCV does not contain three ACRs for freshwater species. EPA invited comment on the preference for freshwater ACRs in calculating a FCV to protect species in the Great Lakes System.

b. Comments: Some commenters preferred using saltwater ACRs only when there were not an adequate number of freshwater ACRs, while other commenters wanted to use fresh and saltwater ACRs interchangeably, and others suggested not using any saltwater ACRs.

EPA agrees with those comments suggesting that saltwater ACRs should only be used when there are an inadequate number of freshwater ACRs. As stated in the proposal, because the Great Lakes are freshwater lakes, the preference is to use freshwater ACRs when deriving FCV for freshwater animals. However, there may be situations where the freshwater data needed to derive a freshwater ACR is limited. In these situations, EPA believes it is appropriate to use saltwater ACRs in place of the freshwater ACRs (see 1985 National Guidelines, pgs. 14 and 15).

c. Final Guidance: The final Guidance retains the provision that saltwater ACRs may be used to derive a FCV when the data set does not contain three ACRs for freshwater species as specified and if the freshwater and saltwater ACRs are within a factor of 10 (as described in the aquatic life Tier I criteria methodology, appendix A, VI.K.2 and the 1985 National Guidelines).

6. Bioavailability

a. Proposal: The criteria for metals in Tables 1 and 2 of part 132 were expressed as total recoverable concentrations. EPA invited comment on whether the bioavailability of contaminants was adequately addressed using site-specific modification approaches, as well as alternatives to address the issue of expressing toxicity of both bioavailable and total contaminant concentrations.

Subsequent to the proposal, EPA issued a memorandum to all EPA Regional Water Management Division Directors providing policy and guidance on the interpretation and implementation of aquatic life criteria for the management of metals (The Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria (Prothro, 1993). The memorandum covered a number of areas including the expression of aquatic life criteria, total maximum daily loads, permits, effluent monitoring, compliance, and ambient monitoring. With regard to expression of aquatic life criteria, the memorandum recommended that State water quality standards be based on dissolved metals because dissolved metal concentrations more closely approximate the bioavailable fraction of metal in the water column than does total recoverable metal concentrations. However, because the present National aquatic life criteria were developed using total recoverable measurements, it is necessary to use a conversion factor to convert the total recoverable metal concentrations to equivalent dissolved metal concentrations. The Prothro (1993) memorandum suggested conversion factors for 10 metals.

Given EPA's policy and guidance and the comments received on this issue, EPA made available data to convert the proposed total recoverable metals criteria to the comparable dissolved metal criteria on August 30, 1994 (59 FR 44678). EPA invited comment on the procedure used to derive conversion factors for the nine proposed metals criteria in the "Draft Report: Results of Simulation Tests Concerning the Percent Dissolved Metal in Freshwater Toxicity Tests (Stephan, 8/1994). EPA also invited comment on the data collected utilizing the procedures as well as the calculated conversion factors for seven of the nine proposed metals. However, this draft report did not contain data or conversion factors for cadmium or mercury(II) because the testing was not yet complete for those metals at the time of the notice.

b. Comments: Numerous commenters stated that the proposed criteria for metals overestimate the bioavailability of metals and that recent technical and policy developments of EPA suggest the criteria are overprotective. These same commenters urged EPA to modify the proposed Guidance to base the numeric metals criteria on the dissolved metal fraction instead of the total recoverable metals approach used in the proposed Guidance. Some commenters, however, stated a preference for expressing the criteria as total recoverable concentrations. Many commenters asked EPA to maintain the flexibility for the State or Tribe to choose the form of pollutant used to develop criteria.

Comments received from the August 30, 1994, Federal Register notice generally favored using dissolved metals criteria for the final Guidance. Many commenters agreed that repeating all of the toxicity tests to generate new dissolved metals criteria was too resource-intensive and that the simulation tests contained in the report were technically preferable. Some commenters also stated that dissolved metals criteria may allow potential increases in metals loadings and potential impairment to the aquatic ecosystem by ignoring fate and transport of particulate bound metals.

Some commenters suggested that, except for chromium(III) and lead, EPA should treat the current total recoverable metal criteria as dissolved concentrations (i.e., make the conversion factor 1.0). Many commenters requested the opportunity to comment on any new data used to derive the conversion factors for cadmium and mercury(II).

Although the draft report (Stephan, 1994) did not discuss implementation of the dissolved metals criteria, EPA received considerable comment regarding implementation. Generally commenters felt that it was important for EPA to specify in the final Guidance how the dissolved criteria should be implemented. Commenters cautioned EPA against adoption of the dissolved criteria without guidance on Water Effect Ratios (WERs), modelling, translation for limits, clean analytical and sampling methods and use of appropriate historical data. Some commenters suggested that EPA adopt the Prothro (1993) memorandum into the final Guidance and others suggested that existing guidance was insufficient and EPA should update and/or revise existing implementation guidance. Comments were received regarding use of the acidification method in place of the total recoverable method in the simulation tests and the implications to analytical testing for compliance purposes.

EPA agrees with comments that, in general, the dissolved metal fraction more closely approximates the bioavailable fraction of metal in the water column than does total recoverable metal. Aquatic life criteria are designed to protect aquatic organisms from water column toxicity. The primary mechanism for water column toxicity is adsorption at the gill surface which requires metals to be in the dissolved form. The use of the dissolved form of the metal will, therefore, better approximate the toxicity to the aquatic organism.

This does not suggest, however, that the expression of metals criteria as total recoverable is not scientifically defensible, nor does this imply that State and Tribes are required to adopt the dissolved metals criteria. EPA agrees with commenters that States and Tribes should be allowed to choose the form of pollutant for which to develop criteria. EPA, while stating a preference for dissolved metals criteria in the final Guidance, realizes that there may be situations, such as consideration of sediments or food chain effects, where a State or Tribe believes the expression of metals criteria as total recoverable is preferable. EPA will allow the States and Tribes the flexibility to adopt total recoverable criteria for metals as stated in the Prothro (1993) memorandum.

EPA recognizes that many of tne conversion factors published in the draft report are very close to 1.0. EPA chose to create experimentally derived conversion factors rather than to assume that the existing total recoverable criteria to be 100 percent dissolved. EPA believes that this approach is more technically sound.

EPA recommends use of "The Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria" (U.S. EPA, 1993) and the report titled "Interim Guidance on Determination and Use of Water Effect Ratios for Metals" (U.S.EPA, 1994) for guidance on implementation of dissolved metals criteria. U.S.EPA (1993) contains guidance on dynamic modelling and translators (Attachment #3), and monitoring (Attachment #4). U.S. EPA (1994) presents an effluent-specific approach for calculating a total recoverable permit limit from a dissolved criterion (see pages 116 and 128-130 of U.S. EPA, 1994). This approach is based on the percent of the total recoverable metal in the effluent experimentally determined as described on pages 112 and 125 (U.S. EPA, 1994). A similar approach can be used to calculate a permit limit for criterion expressed as free cyanide; in this case the calculation is based on the percent of the total cyanide in the effluent that becomes free cyanide in the downstream water. EPA will continue to update implementation guidance as needed in the future.

For purposes of this rulemaking, Attachment #2 of U.S. EPA (1993) is superseded by the conversion factors and data in the report titled "Derivation of Conversion Factors for the Calculation of Dissolved Freshwater Aquatic Life Criteria for Metals" (U.S. EPA, 1995). These conversion factors are also found in Table III-1.

EPA used the acidification method in the simulation tests, in place of the total recoverable method, because the metals potentially bound within the test water would have been released by acidifying the samples. The acidification method is generally more accurate because it produces smaller coefficients of variation than the total recoverable method. In whole effluent, metals may form stronger bonds to other components of the effluent. Hence, for measuring total metals in effluent the total recoverable method is the appropriate method. The steps of heating and digesting the sample in the total recoverable analytical method were not deemed necessary for purposes of the simulation tests. Moreover, the fraction of metal in the dissolved phase may be different between effluent and surface waters. In order to account for all the metal being discharged into surface waters, and then calculate the fraction that is dissolved, the permitting authority must know the total amount of metal in effluent. Use of the acidification method was appropriate for the simulation tests, but this method is not being considered for regulatory use.

Due to resource constraints, EPA did not complete additional testing required to update the conversion factors for mercury given in earlier EPA guidance (Prothro, 1993). "The Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria" (Prothro, 1993) did not contain conversion factors for the CMC for selenium or for the for selenium and mercury. Prothro (1993), however, did contain a conversion factor of 0.85 for the National mercury CMC. EPA made available data to convert the proposed total recoverable metals criteria to the comparable dissolved metal criteria on August 30, 1994 (59 FR 44678) for selenium and mercury. The conversion factor for the CMC for mercury came from Prothro (1993) and this value was proposed in the August 30, 1994, notice for the mercury CCC.

Conversion factors were derived for selenium, even though Prothro (1993) stated that it is not appropriate to adjust the CMC and CCC for selenium or the CCC for mercury because these are bioaccumulative chemicals. Regardless of whether these metals bioaccumulate, the important consideration is the exposure that relates to the effect on which the CMC or CCC is based. The CMC is based on acute toxicity and so a relevant consideration is the bioavailability of the metal in the water column; therefore, a total recoverable CMC may be converted to a dissolved CMC if an appropriate conversion factor is used and if there are no unacceptable risk management considerations. For a CCC, the exposure can be from the water column and from the food, with the food chain consisting of some organisms whose primary exposure is to pollutants in the water column and other organisms whose primary exposure is to pollutants in the sediment. It appears that exposure to the sediment contributes substantially to the concentration of mercury in the food chain, but does not contribute substantially to the concentration of selenium in the food chain. Therefore, it is as acceptable to convert the total recoverable CCC for selenium to a dissolved CCC as it is to convert, for example, the total recoverable CMC for copper to a dissolved CMC. In contrast, it is not acceptable to convert a total recoverable CCC for mercury to a dissolved CCC if the CCC for mercury is based on mercury residues in aquatic organisms. It can, however, be acceptable to convert a CCC for mercury to a dissolved CCC if the CCC is based on the toxicity of mercury to aquatic organisms because the important exposure is through the water column; as before, a dissolved criterion may be derived if an appropriate conversion factor is used and if there are no unacceptable risk management considerations. Although a conversion factor cannot be used to derive a dissolved CCC for mercury if the CCC is based on mercury residues in aquatic organisms, this does not necessarily mean that losses due to fate and transport processes, such as volatility, cannot be taken into account in the derivation of a permit limit.

EPA believes that use of the CMC conversion factor to convert the total recoverable mercury CMC and CCC is technically preferable to having no conversion factor for the mercury(II) CCC or requiring the CCC for mercury be expressed as total recoverable. EPA will make available any new information regarding alternative conversion factors for the mercury(II) CCC.

EPA has completed testing to determine acceptable conversion factors for cadmium. Because these conversion factors are substantially different from those in the Prothro (1993) guidance, EPA will request public comment on the data used to derive these factors. EPA intends to amend the final Guidance for the aquatic life cadmium criteria after comment is received on the data for the cadmium conversion factors.

One commenter suggested that EPA consider the relationship of the dissolved concentration of lead to hardness. In the simulation tests it was found that the dissolved concentration consistently fluctuated with variations in hardness. Therefore, EPA has amended the conversion factors for lead to account for this hardness relationship. Although Tier I criteria are not provided for lead, EPA has included a conversion factor for lead in the final report (Stephan, 1995) for computing dissolved Tier II values or Tier I criteria.

Table III-1

Metal	Recommended Conversion Factors	
	CMC	**CCC**
Arsenic(III)	1.000	1.000
Cadmium	0.850	0.850
Chromium(III)	0.316	0.860
Chromium(VI)	0.982	0.962
Copper	0.960	0.960
Mercury(II)	0.850	0.850
Nickel	0.998	0.997
Selenium(IV)	0.922	0.922
Zinc	0.978	0.986

These recommended conversion factors are given to three decimal places and are not rounded off because they are intermediate values in the calculation of dissolved criteria.

c. Final Guidance: For the reasons stated above, the final Guidance contains metals criteria expressed as dissolved concentrations and as total recoverable concentrations. EPA converted the proposed criteria for total recoverable metals to their comparable dissolved criteria using the conversion factors found in Table III-1. The final conversion factors and supporting data are contained in the Final Report: "Derivation of Conversion Factors for the Calculation of Dissolved Freshwater Aquatic Life Criteria for Metals" (U.S. EPA, 1995). The conversion factors for the final GLI mercury(II) CMC and CCC are 0.85 from "The Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria" (Prothro, 1993). EPA has also included the conversion factors from the Prothro (1993) guidance for cadmium in the final Guidance. EPA intends to amend the final Guidance for the aquatic life cadmium criteria after comment is received on the data for the cadmium conversion factors. States and Tribes may adopt criteria as total recoverable metals. The total recoverable analytical methods found in 40 CFR § 136 must be used for purposes of compliance monitoring in NPDES permit limits.

7. Averaging Period/Frequency of Exceedance

a. Proposal: The proposed Guidance, consistent with the current National guidance, required that, except possibly where a locally important species is very sensitive, aquatic organisms and their uses should not be affected unacceptably if the following conditions are met: for chronic criteria, the four-day average concentration of a chemical does not exceed the CCC or Secondary Continuous Concentration (SCC) more than once every three years on the average; for acute criteria, the one-hour average concentration of a chemical does not exceed the CMC or Secondary Maximum Concentration (SMC) more than once every three years on the average.

Averaging periods are time periods over which ambient concentrations are to be averaged to determine whether criteria are exceeded. If the mean ambient concentration of a pollutant exceeds the criteria over the averaging period, adverse impacts on the resident aquatic life could occur. Averaging periods are one means of accounting for the exposure time required to elicit toxic effects.

An allowable frequency for exceeding the criteria is incorporated into the criteria because it is not necessary for concentrations to be below criteria at all times in order to adequately protect aquatic ecosystems. Also, it is not generally possible to ensure that criteria are never exceeded. Frequently, concentrations above criteria may occur without corresponding impacts on the aquatic biota if the duration is less than the averaging period. This is dependent on the magnitude and duration of the exceedance.

b. Comments: A few commenters questioned the validity of the one-hour and four-day averaging periods, and the once-in-three-year frequency stating that these components may be overly stringent and inappropriate for chemicals such as bioaccumulative chemicals of concern. Commenters stated that a four-day averaging period is too short for bioaccumulative chemicals.

EPA agrees that the averaging periods proposed in the Tier I and II methodologies will protect ecosystems from the effects of toxicants to which they are applied but that other averaging periods may also be appropriate for certain pollutants. The one-hour averaging period proposed for the CMC and SMC and the four-day averaging period or duration for the CCC and SCC were based on fast acting toxicants. Because different pollutants cause effects to aquatic organisms at different rates, these assumptions might be overly protective for some pollutants in some situations.

EPA's rationale for the once-in-three-year frequency proposed for acute and chronic criteria and values is presented in the 1985 National Guidelines and is also explained in appendix D of the "Technical Support Document for

Water Quality-Based Toxics Control" (U.S. EPA, 1991) which is included in the docket for this rulemaking.

c. Final Guidance: EPA believes that attainment of the one-hour or four-day averaging periods and the once-in-three-year frequency will protect ecosystems from adverse effects of toxicants to which they are applied. Consistent with the available data, however, EPA agrees with commenters that alternate averaging periods and frequencies may also be appropriate for certain pollutants. Consequently, the final Guidance allows the use of alternative averaging periods and frequencies if States or Tribes can demonstrate to EPA that they are scientifically defensible.

In evaluating whether an alternative averaging period is scientifically defensible, EPA will pay particular attention to those toxicity tests which account for the time needed to elicit effects. Greatest emphasis will be placed on results for sensitive species (e.g., those affected at relatively low concentrations). In assessing lethality from acute or chronic toxicity tests, EPA will pay particular attention to those relationships (a) between effect concentrations and time of exposure, or (b) between time to death and concentration. In assessing sublethal (e.g., growth and reproductive) effects, EPA will consider data from growth or reproductive tests comparing time-varying exposure with steady exposure. In such tests, evidence would be considered supportive of a longer-term averaging period where time-variable and steady concentrations yield the same growth or reproductive effects.

In considering alternative frequencies of exceedance, EPA recognizes that a substantial excursion above a criterion is likely to affect more taxa more severely than a marginal excursion, and that the setting of the allowable frequency for marginal excursions implicitly sets even lower frequencies for more severe excursions. Consequently, in evaluating whether an alternative is scientifically defensible, EPA will consider assessments that either explicitly or implicitly account for (a) the probable frequency of lethal events for an assemblage of taxa covering a range of sensitivities to pollutants; (b) the probable frequency of sublethal effects for such taxa; (c) the differing effects of lethal and sublethal events in reducing populations of such taxa; and (d) the time needed to replace organisms lost as a result of toxicity. For an assemblage of taxa for which toxicity data are available, such an assessment should yield an overall measure of toxic impacts that would result from the alternative excursion frequency being proposed. One such measure of toxic impacts could be the projected aggregate population deficit, compared to a system unaffected by pollutant toxicity.

Alternatively, EPA will consider information from well-designed field biological surveys indicating the relationship between biological quality and chemical criteria excursion frequency, provided that confounding factors such as bioavailability are appropriately taken into account and providing that the field surveys are adequately sensitive.

8. Final Tier I Criteria

a. Proposal: The proposal provided a detailed discussion of how EPA selected the 16 pollutants for which Tier I criteria were calculated. EPA chose not to propose specific numeric criteria for ten pollutants (aldrin, aluminum, chlordane, chlorpyrifos, DDT, endosulfan, heptachlor, lead, PCBs, and toxaphene) for which EPA has National aquatic life criteria for the reasons stated in the proposal (See 58FR20852). EPA requested comment on the proposed alternative of requiring States and Tribes to adopt the current National criteria for those 10 pollutants.

EPA proposed acute criteria for 16 pollutants and chronic criteria for 15 pollutants (See Tables 1 and 2 of proposed part 132). Footnotes within the tables delineated which proposed criteria were hardness or pH dependent and those criteria were listed at a hardness of 50 mg $CaCO_3$/L or a pH of 6.5.

b. Comments: Several commenters asked EPA to perform the testing needed to develop, or to develop, Tier I criteria for the ten remaining pollutants. Numerous commenters argued against using National Criteria where the data set for the pollutant did not meet the proposed Tier I aquatic life data requirements. Some commenters favored using Tier II methods for these pollutants. One commenter thought that EPA was obligated to require adoption of National aquatic life criteria (where Tier I criteria do not exist) by States and Tribes to meet the "no less restrictive" clause of the Critical Programs Act.

EPA disagrees that it should be solely responsible for developing the additional data to derive Tier I criteria for the 10 pollutants with National criteria. As discussed in section II.C. of this document, EPA in cooperation with States and Tribes will establish a Clearinghouse to assist States and Tribes in developing numeric Tier I water quality criteria and Tier II water quality values.

EPA agrees with commenters that States and Tribes should not be required to adopt the current National criteria for the 10 pollutants that do not meet the minimum data requirements for a Tier I criteria.

In the preamble to the proposed Guidance, EPA explained that the proposed Great Lakes criteria for aquatic life would not be less restrictive than the National criteria because States and Tribes would be required to generate Tier I criteria or Tier II values to regulate these 10 pollutants. EPA's position has not changed even though, as explained below, the final Guidance provides States and Tribes the option of regulating pollutants lacking a sufficient data set to derive Tier I criteria by either using Tier II values or establishing limits based on an indicator parameter. In the National program, where a State or Tribe must regulate a pollutant that lacks a promulgated numeric criterion, the State or Tribe may base a permit limit on either a numeric value or an indicator parameter. Consequently, EPA does not consider its decision to allow States and Tribes to use indicator parameters in place of Tier II values to make the final Guidance less restrictive than the National program for these 10 pollutants.

EPA also notes that the final Guidance contains numeric Tier I criteria for human health or wildlife for chlordane, DDT, PCBs, and toxaphene that are more stringent than the current National aquatic life criteria for the same pollutants. These criteria will help ensure that the final Guidance will protect aquatic life species as effectively as the National program for these four pollutants.

Several commenters requested that EPA provide the final acute and chronic equations within the final rule. EPA agrees that these equations should be part of Tables 1 and 2. EPA historically has provided criteria for pollutants that are hardness dependent in the form of an equation that accounts for hardness as part of the National criteria statement.

c. Final Guidance: For the reasons stated above, EPA has determined that it is appropriate to require States and Tribes to regulate these 10 pollutants by developing Tier II values. The final Guidance includes the acute and chronic hardness-dependent criteria for cadmium, chromium(III), copper, nickel, and zinc. The hardness and pH equations are found in Table III-2 as well as each individual criteria document for the above chemicals.

Table III-3 presents the CMCs calculated using the Tier I methodology for aquatic life. CMCs for metals are expressed as dissolved concentrations and total recoverable concentrations. Conversion factors utilized to convert the metals criteria from total recoverable concentrations to dissolved concentrations are found in Table III-1. For comparison the CMCs of existing National criteria are also included. Hardness-dependent CMCs for cadmium, chromium(III), copper, nickel, and zinc are found in Table III-2. A pH-dependent CMC for pentachlorophenol is also found in Table III-2.

A technical support document, Great Lakes Water Quality Initiative Criteria Document for the Protection of Aquatic Life in Ambient Water (EPA 820-B-95-004) (Final Criteria Documents), (available in the administrative record to this rulemaking) presents the derivation of each of the final Tier I CMCs and the toxicity studies from which the criteria were derived. The final Guidance requires that the numeric criteria in Table 1 to part 132 modified as appropriate to reflect site-specific conditions (or more stringent criteria) be adopted by the Great Lakes States and Tribes and incorporated into their ambient water quality standards. The specific requirements on how these criteria are to be incorporated into State and Tribal water quality standards are discussed in section II (Regulatory Requirements) of this document.

Table III-4 presents final CCCs calculated using the final Tier I methodology for aquatic life. Final CCCs for metals are expressed as dissolved concentrations and total recoverable concentrations. Conversion factors utilized to convert the metals criteria from total recoverable concentrations to dissolved concentrations are found in Table III-1. For comparison the CCCs in existing National criteria are also included. Differences between proposed and final Great Lakes Tier I CMCs and CCCs are described later in this section.

The derivation of each of these final CCCs, and the toxicity studies upon which they are based, are also discussed in Final Criteria Documents. This document is available in the administrative record for this rulemaking. Hardness-dependent CCCs for cadmium, chromium(III), copper, nickel, and zinc are found in Table III-2. A pH-dependent CCC for pentachlorophenol is also found in Table III-2. Criteria may be calculated at different concentrations of hardness (measured as mg/L of $CaCO_3$ or pH. For example, using the equations given in Table III-2, the total recoverable CMCs for zinc at a hardness of 10, 50, 100, or 200 mg/L $CaCO_3$ are 17, 67, 120, or 220 μg/L respectively. The hardness equations used to calculate hardness dependent freshwater criteria for metals (i.e., cadmium, chromium(III), copper, nickel, and zinc) can be used at any hardness. Most of the data used to develop these hardness formulas were in the range of 25 mg/L to 400 mg/L $CaCO_3$ and the formulas are therefore most accurate in this range. Irrespective of this data set, for waters with a hardness less than 25 mg/L $CaCO_3$ criteria should be calculated using the actual ambient hardness of the surface water. Limiting use of the equation only to hardness above 25 could result in underprotective criteria where the actual ambient hardness is below 25 mg/L $CaCO_3$. The majority of waters nationwide have a hardness of less that 400 mg/L $CaCO_3$. If however, the hardness is over 400 mg/L $CaCO_3$, two options are available for the State or Tribe: 1) use 400 mg/L $CaCO_3$ for the criteria calculation or 2) require an analysis to calculate a water-effect ratio for the site with hardness above 400 mg/L $CaCO_3$ and modify the final criteria concentration using the calculated water-effect ratio. Use of a water-effect ratio in this instance is recommended at a hardness above 400 mg/L $CaCO_3$ because other confounding factors, which may cause this hardness, can also affect the toxicity of the metal.

The final Guidance requires that the numeric criteria in Table 2 of part 132 (or more stringent criteria) be adopted by the Great Lakes States and Tribes and incorporated into their ambient water quality standards. The specific requirements on how these criteria are to be incorporated into State and Tribal water quality standards are discussed in section II of this document.

Table III-2

Hardness and pH Equations[1]

Chemical	Final Acute Equation	Final Chronic Equation
Cadmium	$e^{1.128 (\ln hardness) - 3.6867}$	$e^{0.7852 (\ln hardness) - 2.715}$
Chromium(III)	$e^{0.819 (\ln hardness) + 3.7256}$	$e^{0.819 (\ln hardness) + 0.6848}$
Copper	$e^{0.9422 (\ln hardness) - 1.700}$	$e^{0.8545 (\ln hardness) - 1.702}$
Nickel	$e^{0.846 (\ln hardness) + 2.255}$	$e^{0.846 (\ln hardness) + 0.0584}$
Pentachlorophenol	$e^{1.005 (pH) - 4.869}$	$e^{1.005 (pH) - 5.134}$
Zinc	$e^{0.8473 (\ln hardness) + 0.884}$	$e^{0.8473 (\ln hardness) + 0.884}$

1 These equations are for criteria expressed as total recoverable concentrations. Conversion factors should be applied to the resulting value if criteria expressed as dissolved concentrations are desired.

TABLE III-3
Acute Ambient Water Quality Criteria for Aquatic Life

Chemical	Great Lakes Final CMC[a] (dissolved)	Great Lakes CMCs[a] (total)	National CMC[a]
Arsenic(III)	340	339.8	360
Cadmium [b]	1.8	2.1	1.8
Chromium(III) [b]	320	1000	980
Chromium(VI)	16	16.02	16
Copper [b]	7.0	7.3	9.2
Cyanide, free	n/a	22	22
Dieldrin	n/a	0.24	2.5 [d]
Endrin	n/a	0.086	0.18 [d]
Lindane	n/a	0.95	2.0 [d]
Mercury(II)	1.4	1.694	2.4
Nickel [b]	260	260	790
Parathion	n/a	0.065	0.065
Pentachlorophenol [c]	n/a	5.3	5.5
Selenium	18	19.34	20
Zinc [b]	65	67	65

[a] All values are in µg/L.

[b] The toxicity of this chemical is hardness-related; the criterion expressed is at a hardness of 50 mg/L.

[c] The criterion for this chemical is pH dependent; the criterion expressed is at a pH of 6.5.

[d] This value is an FAV that was calculated according to the 1980 guidelines. Although the CMC = FAV/2 in the 1985 National Guidelines, there is no CMC in the 1980 guidelines and the procedure used to derive the FAV is different from that used in the 1985 National Guidelines.

Note: The term "n/a" means not applicable.

Table III-4
Chronic Ambient Water Quality Criteria for Aquatic Life

Chemical	Great Lakes Final CCC[a] (dissolved)	Great Lakes CMCs[a] (total)	National CCC[a]
Arsenic(III)	150	147.9	190
Cadmium [b]	1.2	1.4	0.66
Chromium(III) [b]	42	49	120
Chromium(VI)	11	10.98	11
Copper [b]	5.0	5.2	6.5
Cyanide, free	n/a	5.2	5.2
Dieldrin	n/a	0.056	0.0019 [d]
Endrin	n/a	0.036	0.0023 [d]
Mercury(II)	0.77	0.9081	0.012 [d]
Nickel [b]	29	29	88
Parathion	n/a	0.013	0.013
Pentachlorophenol [c]	n/a	4.05	3.5
Selenium	4.6	5	5.0
Zinc [b]	66	67	59

[a] All values in µg/L.

[b] The toxicity of this chemical is hardness-related; the criterion expressed is at a hardness of 50 mg/L.

[c] The toxicity of this chemical is pH related; the criterion expressed is at a pH of 6.5.

[d] Based upon Final Residue Value.

Note: The term "n/a" means not applicable.

9. Tier I Criteria

a. Proposal: The proposal contained CMCs (i.e., acute criteria) for sixteen pollutants calculated using the proposed Tier I methodology for aquatic life. CMCs were proposed for arsenic(II), cadmium, chromium(III), chromium(VI), copper, cyanide, dieldrin, endrin, lindane, mercury, nickel, parathion, pentachlorophenol, phenol, selenium, and zinc. CCCs (i.e., chronic criteria) were proposed for fifteen of the sixteen chemicals listed above. EPA did not propose a CCC for lindane because the minimum data requirements were not met.

b. Comments: Several commenters noted the lack of information or lack of explanation in the proposed aquatic life criteria documents. For example, it was pointed out that EPA did not present the ACRs in the arsenic(III) document. In addition, commenters noted several small errors within the documents, such as mathematical calculation errors.

Several commenters questioned the data used in the derivation of criteria. For example, for mercury EPA chose a 96-hour LC_{50} for Crangonyx which was two to three orders of magnitude lower than the 48-hour LC_{50}. Several commenters indicated that some criteria derived were unrealistically stringent, but generally did not present data to support this opinion.

c. Final Guidance: EPA agrees with comments that the criteria documents could have been more descriptive in the derivation of intermediate values such as the FACR and in how the final CMCs and CCCs were calculated. In response to these comments EPA has attempted to better explain how the criteria were derived. EPA notes that the most recent National aquatic life criteria document and the final GLI document together contain the complete data set for the chemical. In addition, the final criteria for endrin, cadmium, mercury, arsenic(III), lindane, nickel, zinc, copper, dieldrin, and parathion were changed from the proposal for the reasons cited below. The proposed criteria concentrations for chromium(III), chromium(VI), cyanide, and selenium are the same as the proposal. Some explanatory language was added to all the documents to better explain how the criteria were derived and the documents were slightly reformatted.

Some data were removed in response to comments. Chemicals for which data were deleted are cadmium, endrin, and mercury. The proposed endrin document stated that some acute toxicity data from the EPA endrin criteria document were not used in development of the GLI criteria because the test protocols did not meet current acceptable toxicity testing procedures. Some of these data, however, were not deleted and was used to calculate the proposed endrin criteria. EPA has deleted this data from the criteria derivation for the final GLI endrin criteria. This resulted in a slight change from the proposed criteria.

In reviewing the cadmium document EPA ascertained that the concentrations of cadmium were not measured in a chronic test with Moina. This data was deleted along with several acute and chronic tests conducted in river water (Spehar and Carlson, 1984). The Spehar and Carlson (1984) tests were deleted because variables within the water which might affect the toxicity of cadmium are unknown. These changes resulted in raising the CCC by nearly a factor of two. In the proposed cadmium document, the range of Species Mean Acute Value (SMAVs) was greater than a factor of five for the genus Morone. Because of this wide range, EPA set the Genus Mean Acute Value (GMAV) for Morone equal to the lowest SMAV for that genus.

In the final cadmium document, EPA also set that the GMAV for Daphnia equal to the lowest SMAV because the range of SMAVs was greater than a factor of five. EPA also has made the Genus Mean Chronic Value (GMCV) for Daphnia equal to the lowest SMCV for this genus. These changes also contributed to the' the higher CCC for cadmium. The CMC did not change as a result of these corrections. EPA believes the approach used for selecting the GMAV is more appropriate than the approach used for selecting the GMCV when there is a wide range in the SMAVs or SMCVs.

In the mercury document, the 96-hour LC_{50} for Crangonyx was deleted and the 48-hour LC_{50} was not used because these values were from the same test. EPA determined that the concentration measured was too great a change from 48 to 96 hours, making the test or measurements suspect. This change resulted in an increase in both the CMC and CCC.

Some of the data which was listed in the references and used to derive the criteria did not appear in the data tables. For example, the ACRs used in the derivation of the arsenic(III) CCC did not appear in Table 3 as referenced. EPA did include all of this data in the references and most of the information was located in the National arsenic criteria document. EPA has amended the final arsenic(III) GLI criteria document to include all data referenced. References and data within the tables were examined and similar corrections were made as necessary to the documents for arsenic(III), copper, dieldrin, and endrin.

Minor mathematical and rounding errors were found in the proposed criteria arsenic(III), cadmium, endrin, lindane (acute), nickel, and zinc. Simple mathematical errors in addition, subtraction, multiplication and division were corrected where found. In addition, all the documents were checked to ensure that intermediate values were not rounded. The criteria for lindane and nickel did not change as a result of these corrections.

A new FACR was calculated for zinc. The proposed CCC was derived with a FACR which contained a saltwater ACR. Upon additional review of the data, EPA determined that this saltwater ACR was not needed. The FACR for zinc was recalculated based only on freshwater ACRs. This changed the CCC some what and made it equal to the CMC.

EPA found similar data trends (wide ranges in SMAVs) in the copper, dieldrin, and parathion data sets. EPA consistently applied the procedure of making the GMAV or GMCV equal to the lowest SMAV or SMCV (respectively) when the range of SMAVs or SMCVs is greater than five. EPA believes that this is consistent with section XI.B. of appendix A to part 132 which asserts that appropriate modifications of the methodology shall be used consistent with sound scientific evidence where warranted. EPA believes that this modification is warranted to ensure protection to the more sensitive species within a genus. In this situation, the mean of the data could result in underprotection for these species if the genus is very sensitive. EPA, therefore, consistently applied this procedure. Applying this procedure to copper, dieldrin, and parathion did not result in changes to the proposed criterion concentrations.

After the Tier I criteria for phenol were proposed, EPA reevaluated the data used to derive the criteria. EPA has determined that at this time there is insufficient data of adequate quality to finalize the CCC for phenol. EPA also realized that not all of the data which could be used to derive the CMC and CCC for phenol were made available for public comment at the time of the proposal. Because of the withdrawal of some of data used to derive the proposed criteria and the inability for public comment on other data available prior to proposal, EPA will not finalize the proposed criteria for phenol. EPA will review the additional data which was not used in the proposal and make it available through the clearing house once established.

10. Potential Changes to National Guidelines

a. Proposal: In the proposal, EPA noted that the 1985 National Guidelines were being revised. To date, no revisions have been proposed for the 1985 National Guidelines.

b. Comments: Several commenters asked for clarification about what will happen when the 1985 National Guidelines are revised.

c. Final Guidance: Due to current resource constraints on EPA, revisions to the 1985 National Guidelines are not anticipated in the near future. When revised National Guidelines are proposed, EPA will announce whether the revisions should replace or supersede any portion of the final Guidance. Until such time, Great Lakes States and Tribes are required to use the final Tier I methodology herein.

C. Final Tier II Methodology

The proposed Guidance required the use of a Tier II value where a State or Tribe lacked the full eight families of toxicity data needed to set a chemical-specific Tier I criterion for a pollutant. As proposed, the Tier II methodology would allow derivation of a chemical-specific value using toxicity data for as few as one species. It contained adjustment factors to compensate for the missing data. EPA proposed to require use of methodologies consistent with the Tier II methodology to interpret narrative criteria (such as the prohibition on the discharge of no toxic chemicals in toxic amounts) in all cases where a State or Tribe determined using proposed procedure 5 of appendix F to part 132, that an effluent discharging into the Great Lakes system contained a pollutant in an amount that causes, has the reasonable potential to cause, or contributes to an excursion above any water quality standard, including the narrative criterion for water quality. EPA also proposed to require the use of methodologies consistent with the Tier II values as the applicable water quality standard for use in "reasonable potential" determinations under procedure 5 of appendix F to part 132 where there is no Tier I criterion nor sufficient data to calculate Tier I criteria.

1. Requirement for use in Interpreting the Narrative Toxics Criterion

Under the current National permitting requirements, where a State or Tribe determines that the discharge of a pollutant causes, has reasonable potential to cause, or contributes to an excursion above a State's or Tribe's narrative criterion, the State or Tribe must, in the absence of a numeric criterion for that pollutant, interpret the narrative criterion and include water quality-based effluent limitations (WQBELs) in the permit that are derived from and comply with the narrative as interpreted. Depending on the case-specific circumstances, such limits may currently be required for the specific pollutant of concern and/or for whole effluent toxicity (WET) (see 40 CFR section 122.44(d)(1)(vi)).

a. Proposal: The Tier II methodology developed for the proposed Guidance provided a consistent means for interpreting narrative criteria that protect aquatic life for all toxic pollutants with a very small number of data. EPA proposed to require States and Tribes to use the Tier II methodology to interpret their narrative criteria and where necessary to establish WQBELs. Under procedure 6 of appendix F to part 132, EPA also proposed the specific circumstances under which WET limits would be required in a permit. Both EPA and the Initiative Committees thought that requiring permit limits based on Tier II values would increase consistency among Great Lakes States and Tribes. The Steering Committee also hoped that the relatively stringent Tier II values would motivate some permittees to develop the toxicity data needed to derive a Tier I criteria.

At the same time, EPA recognized that a facility with a WET limit could argue that it had already reduced each of the individual pollutants in that effluent sufficiently to protect the tested aquatic species in the receiving water body (which often would be identical to the single species required as the minimum data for a Tier II value), and that further reductions in the amounts of individual pollutants based on a chemical-specific Tier II goal for the water body were unnecessary. Consequently, EPA asked for comment on the need for requiring both permit limits based on Tier II values and permit limits for WET, as well as other options for harmonizing the two requirements.

b. Comments: Many commenters suggested that the Whole Effluent Toxicity (WET) criteria be used in place of the aquatic life Tier II values and furthermore, that the Tier II methodology be published as merely guidance to the States and Tribes. Some commenters suggested that the Tier II values and WET protocols overlap substantially. These commenters recommended that both the Tier II methodology and guidance require that WET protocols be utilized to interpret the narrative criteria, in lieu of the proposed Tier II values. Some commenters thought that values derived using the Tier II method would actually create less consistency among States and Tribes. Other commenters preferred the proposed option of requiring use of both the Tier II values and WET.

EPA disagrees that WET be used in place of the Tier II aquatic life methodology and that the Tier II methodology be published as guidance. EPA notes that the Tier II aquatic life methodology offers some significant practical benefits for both the regulated community and the States and Tribes. For the regulated community, the chemical-specific Tier II approach offers the advantage of allowing the permittee to focus immediately on a single contaminant for the purposes of designing effluent treatment. In contrast, WET often leads to a facility conducting fairly extensive investigations to identify the cause of adverse effects on the tested organisms and to develop an effective approach to reducing the effects.

EPA notes that an individual discharger will not always need to have both Tier II and WET limits in its permit in order to protect the narrative water quality standards. However, EPA maintains as it did in its rulemaking promulgated on June 2, 1989 at 40 CFR 122.44(d)(1)(vi)(C), that once a finding is made that the discharge of a pollutant causes, has the reasonable potential to cause, or contributes to the excursion above the narrative criterion, reliance on WET alone, in lieu of chemical-specific limits must only be done where the discharger can demonstrate that WET sufficiently guards against excursions above the applicable water quality standard (i.e., the Tier II interpretation of the narrative standard). EPA continues to believe that the use of the Tier II methodology is important for deriving Tier II values to determine whether a pollutant has the reasonable potential to exceed a Water Quality-Based Effluent Limit (WQBEL).

c. Final Guidance: The final Guidance specifies the Tier II methodology as the methodology States and Tribes will have to use in interpreting their narrative water quality criteria for the protection of aquatic life. Procedures 5 and 6 of appendix F to part 132 specify the conditions under which chemical-specific and/or WET limits will be required for an individual discharger. Both kinds of limits will not always be necessary or required for a discharger. As described in section VIII.E of this document, and consistent with 40 CFR 122.44(d)(1)(vi)(C), limits on indicator parameters may be used in lieu of limits on the pollutant of concern when implementing the narrative criteria, including, a WET limit in lieu of a chemical numeric limit. However, when an indicator parameter is used, the State or Tribe must ensure that the indicator parameter will attain the Tier II interpretation of the "applicable water quality standard" (as described in 40 CFR 122.44(d)(1)(vi)(C)).

It should be noted that a WET limit can not be used in lieu of a chemical-specific limit where a total maximum daily load (TMDL), developed pursuant to 40 CFR 130.7 and approved by EPA, and corresponding wasteload allocation specifies the acceptable level for that chemical in a discharger's effluent. A State, Tribe or permittee in the Great Lakes System that wished to base permit limits on a TMDL, would need to generate a Tier I criterion or a Tier II value that could then be apportioned among contributing sources(40 CFR 122.44(d)(1)(vii)(B)).

Finally, it should be noted that Tier II values derived using the Tier II methodology are the appropriate means of determining whether a pollutant is or may be discharged into the Great Lakes System at a level which causes, has the reasonable potential to cause, or contributes to an excursion above a narrative criterion. WET testing is not an appropriate substitute for this chemical-specific determination. EPA does not believe that the Tier II method by itself would cause less consistency among the Great Lakes States and Tribes. Currently, States have different mechanisms to translate narrative criteria. EPA believes that the Tier II methodology enables States and Tribes to translate their narrative criteria with the same mechanism.

2. Data Requirements

a. Proposal: The proposed Tier II methodology utilized all available data and provided for derivation of a Tier II value when data sufficient to derive a Tier I criterion are not available.

b. Comments: Several commenters were concerned that the data requirements for the Tier II methodology were not adequate. Some commenters recommended that EPA require a minimum of three to seven of the eight taxonomic families specified. A few commenters further suggested that EPA, at a minimum, require data for a daphnid, rainbow trout and fathead minnow.

c. Final Guidance: EPA believes that the Tier II minimum data requirements are sufficient given the purpose of the Tier II methodology. As described in the proposal (58FR20835), the Initiative Committees sought to ensure consistency among States in the Great Lakes System as to how limited toxicity data are used to interpret narrative standards. The proposed aquatic life Tier II methodology fulfilled this goal. Section 303(c)(2)(B) of the CWA specifies that States and Tribes shall adopt criteria for all toxic pollutants for which presence in the affected waters could reasonably be expected to interfere with designated uses adopted by the State or Tribe. The minimum data required for the Tier II methodology promotes consistency in how this requirement is implemented. The proposal provided a standardized process for utilizing available data to derive values for purposes of interpreting narrative standards, thereby achieving greater consistency among the States and Tribes in this activity.

3. Other Methods for Tier II Values

a. Proposal: EPA's Science Advisory Board (SAB), in its report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," suggested the use of short-term and short-cut chronic toxicity tests to derive a Tier II value. The SAB believed this could overcome the cost of completing standard chronic toxicity tests. EPA invited comment on the appropriateness of short-term and short-cut chronic tests for the derivation of Tier II values.

b. Comments: Many commenters did not feel short-term or short-cut chronic tests were appropriate for criteria or value derivation. Other commenters supported the use of short-cut chronic tests, but did not provide any examples of acceptable short-cut tests. One commenter did recommend a short-term chronic test (7-day fathead minnow test, EPA/600/4-89/001).

At this time, EPA does not consider short-cut chronic tests appropriate for the derivation of a Tier I criterion or Tier II values. EPA has serious concerns over whether short-cut chronic tests can accurately predict effects from long-term exposures. A short-cut chronic test is a short-term exposure to an aquatic organism during a sensitive life stage(s) which might yield toxicity results similar to those obtained from complete life-cycle, partial life-cycle, or early life-stage tests. Although this type of test might yield results that are similar to those from a complete chronic test for some chemicals, significant exceptions can occur. No commenter pointed to any studies in which a short-cut chronic method was compared to a complete life-cycle toxicity test for the same species. Without such validation or verification of a short-cut chronic test, EPA is hesitant to allow its use as a replacement for a life-cycle, partial life-cycle or early life-stage test.

EPA does, however, think that the 7-day Ceriodaphnid test, which measures survival, growth and reproduction, is acceptable for use in deriving Tier I criteria and Tier II values, because this is a life-cycle test according to the American Society for Testing and Materials (See ASTM Definition in the Administrative Record). EPA does not consider this test a short-cut test because it is a life-cycle test. The 7-day duration is appropriate for a life-cycle test with species in the genus *Ceriodaphnia*, whereas a 21-day duration is appropriate for species in the genus *Daphnia*.

c. Final Guidance: The final Guidance does not allow data from short-cut tests to be used in deriving a Tier I criterion or Tier II value. However, the final Guidance does allow use of the 7-day Ceriodaphnid life-cycle test for derivation of both Tier I criteria and Tier II values.

4. Adjustment Factors

a. Proposal: The proposed Tier II methodology uses adjustment factors obtained in the statistical analysis described by Host, *et al.* (1991) in the draft paper, "Analysis of Acute and Chronic Data for Aquatic Life," (which may be found in the administrative record for this rulemaking) to derive Tier II values from data for one to seven of the eight taxonomic families required for Tier I calculations. Depending upon the number of Tier I minimum data requirements satisfied by the data base, different adjustment factors are applied to the lowest Genus Mean Acute Value to arrive at the Secondary Acute Value (SAV). These adjustment factors are intended to relate the results of one to seven toxicity tests to a FAV. EPA invited comment on the selection of an 80th percentile in establishing the proposed adjustment factors. EPA also invited comment on the use of a set of lower adjustment factors to be used only where daphnid data were available as opposed to the higher adjustment factors that would be necessary if data for the specified daphnids are not required.

b. Comments: Several commenters also suggested that EPA set up a hierarchy of toxicity testing requirements for Tier II. This would establish the order in which data are added to the Tier II data set. Several of these commenters suggested that EPA establish the hierarchy where more sensitive species would be tested first.

It would be very difficult to set up a hierarchy of toxicity testing requirements for Tier II because there is a range of sensitivities among species that satisfy any one minimum data requirement and because the species sensitivity varies with the pollutant under consideration. EPA believes it would be speculative to create such a hierarchy and impose it on diverse pollutants which elicit varying toxic responses.

Many commenters stated that the 80th percentile was too conservative and recommended that EPA establish median or 50th percentile adjustment factors. Some commenters supported the use of the 80th percentile adjustment factors. A few commenters recommended that the level of protection for adjustment factors be set at the 95th percentile to provide the same level of protection as a Tier I criterion. Many of the comments supported the use of adjustment factors with daphnid data rather than those without.

c. Final Guidance: When deriving Tier II values for chemicals for which limited data are available for establishing permit limits, EPA desires to be highly certain that adequate protection is afforded. EPA must be highly certain that Tier II values provide a level of protection greater than or equal to a Tier I criterion. EPA believes that use of a procedure that would result in less protection than use of the 80th percentile would cause Tier II values to be significantly less protective than Tier I criteria. Use of the

50th percentile would allow less protection than a Tier I criterion in 50 percent of the cases. EPA does not believe that 50th percentile factors would ensure that adequate protection is afforded in most cases. If the Tier II value is thought to be unnecessarily low, the State, Tribe, or discharger can generate the data necessary to allow derivation of a different (usually higher) Tier II acute value or a Tier I FAV.

Possible factors were calculated in a number of ways in the draft report on which the proposed adjustment factors were based. The proposed factors were calculated as "overall 80th percentiles," i.e., the percentiles were calculated as percent of the simulations rather than as percent of the chemicals. After further consideration, EPA has decided that the most appropriate adjustment factors to use are those that were calculated as "medians of the 95th percentiles" on page 62 of the draft report because these percentiles were calculated as percent of the chemicals (Host, *et al.*, 1991). These final adjustment factors (with daphnid required) are given in Table III-5. In addition, some minor anomalies occur in the overall 80th percentile values, but no such anomaly occurs in the medians of the 95th percentiles. Further, the calculation of the assumed ACR is based on the percent of the chemicals.

It might seem that the adjustment factors and the assumed ACR should be based on the same percentile. Because the assumed ACR will often be used with a Tier II acute value, it does not seem reasonable to increase the level of protection by having both be at the 95th percentile; in this case it might be appropriate to have the ACR at a lower percentile. In some cases, however, an assumed ACR will be used with a Tier I FAV; in these cases it might be appropriate to have the assumed ACR be the 95th percentile. It does not seem prudent to use two different values for the assumed ACR, and so EPA has retained the value of 18, which is based on the 80th percentile (see the next section). The final Guidance also retains the use of adjustment factors "with daphnid data."

Table III-5

Adjustment Factors (with Daphnid Data Required)

Percentile	Sample Size (Number of Data Requirements Fulfilled) 1	2	3	4	5	6	7
95	21.9	13.0	8.0	7.0	6.1	5.2	4.3

5. Assumed ACRs

a. Proposal: In the proposal, EPA requested comment on the use of assumed ACRs in place of experimentally derived ACRs, and particularly on the use of 18 as the assumed ACR. When there are less than three experimentally derived ACRs, the proposal required the use of enough assumed ACRs of 18 (along with experimentally derived ACRs) to bring the total number of measured and assumed ACRs to three (See appendix A.XIII. of proposed part 132).

b. Comments: Several commenters supported the use of assumed ACRs and the proposed assumed ACR of 18. One of those commenters suggested that the assumed ACR of 18 be used as a cap. No comments were received which questioned the use of assumed ACRs. Commenters suggested using alternate assumed ACRs developed by the European Centre for Ecotoxicology and Toxicology. These ACRs are median values generated for various chemical classes (e.g., pesticides, metal/organometals, etc.).

EPA agrees with commenters that use of assumed ACRs are appropriate when experimentally derived ACRs are not available. EPA disagrees with that ACRs should be developed using median values. EPA does not believe it is appropriate to base ACRs on median values whether they are generated across chemical classes or for a single class of chemicals, because the median will be too low for half of the chemicals.

c. Final Guidance: The final Guidance retains the use of assumed ACRs when insufficient experimentally derived ACRs exist. A final assumed ACR of 18, based on an 80th percentile shall be used when there are insufficient measured ACRs. EPA believes that it is inappropriate to alter experimentally derived ACRs capping them at 18. The final Guidance requires experimentally derived ACRs when available, but assumed ACRs shall be used where data are lacking. Since the value of 18 is the 80th percentile, twenty percent of the chemicals are expected to have larger ACRs. The final Guidance does not preclude a State or Tribe from choosing an assumed ACR which is more stringent (or greater than 18).

D. Comparison with the CWA and EPA's National Guidance

Section 118(c)(2)(A) of the CWA requires the water quality criteria for the Great Lakes to be "no less restrictive" than the National criteria and guidance. As EPA explained in the proposal, it will not promulgate Tier I criteria for several pollutants for which National criteria exist. EPA continues to believe that this decision does not make the Great Lakes criteria "less restrictive" than National criteria. Moreover, EPA notes that its decision to change the adjustment factors used to compute Tier II values makes the Tier II values more closely resemble Tier I criteria. Tier II values will now be as or more restrictive as Tier I criteria in 95 percent of all cases, rather than 80 percent.

In the proposal EPA also explained that the Great Lakes Tier I criteria for four pollutants that appeared to be less conservative than the National criteria for the same pollutants were not actually less restrictive. EPA continues to rely on that analysis. Similarly, EPA continues to rely on the proposal's conclusion that the Tier II methodology is not less stringent than the more general narrative standards allowed under the National program.

In response to comments on the proposal EPA has decided to express all Tier I criteria for metals in terms of dissolved rather than total recoverable concentrations. This change results in criteria that are more appropriate but, arguably, less stringent than the National criteria (which are expressed as total recoverable concentrations). As explained above in the discussion of this issue, EPA has already begun to allow the use of dissolved values for metals under the National program. EPA intends to continue revising the National program to be more consistent with the Great Lakes program on this issue.

E. Conformance with the Great Lakes Water Quality Agreement

1. Tier I Aquatic Life Criteria and Methodology

The Great Lakes Water Quality Agreement (GLWQA)sets out both general and specific "objectives" for water quality in the Great Lakes. The specific objectives include a list of concentration levels for individual pollutants set out in Annex 1 to the GLWQA. The Annex indicates that some of these levels were chosen to protect aquatic life. (Other levels protect either human health or wildlife.) Some of the Annex 1 concentrations for the protection of aquatic life, however, appear to be more conservative than the corresponding final Tier I criteria for aquatic life. EPA nevertheless believes that the final criteria, as well as the methodology from which they were derived, conform with the provisions and objectives of the GLWQA.

In the first place, the language of the GLWQA itself shows that neither the general not the specific objectives are legally binding, precise standards. Article III (general objectives), Article IV (specific objectives) and Annex 1 (specific objectives) all describe their provisions as "objectives," or goals, rather than requirements. Further, both Article II and Annex I use the permissive term "should" rather than the mandatory "shall." Article IV contains some provisions that appear more mandatory, but they do not relate to the achievement of specific water quality requirements. Moreover, it describes the Annex 1 numbers as "desired" levels rather than requirements. Consequently, EPA thinks it is reasonable to believe that the framers of the GLWQA did not intend the Annex 1 numbers to become enforceable, mandatory requirements under U.S. or Canadian law. (The U.S. Department of State reached the same conclusion where it analyzed the GLWQA for the Office of Management and Budget in 1978.)

EPA also believes that the Great Lakes Critical Programs Acto of 1990 did not change the legal status of the GLWQA's objectives or provisions. Section 118(c)(2)(A) of the CWA directs EPA to adopt guidance that "conforms" with the objectives of the GLWQA. "Conform" means to "make similar" or "bring into harmony," not to "duplicate" or "follow precisely." The very same sentence in section 118 of the CWA shows that Congress knew how to require a closer relationship when it wanted to impose one: it requires EPA's guidance to be "no less restrictive than the provisions of [the CWA] and National water quality criteria and guidance." Clearly, Congress did not impose the same standard with respect to the general and specific objectives of the GLWQA.

EPA also finds it significant that section 118(c)(2)(A) of the CWA directs EPA to develop numeric limits for the Great Lakes waters rather than simply to incorporate the GLWQA numeric values. EPA believes that Congress would have been very explicit if it had intended to deprive EPA of the authority to exercise its own judgement on the technical and scientific issues involved. Moreover, the legislative history shows that Congress knew and approved of the ongoing work of the Great Lakes Initiative Committees. S. Rep. 101-339. 101st Cong., 2d Sess. at 18 (June 27., 1990); 136 Cong. Rec. S15616 (Oct. 17, 1990). Since the legislative history so prominently acknowledges the committees' work, it is reasonable to assume that Congress expected EPA to develop its own criteria. Consequently, EPA does not believe that "conformance" with the GLWQA requires the numeric criteria proposed to be identical to or no less restrictive than the GLWQA objectives, including individual Annex 1 values. Rather, EPA's guidance as a whole needs to further the objectives of the GLWQA. In EPA's judgement, the final Tier I aquatic life criteria are consistent with the general objective that Great Lakes waters should be "free from materials...that...will produce conditions that are toxic or harmful to ...aquatic life." Great Lakes Water Quality Agreement of 1978, Art. III, para. (d).

In the preamble to the proposed rule, EPA stated that it would seek to revise some of the Specific Objectives of the Agreement. EPA, however, has reconsidered this approach. In light of all the strong evidence that the

Specific Objectives were meant to be goals rather than requirements, EPA believes revisions are unnecessary. It does not intend to pursue them at this time.

2. Tier II Values and Methodology

Tier II is a conservative methodology designed to establish environmentally protective limits on the discharge of pollutants into the Great Lakes System. The methodology will regulate the discharge of certain pollutants which, in certain Great Lakes States, may have been regulated by narrative criteria rather than specific numeric criteria. The Tier II methodology is consistent with the general objective of the GLWQA cited above. Moreover, it serves as a translator mechanism for that "narrative" objective. The Tier II methodology will enhance protection of aquatic life in the Great Lakes basin and will serve the GLWQA's purpose of promoting consistency in the regulation of toxics in the Great Lakes basin. Therefore, it also "conforms" to the GLWQA.

IV. BIOACCUMULATION FACTORS

A. Summary of Final Rule

The final Guidance is similar in substance to the Guidance proposed on April 16, 1993, except for the following changes:

-- Taking into account the freely dissolved concentration of a chemical in the derivation of bioaccumulation factors (BAFs) for organic chemicals.

-- Use of the equation, baseline BCF = K_{OW} in place of the equation originally proposed, when predicting a bioconcentration factor (BCF) from a chemical's octanol-water partition coefficient (K_{OW}) for organic chemicals.

-- Use of a model adapted from Gobas (1993) rather than the model discussed in the proposal to determine food-chain multipliers (FCMs) for organic chemicals, which provides FCMs for the entire range of K_{OW}s, rather than defaulting to one for log K_{OW}s greater than six.

-- Addition of an option for predicting a BAF based on the biota-sediment accumulation factor (BSAF) methodology as the second most preferred method in the hierarchy for derivation of BAFs for organic chemicals.

-- The use of standard lipid values of 3.10 percent in edible tissue of trophic level 4 fish and 1.82 percent in edible tissue for trophic level 3 fish for use in determining human health BAFs for organic chemicals in place of the lipid value originally proposed. The use of standard lipid values of 10.31 percent in whole body of trophic level 4 fish and 6.46 percent in whole body for trophic level 3 fish for use in determining wildlife BAFs for organic chemicals in place of the value originally proposed.

-- BAFs for individual PCB congeners, weighted by their relative concentrations in salmonids, which is the predominant route of exposure, rather than the mean of the nine most common congeners or calculation from concentrations of total PCBs in fish and ambient water.

B. Explanation of Final Provisions

1. BAFs

Aquatic organisms are exposed to chemicals through the water that they live in, the food that they eat, and contact with sediment. Chemicals enter these organisms via gills, epidermis, or the gastrointestinal tract; this uptake of chemicals process is called bioaccumulation. For certain chemicals, uptake through the food chain is the most important route of exposure. As lower trophic level organisms are consumed by higher trophic level organisms, the tissue concentrations of some chemicals increase through one or more trophic levels so that residues in organisms at trophic level 3 and 4 might be many orders of magnitude greater than the concentration of the chemical in the ambient water. While the concentration in the ambient water may be too low to affect the lowest level organisms, this biomagnification process can result in exposure concentrations for the consumers of top trophic level aquatic organisms that are above the fish tissue concentrations that correspond to current Clean Water Act (CWA) section 304(a) water quality criteria by several orders of magnitude (58 FR 20816). Table I-1 in the proposed Guidance (58 FR 20816) compares the measured concentrations of PCBs and three pesticides found in fish tissue (De Vault 1993a) with the fish tissue concentrations corresponding to current CWA section 304(a) water quality criteria at a 10^{-5} risk level. Consumers of these fish would be consuming fish that contain up to 200 times the levels of PCBs calculated in the 304(a) criteria to correspond to a 10^{-5} risk.

In the final Guidance, as in the proposal, EPA relies on BAFs to reflect the propensity of a chemical to accumulate in the tissues of aquatic organisms, accounting for exposure from all sources of a chemical. In order to properly account for exposure to a chemical, both the wildlife criteria and the human health criteria and values have been developed to incorporate appropriate BAFs. In addition, the human health BAFs are used to identify Bioaccumulative Chemicals of Concern (BCCs) which warrant increased attention, and more stringent controls, within the basin. See discussion of BCCs in section II.C.8 of this document.

As discussed in the proposal, bioaccumulation refers to the net accumulation of a substance by an aquatic organism from its ambient water, sediment and food. A BAF represents the ratio (in L/kg) of a substance's concentration in the tissue of aquatic organisms to its concentration in the ambient water in situations where both the organism and its food are exposed and the ratio does not change substantially over time. Measured BAFs are based on field data.

A BCF (in L/kg) is the net accumulation of a substance by an aquatic organism from the ambient water only through gill membranes or other external body surfaces. BCFs are determined either by measuring bioconcentration in laboratory tests (comparing fish tissue residues to chemical concentrations in test waters), or by predicting the BCF from the octanol-water partition coefficient (K_{OW} or P) of a chemical. The equation, log BCF = 0.79 log K_{OW} - 0.40, was used in the proposal to relate the BCF and the octanol-water partition coefficient for a chemical (see 58 FR 20859).

EPA's 1991 National guidance documents, the "Technical Support Document for Water Quality-based Toxics Control" and draft "Assessment and Control of Bioconcentratable Contaminants in Surface Waters," recommend a methodology for estimating the BAF where a field-measured BAF is not available. This methodology predicts the BAF by multiplying the BCF by a factor which accounts for the biomagnification of a chemical through trophic levels in a food chain. The numerical factor which represents the magnitude of this biomagnification through the food chain is called the food-chain multiplier (FCM) in these 1991 National guidance documents. In the 1991 documents and the proposed Guidance, EPA calculated the FCMs using a model of the step-wise increase in the concentration of an organic chemical from phytoplankton (trophic level 1) through the top predatory fish (trophic level 4) of a food chain (Thomann, 1989) (see 58 FR 20859 for a discussion of the Thomann model).

2. Measured and Predicted BAFs

a. Hierarchy of Methods.

i. Proposal: The proposed Guidance listed three methods for deriving BAFs for organic chemicals, described below in order of decreasing preference:

(1) A BAF measured in the field, preferably in fish collected in the Great Lakes which are at the top of the food chain;

(2) A BAF predicted by multiplying a BCF measured in the laboratory, preferably on a fish species indigenous to the Great Lakes, by the food-chain multiplier; and,

(3) A BAF predicted by multiplying a BCF calculated from the log K_{OW} (using the equation, log BCF = 0.79 log K_{OW} - 0.40 (Veith and Kosian, 1983)) by the food-chain multiplier.

Subsequent to the proposed Guidance, EPA requested comment in a Notice of Data Availability (59 FR 44678) on incorporation of a BAF derived from the

BSAF methodology as the second method in the hierarchy for deriving BAFs for organics.

ii. Comments: Many commenters stated that field-measured BAFs and predicted BAFs for a chemical do not correlate well and in most cases the predicted BAF for a chemical overestimates the field-measured BAF. Because of this the commenters advocated using only field-measured BAFs when deriving human health and wildlife criteria.

Several commenters argued that BCFs should be used instead of BAFs because of the high degree of variability and site-specificity in field-measured BAFs; the current state of the science does not support the transition from BCF to BAF; and biomagnification might be due to data anomalies and oversimplification of the food chain rather than trophic transfer of a chemical.

Many commenters wanted EPA to discuss the uncertainty associated with the BAFs because they were concerned that all the uncertainties inherent in each portion of the methodology could produce an aggregate uncertainty larger than the BAF.

Several commenters questioned the use of a combination of the Veith and Kosian (1983) regression equation with the Thomann model (1989), and suggested using either the whole Thomann approach or testing the validity of the combination approach.

Many commenters suggested using the BSAF or Bioavailability Index (BI) for derivation of criteria in place of the BAF. Along the same lines, many commenters advocated using the concentration in sediments instead of ambient water when deriving criteria because sediments are the primary repository of chemicals with log K_{ow}s greater than four and using minute, trace water concentrations of chemicals with log K_{ow}s greater than four in the derivation of BAFs will result in inappropriately high values.

Finally many commenters wanted the flexibility to revise the BAF when new data become available, while others stressed the need for communication between EPA and the regulatory agencies to share data on BAFs.

EPA does not agree that the field-measured BAFs and predicted BAFs for a chemical do not correlate well. The adaptation of the Gobas model for estimating FCMs (see discussion in section IV.B.4 below on the Gobas model) reduces much of the uncertainty and variability associated with comparing field-measured BAFs and predicted BAFs. A comparison of the BAFs predicted by the Gobas model (1993) against the field-measured BAFs from Oliver and Niimi (1988) for the 52 chemicals which have field-measured BAFs for at least three fish shows that differences between the mean BAFs are less than a two-fold for 46 of the 52 chemicals, and less than a three-fold for 51 of the 52 chemicals (Zipf, 1995). EPA concludes that when field-measured BAFs are not available, the model used in the final Guidance acceptably predicts BAFs for the Great Lakes System.

EPA partially agrees with commenters who advocate using field-measured BAFs when deriving criteria. In the proposal, Tier I criteria and Tier II values for human health and wildlife were differentiated based on the quantity and quality of toxicological data only. After reconsideration, EPA has decided to differentiate the Tier I criteria and Tier II values for human health and Tier I criteria for wildlife based on the quantity and quality of both the toxicological and bioaccumulation data. The minimum toxicological data for human health is discussed in section V and for wildlife in section VI. The new minimum BAF data required to derive Tier I human health criteria for organic chemicals include either: (a) a field-measured BAF; (b) a BAF derived from the BSAF methodology, or (c) a chemical with a BAF less than 125 regardless of how the BAF was derived. The new minimum BAF data required to derive Tier I wildlife criteria for organic chemicals include either: (a) a field-measured BAF, or (b) a BAF derived from the BSAF methodology. For all inorganic chemicals, including organometallics such as mercury, the minimum BAF data required to derive a Tier I human health and wildlife criteria include either: (a) a field-measured BAF or (b) a laboratory-measured BCF. For the majority of inorganic chemicals, the BAF is equal to the BCF (i.e., FCM = 1) because there is no apparent biomagnification or metabolism. The basis for these new requirements is explained below.

Requiring the use of field-measured BAFs or field-measured BSAFs when deriving Tier I criteria for organic chemicals with predicted BAFs greater than 125 eliminates for these Tier I criteria concerns about the effect of metabolism on the BAF. This is the case because field studies measure chemical concentrations in the tissues of the fish that are exposed to the chemical from food, ambient water and sediment. The measured concentrations in the fish inherently account for the effect of metabolism from all sources of exposure. On the other hand, the concentration of the chemical in fish tissue from laboratory-measured BCF accounts for exposure from ambient water only. Consequently, BCFs do not account for the effect of metabolism of chemicals accumulated from exposure through the diet of the aquatic organism. Metabolism may either increase or decrease the concentration of a chemical and its by-products in the tissue of an aquatic organism. EPA's BAF methodology uses a model (Gobas, 1993) to predict the accumulation of a chemical from food sources. The model of Gobas (1993), however, does not account for the effects of metabolism; in other words, the entire concentration of the chemical input to the model plus the concentration biomagnified through the food chain is predicted to accumulate in the fish tissue. Consequently, BAFs based on multiplying a laboratory-measured BCF times a FCM (predicted from Gobas, 1993) may either under- or overestimate the amount of a chemical a fish will bioaccumulate. In addition, predicted BAFs that are obtained by multiplying a predicted BCF by a FCM make no allowance for metabolism.

EPA has decided that Tier I criteria, which must be adopted into State regulations and become the goal for permit limits throughout an entire State, should accurately account for the effects of metabolism. Accordingly, EPA is requiring the use of field studies for determining a BAF to be used in the derivation of a Tier I criterion for human health.

Tier I human health criteria may also be derived for chemicals with BAFs less than 125 regardless of which of the four methods specified in the final Guidance is used to derive the BAF. For chemicals with a BAF less than 125, exposure from consumption of fish is less than or equal to the exposure from consumption of drinking water. This assumes a fish consumption rate of 15 grams per day and drinking water consumption of two liters per day. Thus for these chemicals the effects of metabolism by aquatic organisms are not as significant a determinant of ultimate human exposure as for chemicals with larger BAFs. Therefore, for organic chemicals with a BAF less than 125, all four methods specified in the final Guidance can be used to obtain a BAF used to derive Tier I criteria.

EPA has decided, notwithstanding the fact that predicted BAFs will at best only partially account for the effects of metabolism, to allow derivation of Tier II human health values using BAFs based on BCFs and the FCM. EPA's decision is based on several factors. First, as described elsewhere in this document, available information indicates a very good correlation between predicted BAFs based on the methodology in the final Guidance and field-measured BAFs. Therefore, it appears that the error introduced by using predicted BAFs rather than field-measured BAFs may be relatively small for many chemicals. Second, Tier II values by definition are based on a less than ideal data base. Acknowledging that the data available is not perfect for Tier II chemicals, EPA believes that it is nevertheless important to protect human health from potential adverse effects resulting from their discharge to surface waters. The Tier II methodology, including use of predicted BAFs, specifies the best available protocols for assessing protective ambient levels for these chemicals for which Tier I data are not available This will provide consistency among Great Lakes States and Tribes in the interpretation of narrative human health criteria when establishing water quality-based effluent limitations (WQBELs). To the extent that a discharger of a chemical for which a Tier II value is established on the basis of a predicted BAF questions whether a field-measured BAF would not provide a more accurate measure of bioaccumulation, that discharger is free to conduct an adequate field study and request that it be utilized by the appropriate regulatory authority in establishing a Tier II value or Tier I criterion. Finally, for those chemicals where available data indicates that metabolism is likely to considerably increase or decrease a predicted BAF, appendix B section VIII of the final Guidance allows States and Tribes to modify the predicted BAFs accordingly. EPA believes that derivation of an "effective FCM" for certain chemicals, as described in the proposed Guidance, may in many cases reasonably account for the metabolism. However, States and Tribes are not limited to the use of an "effective FCM" in correcting a predicted BAF for metabolism.

EPA disagrees with commenters that BCFs should be used instead of BAFs. Bioaccumulation is what occurs in nature, and is what determines the total concentration of chemicals in aquatic organisms that are consumed by humans and wildlife. For some chemicals the biomagnification of a chemical through the food chain can be substantial. Using BCFs, which only account for exposure from the ambient water, could substantially underestimate the potential exposure to humans and wildlife for some of these chemicals and result in criteria or values which are underprotective. The use of BAFs, which account for uptake from all sources, will ensure that the potential exposure from these chemicals is adequately accounted for in the derivation of human health and wildlife criteria. Using BAFs is the most comprehensive and scientifically valid approach. As mentioned in the proposal (58 FR 20858), BAFs have been used in deriving human health criteria development since 1980.

EPA recognizes that field-measured BAFs will have some variability from site to site. In recognition of this, EPA allows the derivation of site-specific BAFs as discussed in procedure 1 of appendix F to part 132. Although there might be some variability in field-measured BAFs, it does not invalidate their usefulness in estimating the potential exposure to humans and wildlife, nor does it imply that BAFs are less accurate than BCFs in predicting that exposure.

In addition, EPA does not agree with commenters that biomagnification might be due to data anomalies and oversimplification of the food chain. There is ample evidence of biomagnification occurring because of trophic transfer of chemicals. The importance of uptake of chemicals through the diet and the potential for a stepwise increase in bioaccumulation from one trophic level to the next in natural systems has been recognized for many years (Hamelink, et. al., 1971). Many researchers have noted that the BAFs of some chemicals in nature exceed the BCFs measured in the laboratory or estimated by log K_{OW} models (e.g., Oliver and Niimi 1983, Oliver and Niimi 1988, Niimi 1985, Swackhammer and Hites 1988).

Further, EPA believes that the state of the science supports the use of BAFs. EPA's Science Advisory Board (SAB) in its December 16, 1992, report on the Evaluation of the Guidance for the Great Lakes Water Quality Initiative stated that the BAF procedure is more advanced and scientifically credible than existing BCF procedures and that the use of the BCF, FCM, and BAF approach appears to be fundamentally sound (EPA-SAB-EPEC/DWC-93-005). In a subsequent SAB report on August 12, 1993 on the ongoing revision of the methodology for deriving National Ambient Water Quality Criteria for the protection of human health (EPA-SAB-DWC-93-016), the Drinking Water Committee reported on a similar BAF methodology. Although cautioning that its "criticisms should not be taken as a recommendation to relax standards or to ignore the potential for bioaccumulation where it is known to play an important role," the Drinking Water Committee also stated that "for the time being, the Agency should focus attention on BCFs rather than BAFs, because of the higher likelihood of collecting an adequate BCF data base." In evaluating the two SAB committee reports, it is important to keep in mind that the first committee was reviewing the proposed BAF methodology for the Great Lakes Guidance, while the second committee was reviewing a similar proposed methodology that would be applicable nation-wide. Thus, the second committee's recommendation that a sufficient BAF data base may not be available at the present time to derive BAFs for chemicals for nation-wide criteria guidance does not imply that sufficient information is not available to develop BAFs for regional water quality standards in the Great Lakes. Indeed, to rely on BCFs in the Great Lakes System would be directly contrary to the Drinking Water Committee's exhortation that their criticism not be taken as a recommendation "to ignore the potential for bioaccumulation where it is known to play an important role." EPA has revised the BAF methodology where possible at this time to take into account the concerns raised by both SAB Committees, and believes after careful review of SAB and public comments that use of BAFs in the final Guidance represents the most scientifically defensible approach for accounting for chemical uptake by aquatic biota in the Great Lakes System.

EPA also recognizes there were some uncertainties in application of the proposed BAF methodology and has addressed these in the final Guidance. For example, to reduce the uncertainty in predicting the biomagnification of chemicals, EPA is using a model in the final Guidance that uses Great Lakes specific parameters and includes a benthic food chain component to estimate FCMs. In addition, the final Guidance takes into account the freely dissolved concentration of a chemical in the derivation of BAFs for organic chemicals. Taking the freely dissolved concentration into account will eliminate much of the variability associated with specific waterbodies because most of the site-specific differences in bioaccumulation arises from the partitioning of the chemical to the particulate organic carbon and dissolved organic carbon of the water column. However, professional judgement is still required throughout the derivation of BAFs and a degree of uncertainty is still associated with the determination of any BAF, BSAF, BCF or K_{OW}. Despite this uncertainty, EPA maintains that BAFs are the most useful measure of the exposure of an aquatic organism to all chemicals.

EPA agrees with those commenters who suggested the use of the BSAF approach for deriving BAFs and has modified the proposed hierarchy of methods for deriving BAFs to include a BAF derived from the BSAF methodology as the second preferred method after field-measured BAFs. The BSAF provides a method by which the concentrations of chemicals in the sediment are related to the concentrations in fish tissue. The concentrations of chemicals with log K_{OW}s greater than 6.5 are greater in the sediment than in the water column and more readily measured; therefore use of the BSAF reduces the uncertainty associated with relating concentration in fish tissue to the concentration in the water column for these chemicals. This is particularly true for chemicals with higher K_{OW}s since these generally show a greater affinity for sediments. The BI is the same method as the BSAF and the terms can be interchanged. For further details on deriving BAFs using the BSAF methodology, and the data supporting the approach, see the final Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors (EPA 820-B-95-005) (BAF TSD) for BAFs which is available in the public docket for this rulemaking.

In response to commenters who wanted EPA to develop sediment criteria instead of water criteria, EPA asserts that ambient water quality criteria provide a measure of acceptable chemical levels in the medium in which non-benthic aquatic organisms primarily exist, and are therefore an important measure of acceptable environmental conditions for these organisms. EPA agrees that sediment criteria may also provide useful indices of acceptable chemical levels, especially when the greatest risks are known to be associated with toxic effects to benthic organisms.

EPA has changed the final Guidance in response to commenters' concerns with the use of the Veith and Kosian regression equation in combination with the Thomann model (1989). In the final Guidance, the equation baseline BCF = K_{OW} that is used to predict BCFs is equivalent to the equation BCF_{ℓ}^{fd} = K_{OW} for log K_{OW}s less than three that is used in the Gobas 1993 model to predict FCMs. Thus there is no longer a need to validate the use of the regression equation by Veith and Kosian (1983) in combination with the Thomann model (1989).

Finally, EPA agrees with commenters that it is important to revise BAFs when new data become available and anticipates that the Clearinghouse discussed in section II.C.1 will provide the mechanism through which new data are evaluated and disseminated. In addition, the final hierarchy of data preference allows for the incorporation of new data. For example, if a field-measured BAF is calculated for a chemical for which only a predicted BAF was previously available, preference would be given to the field-measured BAF.

iii. Final Guidance: EPA revised the proposed hierarchy of methods for deriving BAFs based on public comments. The final Guidance lists four methods for deriving BAFs for organic chemicals, listed below in order of decreasing preference: a BAF measured in the field, in fish collected from the Great Lakes which are at or near the top of the food chain; a BAF derived using the BSAF methodology; a BAF predicted by multiplying a BCF measured in the laboratory, preferably on a fish species indigenous to the Great Lakes, by the FCM; and a BAF predicted by multiplying a BCF calculated from the K_{OW} by the FCM.

b. Field-Measured BAFs

i. Proposal: As discussed above, the proposal stated a preference for using field-measured BAFs over predicted BAFs. This preference stems from the fact that field-measured BAFs automatically account for any biomagnification and metabolism that might occur. The proposal also stated that field-measured BAFs should be based on fish species, preferably living in the Great Lakes at or near the top of the aquatic food chain. In its December 16, 1992 report, the EPA's SAB stated that field-measured BAFs must be interpreted very carefully, and it should be recognized that they might contain substantial errors and variability due to several factors (see 58 FR 20860).

ii. Comments: Many commenters stated that the field-measured BAFs might contain substantial errors and expressed a preference for the more established BCF. Other commenters were concerned that the field-measured BAFs were based on a single data source, that limiting the data base to the Great Lakes for calculation of field-measured BAFs ignores a wealth of information, and that it was important to show that the BAFs measured in one lake accurately predict fish tissue levels in other Great Lakes. Several commenters suggested developing guidelines for measuring and/or evaluating field-measured BAFs which would include provisions for the simultaneous collection of water and fish tissue and accounting for fish mobility, as well as discussing the importance of the sampling location and temporal change.

EPA acknowledges that there can be errors in determining field-measured BAFs, as with any field-measurements, and has attempted to minimize these potential errors when deriving BAFs for the final Guidance by carefully screening the data used to calculate the BAFs. EPA continues to contend that a field-measured BAF is a more accurate gauge of what is occurring in nature than a laboratory-measured or -predicted BCF because the BAF measures the actual impacts of biomagnification, bioavailability, concentration in the sediment, growth dilution, and metabolism rather than predicting them through use of a model.

EPA also agrees with the SAB's comments and with commenters concerned about the difficulty of collecting and interpreting field-measured BAFs. EPA, however, thinks that States and Tribes can adequately use and interpret field studies. To assist them in this task, EPA plans to provide guidance concerning the determination and interpretation of field-measured BAFs before the States and Tribes are required to adopt water quality standards consistent with the final Guidance. This will provide interested parties with a set of procedures that will assist them in collecting and interpreting the field-measured BAFs.

The majority of data used to calculate the field-measured BAFs in the final Guidance came from the data of Oliver and Niimi (1988). This data set is generally recognized as being the most complete set of data available in the Great Lakes for estimating field-measured BAFs. EPA acknowledges that the data from Oliver and Niimi come from Lake Ontario, but believes that the data can be used to predict BAFs in other Great Lakes because the values take into account the percent lipid and are based on the freely dissolved concentration of the chemical in the ambient water. Taking the lipid content into account allows the data to be applied to other fish species. Derivation of the BAFs on a freely dissolved basis from field data eliminates the site-specific nature of the BAFs caused by the amounts of dissolved and particulate organic carbon present at the field site and therefore, allows the use of the derived BAFs in the other Great Lakes.

Using data from the Great Lakes is preferable to using information from other bodies of water because it better represents the physical, chemical, and hydrological conditions present within the Great Lakes.

iii. Final Guidance: The final Guidance requires that field-measured BAFs be the preferred method for deriving BAFs because of their ability to account for biomagnification, growth, metabolism, concentration in the sediment, and bioavailability.

c. Field-Measured BSAFs

i. Proposal: As discussed in the August 30, 1994 Notice of Data Availability (59 FR 44678), BSAFs can be used for measuring bioaccumulation directly from concentrations of chemicals in surface sediments or to estimate BAFs. Because BSAFs are based on field data and incorporate the effects of metabolism, biomagnification, growth, concentration in the sediment, and bioavailability, BAFs derived from the BSAF methodology will incorporate the net effect of these factors. The BSAF approach is particularly beneficial for developing water quality criteria for chemicals such as polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and certain biphenyl congeners which are detectable in fish tissues and sediments but are difficult to measure in the ambient water.

BSAFs are measured by relating lipid-normalized concentrations of chemicals in an organism to organic carbon-normalized concentrations of the chemicals in surface sediment samples associated with the average exposure environment of the organism. The BSAF is defined as:

$$BSAF = \frac{C_\ell}{C_{SOC}}$$

where:

C_ℓ = the lipid-normalized concentration of the chemical in tissues of the biota (µg/g lipid).

C_{SOC} = the organic carbon-normalized concentration of the chemical in the surface sediment (µg/g sediment organic carbon).

For further explanation, see the BAF TSD.

ii. Comments: Commenters generally supported the use of the BSAF methodology in deriving BAFs. Some commenters stated that while chemicals in the sediment may contribute to bioaccumulation, the proposed BSAF model is only valid if limited to a chemical- and site-specific context. Some commenters suggested that EPA more fully address the issue of relative concentrations of a chemical in the sediment and water column.

Other commenters questioned the validity of data for reference chemicals used when deriving BAFs from the BSAF methodology since the data are from a single unpublished study. Others raised questions about the availability of the study.

EPA acknowledges that BAFs derived from field-measured BSAFs require chemical-, species- and site-specific data. EPA is not intending to place an undue burden on the States, Tribes or dischargers to generate data. If pertinent data are available, EPA has set forth a methodology in which they can be used. Basing the BSAF on lipid-normalized concentrations and organic carbon-normalized concentrations eliminates many of the species- and site-specific characteristics, and therefore the BSAF is applicable to a wider area than that at which it was measured.

In response to commenters' concerns about the relative concentrations of a chemical in the sediment and the ambient water, EPA believes that fish are exposed to organic chemicals through contact with water, food and, and to some extent, sediment. At steady-state, the concentrations of these chemicals in water or surface sediment, although numerically quite different, are equally useful for prediction of bioaccumulation in fish. When concentrations of some chemicals are temporally variable and/or nondetectable in water, BSAFs can provide the most reliable field-measurement of bioaccumulation. BAFs are needed, however, to calculate water quality criteria. Fortunately, the BSAF methodology inherently includes a measure of the disequilibrium that usually occurs between the sediment-water distribution of the chemicals by using reference chemicals for which a field-measured BAF is available. The relative concentrations of the chemical in the sediment and water are therefore accounted for in the BSAF. The BSAF method translates the bioaccumulation and disequilibrium information presented by the BSAF into a BAF through comparison to reference chemicals with similar sediment-water disequilibrium at the same site. In this method the reference chemicals provide key relationships between measured BSAFs and BAFs for the ecosystem.

EPA understands the commenters' concerns with the availability of the data used for deriving BAFs from the BSAF methodology. All the BSAF, BAF and K_{OW} data used to derive the BAFs based on the BSAF methodology were presented in the August 30, 1994 Notice of Data Availability (59 FR 44678). EPA acknowledges that some of the fish and sediment analytical data have not been published. However, the use of the Oliver and Niimi data (1988), which have been published, to demonstrate correlations and numerical similarity between BSAFs and BAFs calculated from the two independent data sets should provide additional assurance of the applicability of the unpublished data for demonstration of the BSAF method for deriving BAFs from BSAFs.

iii. Final Guidance: In the final Guidance, a BAF derived from the BSAF methodology is added as the second most preferred method in the hierarchy for derivation of BAFs for organic chemicals.

d. Measured and Predicted BCFs

i. Proposal: The proposed Guidance preamble (58 FR 20859) discussed three analytical techniques that can be used to measure organic chemicals in tissue and water for the purposes of establishing a laboratory-measured BCFs: gas chromatography, high pressure liquid chromatography or radio-labeled organic chemicals.

The proposed Guidance predicted BCFs from the octanol-water partition coefficient (K_{OW} or P) of a chemical using the equation:

$$\log BCF = 0.79 \log K_{OW} - 0.40 \text{ (Veith and Kosian, 1983)}$$

Subsequent to the proposed Guidance, EPA requested comment in the August 30, 1994, Notice of Data Availability (59 FR 44678) on the use of an alternative equation from the proposal to predict BCFs. The equation was:

$$BCF_{\ell}^{fd} = K_{OW}$$

where the BCF_{ℓ}^{fd} is reported on a lipid-normalized basis using the freely dissolved concentration of the chemical in the water.

ii. Comments: Some commenters indicated that use of radio-labeled organic compounds would overestimate the laboratory-measured BCF. Other commenters stated that difficulties with radio-labeled materials are easily avoided in actual practice.

Several commenters stated that predicted BCFs should not be used for chemicals that are suspected of metabolism. Many commenters supported the change from the Veith and Kosian (1983) equation to the equation $BCF_{\ell}^{fd} = K_{OW}$, but recommended that EPA specify the limitations of its use; commenters wanted EPA to be explicit about the assumed percent lipid in derivation of the BCF. Several commenters requested development of guidelines for measuring K_{OW}.

EPA partially agrees with the commenters who recommended against the use of radio-labeled organic chemicals for measuring BCFs because the organism may also accumulate a metabolite of the parent compound, thereby overstating the actual BAF. Attempts to measure the amount of radio-labeled compound obtained through tissue analysis, instead of measuring the radioactivity of the fish, have not been definitive. There is also the possibility of contamination of the labeled compound. Because of these concerns, EPA has decided that BCFs for organic chemicals may be based on measurement of radioactivity only when the BCF is intended to include metabolites or when there is confidence that there is no interference due to metabolites.

EPA partially agrees with commenters who suggest that predicted BCFs should not be used for chemicals that are suspected of metabolism. EPA stated in the Technical Support Document for the Procedure to Determine Bioaccumulation Factors (EPA-822-R-94-002) that the relationship $BCF_{\ell}^{fd} = K_{OW}$ is applicable to organic chemicals which are either slowly or not metabolized by aquatic organisms. Since predicted BCFs do not account for metabolism, they will not be used in the derivation of Tier I human health and wildlife criteria unless the predicted BAF is less than 125. Predicted BCFs, however, can be used in the derivation of Tier II human health values if no laboratory-measured BCF data are available. For a more detailed discussion on Tier II values, see section IV.B.2.a.ii of this document.

In response to commenters' questions regarding the assumed percent lipid, the 1983 average percent lipid associated with the Veith and Kosian equation was 7.6. The BCF in the equation $BCF_{\ell}^{fd} = K_{OW}$ is reported on a lipid normalized basis, and therefore by definition assumes 100 percent lipid. This BCF is then adjusted to the percent lipid appropriate for a given trophic level. See section III.B.3 of this document for further explanation.

EPA is in the process of developing guidelines for measurement of K_{OW}s. In the interim period, section III.F of appendix B to part 132 lists the analytical technique priorities for deriving K_{OW}s. K_{OW}s are an integral factor in developing BAFs used in derivation of human health criteria and values and wildlife criteria; therefore, EPA believes that providing guidance on the acceptability of K_{OW}s will result in more consistent criteria.

iii. Final Guidance: In the final Guidance, predicted BCFs are derived from a chemical's K_{ow} using the following equation:

$$\text{Baseline BCF} = K_{OW}$$

See the final BAF TSD for details.

The BCF based on this equation provides a more consistent and scientifically defensible basis for predicting BAFs than the equation (Veith and Kosian, 1983) used in the proposal. The theoretical basis presented by Mackay (1982) and the experimental data referenced in the August 30, 1994, Notice of Data Availability (58 FR 44678), suggest that octanol is a reasonable surrogate for lipids.

For laboratory-measured BCFs, EPA continues to strongly recommend the use of the procedural and quality assurance requirements specified in the American Society for Testing Materials (ASTM) (1990) "Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs," and in the EPA guidance contained in Stephan et al. (1985), "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses."

e. Inorganic Chemicals

i. Proposal: The proposed Guidance limited the methods for obtaining a BAF for inorganic chemicals to a field-measured BAF or a laboratory-measured BCF. This is because no method is available for reliably predicting BCFs or BAFs for inorganic chemicals. BCFs and BAFs for some inorganic chemicals vary between species, and from one tissue to another within a species. The proposal included BAFs for 17 inorganic chemicals, including mercury.

ii. Comments: Several commenters indicated that there was a wide range of variability in laboratory-measured BCFs for inorganic chemicals. Other comments indicated that in order to check the reliability of measured data, modelling should be allowed for inorganic chemicals. Other commenters advocated site-specific modifications for metals based on each Lake's characteristics.

EPA acknowledges that there is some variability in laboratory-measured BCFs for inorganic chemicals, and that there are real differences between species. For example, saltwater molluscs have substantially higher BCFs for many metals than do freshwater and other saltwater fishes and invertebrates. Variability is not a major concern for the majority of inorganic chemicals, however, because their BCFs are low for species consumed from the Great Lakes. For example, the BAF for ten of the 17 inorganic chemicals in the list of chemicals in Table 6 of part 132 is below ten. This indicates that even though there may be some variability in laboratory-measured BCFs, the impact on the final criteria will be small.

EPA agrees with commenters that modelling should be allowed if the model has been shown to be appropriate. EPA advocates but does not require the use of modelling to verify the reliability of the measured data for inorganic chemicals. In addition, EPA agrees that site-specific modifications should be allowed for BAFs and provides for this in procedure 1 of appendix F to part 132.

iii. Final Guidance: After review of the comments, EPA decided that the proposed Guidance for derivation of BAFs for inorganic chemicals will not be amended. The most accurate measurement of bioaccumulation for inorganic chemicals are field-measured BAFs and laboratory-measured BCFs.

3. Lipid Values

Consistent with the existing National guidance, the proposed Guidance relied on the assumption that an organism's ability to bioaccumulate organic chemicals is related to its lipid content.

Therefore to determine a BAF for organic chemicals for use in deriving wildlife Tier I criteria and human health Tier I criteria and Tier II values it is necessary to know the percent lipid content of the organisms being consumed. Humans typically eat fish fillets which usually have lower lipid content than the whole fish consumed by wildlife. EPA's current recommended National percent lipid values for calculation of human health criteria is 3 percent (U.S. EPA, 1980). There is currently no National guidance for wildlife and thus there is no recommended percent lipid value.

In the proposal, EPA requested comments on a variety of issues including what solvent should be used in the measurement of percent lipids. Some commenters advocated the use of a standardized extraction method and a consistent system to measure lipid content, while a few suggested use of methylene chloride as the extraction solvent. No rationale for selecting between the solvents which have been proposed was presented by commenters. EPA believes that the data is inconclusive as to which extraction method and solvent to use and has therefore has not made a recommendation on which method and solvent to use in the measurement of percent lipids. EPA will be providing additional guidance on which extraction method(s) and solvent(s) to use in the guidance on the determination and interpretation of field-measured BAFs.

a. Lipid Value for Human Health BAFs

i. Proposal: The proposed Guidance used a lipid value of 5.0 percent in edible tissue for use in determining human health BAFs for organic chemicals. Percent lipid data for edible tissue (mostly skin-on fillets) were gathered from the fish contaminant monitoring programs in Michigan, Wisconsin, Ohio, Indiana, New York and Minnesota. The use of skin-on data to determine the lipid values provided an extra margin of safety to the many anglers who remove the skin from the fillet.

In selecting the lipid value for human health BAFs, lipid data for the following fish groups were considered: salmonids only; salmonids and non-salmonid game fish; and all fish (game and nongame species).

The mean lipid value for salmonid and non-salmonid game fish of 5.02 percent lipid was proposed because this option best represented the range of species typically consumed by people in the Great Lakes basin. Also considered was the mean lipid values weighted by human consumption patterns. The resulting consumption-weighted mean for all sport-caught game fish was 4.72 $\pm$ 2.42 percent lipid. Because these results were not statistically different from the unweighted mean, use of the unweighted mean of 5.02 percent (rounded to 5.0 percent) was proposed for the human health BAFs.

ii. Comments: A few commenters did not agree with the use of skin-on filets, and suggested using skin-off filets for lipid measurement with a corresponding lipid value of four percent. Other commenters stated that the five percent lipid value did not provide an adequate margin of safety nor protect high-risk subpopulations (e.g., Tribes and subsistence fisherpersons) and suggested using an 11 percent lipid value. Other commenters suggested using three percent for the tributaries of the Great Lakes, which is consistent with the National guidelines dated November 28, 1980 (45 FR 79347). Some commenters stated that the data did not exist to determine which fish species were consumed and the corresponding percentage of lipid for high-risk groups.

In order to further examine whether the five percent lipid value was appropriate, EPA conducted additional analysis of the data from a second fish consumption survey conducted by West, et al. (1993) (see section V of this document, Human Health, for a complete discussion of this study). EPA requested comments on the appropriateness of the data presented in the study in a Federal Register notice on August 30, 1994 (59 FR 44678). The results from this analysis indicate that the consumption-weighted mean percent lipid value for trophic level 4 fish is 3.10 and 1.82 for trophic level 3. EPA believes that the use of the West et al. (1993) survey to estimate the percent lipid used for deriving BAFs is an improvement on the methods utilized in the proposal because the West survey allows a determination of the actual fish species consumed and the rate of consumption. When this information is coupled with the information on percent lipid values for these fish, it is possible to derive a more accurate reflection of the grams of lipid from fish that are consumed by humans from each trophic level. EPA acknowledges that the West study only covered anglers in the State of Michigan, but concludes it represents the best study to use for deriving consumption-weighted mean percent lipid values for trophic levels 3 and 4. States and Tribes can derive alternative percent lipid values to be used in the derivation of site-specific BAFs whenever they have the information needed to revise the derivation.

EPA does not agree with those commenters advocating the use of skin-off fillets for deriving percent lipid values. Although many people remove the skin and other fatty tissue when they prepare their fish for cooking, the study by West et. al. (1993) indicates that about 37 percent of anglers in Michigan continue to prepare fish with the skin on even though they are aware of the State fish advisories recommendation to trim fat and/or skin from the fish.

EPA also disagrees with those commenters advocating the use of a three percent lipid value for tributaries. Due to the mobility of the prey and its host, it is difficult to characterize their territorial range. The consumption weighted mean percent lipid for the respective trophic levels represents an overall average for the Great Lakes System. The fish lipid data used to determine the percent lipid values were gathered from fish contaminant monitoring programs in the Great Lakes System (including its tributaries) and represent the species consumed by people in the West et al. survey. EPA also does not agree that the lipid values should be increased to 11 percent representative of lake trout, a species with the highest lipid value. In the majority of the cases people consume a variety of species and not simply lake trout, as evidenced by the West survey. The lipid values selected for use in deriving BAFs represent the wide variety of fish consumed by sport anglers in the Great Lakes System. In cases where it can be documented that a subpopulation consumes fish with an average lipid content higher than those prescribed in the final Guidance, then it may be appropriate for a permitting authority to increase the lipid value in deriving a site-specific criterion for waters fished by the subpopulation. The permitting authority should evaluate all aspects of exposure, including amount consumed, before altering just one factor such as percent lipid, since the values for these variables are interrelated.

iii. Final Guidance: EPA has specified the use of a consumption-weighted mean percent lipid value for trophic level 4 fish of 3.10 and 1.82 for trophic level 3 in edible tissue for use in determining human health BAFs for organic chemicals in the final Guidance.

b. Lipid Value for Wildlife BAFs

i. Proposal: A lipid value of 7.9 percent for wildlife BAFs, based on consumption of whole fish, was included in the proposal. The lipid value for the wildlife BAFs was determined using whole fish lipid data from the U.S. Fish and Wildlife Service National Contaminant Biomonitoring Program and the Canadian Department of Fisheries and Oceans. The 7.9 percent lipid value was the mean of lipid values for all fish, game and nongame, in the entire Great

Lakes System. Data for all fish were used because wildlife typically are nondiscriminatory consumers of fish.

ii. Comments: A few comments indicated that the percent lipid value should be based on fattier fish. Other commenters felt that 7.9 percent lipid was based on a reasonable analysis and assumptions, but would like more information on prey preferences and whether high lipid organs are preferentially eaten by wildlife.

iii. Final Guidance: In the final Guidance, the percent lipid for the actual prey species consumed by the representative wildlife species is used to estimate the BAF for the trophic levels at which wildlife consume. The percent lipid is based on the consumption patterns of wildlife and cross-referenced with fish weight and size and appropriate percent lipid (see final TSD for BAFs). This approach is a more accurate reflection of the lipid content of the fish consumed by wildlife species than the approach used in the proposal.

EPA has required use of a percent lipid value for trophic level 4 fish of 10.31 and 6.46 for trophic level 3 in whole fish for use in determining wildlife BAFs for organic chemicals in the final Guidance.

4. FCMs

a. Proposal: As discussed in the proposed Guidance, when a field-measured BAF is not available, a predicted BAF can be calculated by multiplying a laboratory-measured or predicted BCF by a food-chain multiplier. The FCM accounts for the biomagnification of a chemical through trophic levels in the food chain. The FCMs in the proposal were based on a model by Thomann (1989) (see 58 FR 20859 and 20861 for a more complete description of the model and its uses).

In the August 30, 1994 Notice of Data Availability (59 FR 44678), EPA requested comment on use of a food-chain model by Gobas (1993) which, unlike the Thomann 1989 model, includes both benthic and pelagic food chains, thereby estimating exposure of organisms to chemicals from both the sediment and the water column.

b. Comments: Many commenters cited the 1992 SAB report contention that the FCM model (Thomann, 1989) has not been adequately peer reviewed or sufficiently validated to be used in a regulatory framework. Commenters also questioned the applicability of one model to a diverse ecosystem such as the Great Lakes and encouraged EPA to discuss alternate models.

Many commenters criticized the use of the Thomann model for not adequately accounting for metabolism, biotransformation, degradation, persistence, or seasonal or temporal variability. In addition, commenters argued that the model is extremely sensitive to certain input parameters such as the lipid content and that the input parameters for the FCMs that EPA calculated were taken directly from Thomann's paper instead of using Great Lakes specific assumptions. Other commenters questioned the model assumption that the system is at steady state, while others supported this assumption due to the difficulty in describing the ecosystem parameters that would affect the likelihood of reaching equilibrium.

Many comments stated that the Thomann model had little application for chemicals with log K_{OW}s greater than 6.5 because it did not consider sediment as a route of exposure. Commenters suggested using alternative food-chain models such as Thomann (1992) which incorporates sediment as a route of exposure; or Thomann and Connolly (1984) which has Great Lakes specific input parameters.

Some commenters on the August 30, 1994 Notice of Data Availability (59 FR 44678) supported the use of FCMs derived from the Gobas model, assuming that no metabolism occurs, because it incorporates the concentration of the chemical in both sediment and the water column. Other commenters on the Notice requested further explanation as to why some FCMs for trophic level 3 are greater than trophic level 4. Other commenters stated that additional field validation and documentation of both the Thomann 1989 and the Gobas 1993 model is needed before they can be used in a regulation.

EPA acknowledges that the 1989 Thomann model does not account for certain important processes such as metabolism. Similarly, although the 1993 Gobas model includes a metabolic rate constant, it was set equal to zero due to a scarcity of data for individual chemicals. Based on EPA's review of the commenters' concerns regarding metabolism, EPA has decided in the final Guidance to differentiate which BAF data are required to derive Tier I human health and wildlife criteria for organic chemicals based on whether or not metabolism is taken into account.

EPA agrees with commenters that it is important to use Great Lakes-specific parameters whenever possible and that there should be an attempt to account for the most sensitive input parameters to the model. In light of these concerns, EPA has used Great Lakes-specific input parameters in the Gobas model that is used to derive FCMs for the final Guidance. In addition, EPA selected the model of Gobas (1993) to derive FCMs in part because this model, in contrast to the model of Thomann (1992), required fewer input parameters and had input parameters which could be more easily specified.

EPA agrees that assuming a system is at steady state might be a simplifying assumption in some cases, but as noted by commenters it is very difficult to determine the parameters affecting a system reaching equilibrium. This is especially true in a system as large as the Great Lakes. The model of Gobas (1993) when used with conditions that are not at steady-state will predict BAFs which are very similar to those obtained from steady-state conditions. The concentrations of the chemicals in the water and sediment in the Gobas model (1993), are used as input parameters and therefore, the disequilibrium between the water column and the sediments are included in the model calculations. The differences between measured and predicted BAFs when conditions are changing depends upon the rate of change. For the Great Lakes, the rate of change for PCBs and other bioaccumulative chemicals is quite slow because burial in sediments and volatilization into the atmosphere are the major routes of removal for the chemicals from the ecosystem. For all these reasons, EPA concludes that it is reasonable to continue to use a model for estimating the FCMs which assumes that the system is at steady state.

EPA agrees that sediment should be considered as a route of exposure in the model, especially for chemicals with log K_{ow}s greater than 6.5. EPA considers the model by Gobas (1993) an improvement on the 1989 Thomann model because it incorporates the exposure of organisms to chemicals from the sediment by including a benthic food-chain component.

The FCMs for trophic level 3 in some cases are greater than those for trophic level 4. Potential causes of the higher concentrations (on a lipid basis) in the trophic level 3 fish include: 1) growth rates which are much slower than the predator fishes; 2) differing rates of depuration and elimination of the chemical by the predator fishes. Field-measured BAFs derived from the data of Oliver and Niimi (1988) are, in general, consistent with the model results for smelt. For example, DDT, PCB 66, PCB 70+76, PCB 56+60+81, and PCB 49 have field-measured log BAF_l^{fd}s for large smelt (trophic level 3) of 7.93, 7.88, 7.71, 8.12, and 7.66 and for piscivorous fishes (trophic level 4) of 7.78, 7.79, 7.56, 7.96, and 7.13, respectively (Oliver and Niimi, 1988).

EPA in developing the final Guidance FCMs (Table B.1) calculated the trophic level 3 values by averaging (geometric mean) the individual FCMs for sculpin and alewife. The FCMs for smelt were not included in the calculation of the trophic level 3 values because these organisms are at a trophic level higher than 3 but less than 4. The FCMs for trophic levels 3 and 4 in the final Guidance are composed of fish with diets consisting of solely trophic level 2 and 3 organisms, respectively.

EPA, in part, agrees with the comments that using one set of modelling conditions might not be totally representative of the entire Great Lakes System. However, numerous similarities do exist among the food webs in the five Great Lakes. First, all of the Great Lakes have both benthic and pelagic food web components. Second, all of the Great Lakes except for Lake Erie have salmonids as their piscivorous fish. Third, all of the Great Lakes have their piscivorous fish occupying the fourth trophic level. Fourth, all of the Great Lakes have forage fishes occupying the third trophic level. The food web used in the development of the FCMs was based upon a four trophic level food web with both benthic and pelagic food web components taken from Lake Ontario. EPA has determined that enough similarities exist among the five Great Lakes to derive FCMs using one set of modelling conditions taken from Lake Ontario.

In selecting a model to use in developing FCMs, EPA did consider alternative models, ie., Thomann et al. (1992), before selecting the model of Gobas (1993). The model of Gobas (1993) required the specification of fewer input parameters for benthic food-web components in comparison to the model of Thomann et al. (1992). The parameters required by the model of Thomann et al. (1992) for the benthic food web are not readily available and would have required assumptions or guesses for the appropriate values. In contrast, the model of Gobas required no assumptions or guesses for the input parameters used with the benthic food-web components of the model.

EPA does not agree with commenters suggesting that additional validation of the models is needed before use in the final Guidance. EPA does acknowledge that a model is not a perfect simulation of what is occurring in an aquatic ecosystem. However, based on the comparison of field-measured BAFs (from Oliver and Niimi, 1988) to predicted BAFs, the 1993 Gobas model acceptably predicts BAFs for the Great Lakes System.

c. <u>Final Guidance:</u> For the reasons cited above, EPA decided to use the 1993 Gobas model in the development of FCMs to be used in the final Guidance.

For chemicals with log K_{ow}s greater than 6.5, the proposed Guidance recommended that a FCM of one should be used when no chemical-specific data was available. In the final Guidance, this is no longer necessary because the Gobas model allows the derivation of FCMs for the entire range of K_{ow}s.

The resulting FCMs for trophic levels 2, 3, and 4 along with the input parameters for the model, are included in the final TSD for BAFs, and in appendix B of part 132.

5. <u>Accounting for the Effect of Metabolism in Predicted BAFs</u>

a. <u>Proposal:</u> The proposed Guidance acknowledged that many organic chemicals that are taken up by aquatic organisms are transformed to some extent by the organism's metabolic processes, and that the rate of metabolism varies widely from one chemical to another. For most, but not all, organic chemicals, metabolism increases the depuration rate, decreases the BAF, and reduces the harmful effects to the organism.

Because accounting for metabolism is difficult, the proposed BAF methodology included a provision that allowed for predicted BAFs to be modified if justified by the data (e.g., if information showed bioaccumulation was reduced by metabolism).

EPA requested comments on suggested methods to adjust predicted BAFs for chemicals that are metabolized; the types of chemicals or chemical groups for which the BAF might be affected by metabolism; and an approach to account for metabolism by using an "effective FCM" when a field-measured BAF is not available but a laboratory-measured BCF is available.

b. Comments: Some commenters argued that the "effective FCM" should not be used because it did not encourage data generation. According to the commenters, adopting a lower "effective K_{ow}" to back calculate an "effective FCM" implies that elimination at all trophic levels would be enhanced by metabolism. However, this may not be the case given that lower trophic levels may lack metabolic capabilities possessed by higher trophic level animals. Other commenters stated the "effective FCM" was appropriate for conservative protection of fish consumers. Several commenters stated that the GLI does not address the effects of metabolism of pollutants, such as PAHs. However, according to the commenters, no adjustment of BAFs for metabolism should be included in the GLI because no reliable methods are available to predict potential decreases and increases in toxicity due to metabolism of pollutants. Other comments on metabolism have been incorporated in section IV.B.2b.

EPA acknowledges that metabolism is not incorporated in the FCMs or predicted BCFs and that use of the "effective FCM" has limited applicability and may generalize the effects of metabolism. However, by including a BAF predicted from the BSAF methodology as the second data preference, EPA is including an additional method for calculating BAFs that accounts for metabolism. In addition, since only field-measured BAFs, BAFs derived from the BSAF methodology, BAFs less than 125 can be used to derive Tier I criteria for human health and wildlife, metabolism is either accounted for in these measurements or cannot substantially reduce the criterion. Finally, EPA notes that for a chemical such as aldrin, transformation to dieldrin, does not reduce the risk of adverse impacts.

c. Final Guidance: Because of the comments and these modifications to Tier I data requirements, EPA has not required the use of the an "effective FCM," but recognizes that it is a valid method that could be used by States or Tribes to account for metabolism.

6. Bioavailability

a. Proposal: In the proposed Guidance, the predicted human health and wildlife BAFs for organic chemicals were based on the total concentration of the chemical in water and bioavailability was not taken into account. EPA acknowledged in the proposal that for chemicals with log K_{ow}s greater than 6.5, a substantial percentage of the total concentration can be associated with particulate and dissolved organic matter in water and therefore be unavailable for accumulation in the water column. EPA requested comment on deriving BAFs in terms of "freely dissolved" chemical, (i.e., that which is dissolved and not associated with other organic matter) to adjust for the difference in bioavailability between the site water and the water on which the predicted BAFs were based.

In a subsequent Notice dated August 30, 1994 (59 FR 44678), EPA requested comment on an equation which defines the relationship of a BAF reported on the basis of the total concentration of the chemical in the water to a BAF reported on the basis of the freely dissolved concentration of the chemical in the water:

$$BAF_{\ell}^{t} = (f_{fd})(BAF_{\ell}^{fd})$$

where:

BAF_{ℓ}^{t} = BAF (L/kg of lipid) reported on the basis of the lipid-normalized concentration of chemical in the biota (kg/kg lipid) divided by the total concentration of the chemical in the ambient water (kg/L);

BAF_ℓ^{fd} = BAF (L/kg of lipid) reported on the basis of the lipid-normalized concentration of chemical in the biota (kg/kg lipid) divided by the freely dissolved concentration of the chemical in the ambient water (kg/L); and

f_{fd} = fraction of the total chemical in the ambient water that is freely dissolved.

The fraction of the chemical in the ambient water that is freely dissolved, f_{fd}, can be calculated using the K_{OW} for the chemical and the concentration of DOC and POC in the ambient water:

$$f_{fd} = \frac{1}{1 + \frac{(DOC)(K_{OW})}{10} + (POC)(K_{OW})}$$

where:

POC = concentration of particulate organic carbon, kg of organic carbon/L of ambient water;

DOC = concentration of dissolved organic carbon, kg of organic carbon/L of ambient water; and

K_{OW} = octanol-water partition coefficient.

b. <u>Comments:</u> Some commenters stated that using the bioavailable fraction of the chemical in the ambient water would more accurately reflect the fraction of the total chemical available to bioaccumulate in the biota. Other commenters stated that it was not possible to accurately measure the concentration of the chemical freely dissolved in water. Commenters also stated that due to a lack of data, the bioavailable fraction cannot be predicted and it is necessary to use total concentration for derivation of BAFs. Other commenters felt that EPA had not been explicit in the definition of "concentration in water" and requested a more clearly defined statement.

Several commenters wanted clarification on the suggested POC/DOC values from Lake Superior and application of the methodology and an explanation of why the baseline BAFs were converted to total concentration for the derivation of criteria. Other commenters stated that EPA did not evaluate the potential errors associated with the conversion equations, variations over time or throughout a waterbody.

EPA agrees with commenters that taking into account the bioavailable fraction of the chemical in the ambient water would more accurately reflect the fraction of the total chemical available to bioaccumulate in the biota. In the Notice dated August 30, 1994 (59 FR 44678), EPA set forth the equation, $f_{fd} = 1/(1 + POC \bullet K_{OW} + DOC \bullet K_{OW}/10)$, from which the fraction of the chemical that is freely dissolved in the water can be calculated using the K_{OW} for the chemical and the DOC and POC in the ambient water. EPA acknowledges that the freely dissolved concentration of a chemical is difficult to measure, however, the K_{OW}, DOC and POC can be measured or estimated and used to calculate the freely dissolved concentration.

The baseline BAF is based on the freely dissolved concentration of a chemical, while the BAF used in the derivation of the human health and wildlife Tier I criteria will reflect the total concentration of the chemical. In order to implement the criteria, the BAFs need to be based on a total concentration of the chemical in the water column because analytical methods in 40 CFR part 136 that are used for compliance monitoring determine the total amount of chemical in the water. The concentration of POC and DOC estimated from Lake Superior from Eadie et al. (1990) will be used to calculate BAFs based on total concentration for derivation of human health Tier I criteria and Tier II values and wildlife Tier I criteria. EPA believes that the values for POC and DOC are protective of the entire Great Lakes System. Other values for POC and DOC may be used to derive site-specific criteria if scientifically justified.

Concentrations of POC and DOC are those discussed in the August 30, 1994 Notice and are specified (see appendix B to part 132) and are accounted for in the criteria. The BAFs based on the concentration of the freely dissolved chemical in the water when used properly will provide the same predicted residue in aquatic organisms as the BAFs based on the concentration of the total chemical in water.

The calculation of the freely dissolved concentration of a chemical in the water column assumes equilibrium conditions, and therefore variations over time and throughout a waterbody are negligible. In EPA's judgement, the errors associated with the conversion equations are minimal in comparison to the benefit of normalizing the site-specific parameters of POC and DOC in calculation of the BAF.

c. Final Guidance: EPA has decided to use the freely dissolved concentration of organic chemicals in the derivation of baseline BAFs and the total concentration of the chemical for derivation of Tier I human health and wildlife criteria. The fraction of the chemical in the ambient water that is freely dissolved, f_{fd}, will be calculated using the K_{OW} for the chemical and the concentration of DOC and POC in the ambient water. For further details concerning this equation, see the final TSD for BAFs which is available in the public docket for this rulemaking. Basing the measured and predicted baseline BAFs on the concentration of the freely dissolved chemical in water permits the derivation of generic BAFs devoid of site-specific influences and considerations, such as varying concentrations of POC and DOC and allows consistent usage and derivation of the BAFs throughout the final Guidance.

7. Calculation of Baseline BAFs

a. Proposal: In the Technical Support Document for the Procedure to Determine Bioaccumulation Factors - July 1994 (EPA-822-R-94-002) which accompanied the August 30, 1994, Notice of Data Availability (58 FR 44678), equations were set forth for calculating baseline BAFs. Slight modifications were made to the equations in order to correct for the errors in the original equations.

b. Final Guidance: In the final Guidance, a baseline BAF shall be calculated from a field-measured BAF of acceptable quality using the following equation:

$$\text{Baseline BAF} = \left[\frac{\text{Measured BAF}_T^t}{f_{fd}} - 1 \right] \left(\frac{1}{f_\ell} \right)$$

where:

BAF_T^t = BAF based on total concentration in tissue and water.

f_ℓ = fraction of the tissue that is lipid.

f_{fd} = fraction of the total chemical that is freely dissolved in the ambient water.

The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the field-measured BAF.

A baseline BAF for organic chemical "i" shall be calculated from a field-measured BSAF of acceptable quality using the following equation:

$$(\text{Baseline BAF})_i = (BAF_\ell^{fd})_r \cdot \frac{(BSAF)_i \cdot (K_{OW})_i}{(BSAF)_r \cdot (K_{OW})_r}$$

where:

$(BAF_\ell^{fd})_r$ = BAF based on the measurement of freely dissolved reference chemical in the water column.

$(BSAF)_i$ = BSAF for chemical "i".

$(BSAF)_r$ = BSAF for the reference chemical "r".

$(K_{OW})_i$ = octanol-water partition coefficient for chemical "i".

$(K_{OW})_r$ = octanol-water partition coefficient for the reference chemical "r".

The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the BSAF.

A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a laboratory-measured BCF of acceptable quality and a FCM using the following equation:

$$\text{Baseline BAF} = (FCM)\left[\frac{\text{Measured } BCF_T^t}{f_{fd}} - 1\right]\left(\frac{1}{f_\ell}\right)$$

where:

BCF_T^t = BCF based on total concentration in tissue and water.

f_ℓ = fraction of the tissue that is lipid.

f_{fd} = fraction of the total chemical that is freely dissolved in the ambient water.

FCM = the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a K_{OW} of acceptable quality and a FCM using the following equation:

$$\text{Baseline BAF} = (FCM)(\text{predicted BCF}) = (FCM)(K_{OW})$$

where:

FCM = the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

K_{OW} = octanol-water partition coefficient.

8. Other Uses of BAFs

In the final Guidance, human health BAFs are used to identify chemicals of greatest concern within the Great Lakes System. Chemicals identified as BCCs are those for which extra controls are required as specified in the final implementation procedures and under the antidegradation procedures in the final Guidance. See discussion of BCCs in section II.G of this document.

9. Individual BAFs

a. 2,3,7,8-TCDD

i. Proposal: In the proposed Guidance, the $BAF^{l}_{7.9\%}$, for TCDD for derivation of wildlife criteria was 79,000 for trophic level 3 and trophic level 4. The $BAF^{l}_{7.9\%}$, in the August 30, 1994 Notice of Data Availability (59 FR 44678) was 320,000 for trophic level 3 and 160,000 for trophic level 4. The $BAF^{l}_{5.0\%}$, for TCDD for derivation of human health criteria in the proposed Guidance was 50,000 for trophic level 4. The $BAF^{l}_{5.0\%}$, in the August 30, 1994 Notice of Data Availability (59 FR 44678) was 101,000. Differences between the proposed values and those in the Notice were based on differences in the type of data used. The proposed value is based on a laboratory-measured BCF, while the value in the Notice is based on the BSAF methodology.

ii. Comments: Several commenters stated that the documentation for the proposed BAF for 2,3,7,8-TCDD was inadequate and that all relevant studies must be cited and available for review. Many commenters stated that the proposal was inconsistent with the Interim Report on Data and Methods for Assessment of 2,3,7,8-Tetrachlorodibenzo-p-dioxin Risks to Aquatic Life and Associated Wildlife (EPA, 1993) and argued that the inconsistency was due to the fact the EPA was not being forthright with all the available information.

Commenters stated that the basis for the trophic level 3 BAF for 2,3,7,8-TCDD is unexplained and that the scientific basis for what has been done should be made available prior to publication of the final Guidance.

EPA has cited and made available all studies used in the derivation of the BAF for 2,3,7,8-TCDD. The data for the basis of the trophic level 3 BAF was made available in the BSAF section of the Technical Support Document (see EPA-822-R-94-002). Any perception of inconsistency between the Interim Report and the proposal may be due to the way the data are used and the evolution of the BSAF method after the Interim Report was completed. The BSAF method does not require estimation of the concentration of 2,3,7,8-TCDD in water to determine the BAF as was done in the Interim Report on Data and Methods for Assessment of 2,3,7,8-Tetrachlorodibenzo-p-dioxin Risks to Aquatic Life and Associated Wildlife (EPA, 1993).

The BAF for 2,3,7,8-TCDD is greater for trophic level 3 fish than trophic level 4 fish because the Lake Ontario BSAF data for smelt and trout indicated this difference. This may be attributable to growth dilution at trophic level 4 (i.e., with trout).

iii. Final Guidance: For 2,3,7,8-TCDD, the baseline BAF will be based on a predicted BAF derived from the BSAF methodology; the baseline BAF for trophic level 3 is calculated using the ratios of FCMs for log K_{OW} = 7.02. Both baseline BAFs take into account the bioavailability of 2,3,7,8-TCDD in the water column and is lipid normalized. The baseline BAFs for 2,3,7,8-TCDD for trophic level 3 and trophic level 4 are 9,360,000 and 9,000,000 respectively. The BAFs for derivation of Tier I human health criteria for 2,3,7,8-TCDD are 48,490 for trophic level 3 and 79,420 for trophic level 4, based on the total concentration of the chemical in the water column and assuming 1.82 and 3.10 percent lipid, respectively. The BAFs for derivation of Tier I wildlife criteria for 2,3,7,8-TCDD are 172,100 for trophic level 3 and 264,100 for trophic level 4, based on the total concentration of the chemical in the water column and assuming 6.46 and 10.31 percent lipid, respectively.

b. PCBs

i. Proposal: The $BAF^{t}_{7.9\%,\ell}$ for PCB in the proposed Guidance was 1,000,000 for trophic level 3 and 2,800,000 for trophic level 4. The $BAF^{t}_{7.9\%,\ell}$ in the August 30, 1994 Notice of Data Availability (59 FR 44678) was 658,000 for trophic level 3 and 687,000 for trophic level 4. The $BAF^{t}_{5.0\%,\ell}$ for PCB for derivation of human health criteria in the proposed Guidance was 1,776,860 for trophic level 4. The $BAF^{t}_{5.0\%,\ell}$ in the August 30, 1994 Notice of Data Availability (59 FR 44678) was 435,000 for trophic level 4.

ii. Comments: Commenters were concerned that the apparent disequilibrium between the sediment, water column and fish tissue concentration makes predictions of BAFs difficult. In place of the BAF, commenters suggested use of the BSAF.

Other commenters stated that the one BAF for all PCBs was not appropriate but instead BAFs should be congener specific because of varying bioavailability and rates of uptake and metabolism. One commenter suggested developing BAFs for lower chlorinated and higher chlorinated PCBs. Commenters felt that development of a BAF based on the "most prevalent" congeners did not satisfactorily address the problem that there is no single BAF for all PCBs. According to the commenters, data show that BAFs for different congeners vary widely. Other commenters were concerned that the BAF in the August 30, 1994 Notice of Data Availability (59 FR 44678) for trophic level 4 would decrease the BAF four-fold and therefore result in a more lenient water quality criteria and believe that EPA has not justified this proposed relaxation in PCB BAFs.

Commenters criticized the Oliver and Niimi (1988) data set for PCBs because of temporal and spatial variability in the data, use of unadjusted whole fish values, and use of centrifuged water concentrations.

EPA recommends the use of the BSAF, as detailed in section B.2.c above, if a field-measured BAF is not available. For PCBs, however, field-measured BAFs are available for most congeners and therefore will be used in the derivation of the baseline BAF. Field-measured BAFs inherently account for the effects caused by a) metabolism, b) the disequilibrium of the chemical between the sediment and the water column, and c) all the other naturally occurring environmental processes.

EPA has revised the calculation of the BAF for PCBs based on comments that use of the most prevalent congeners in Schultz et al. (1989) is inappropriate. In the calculation of the revised BAF for PCBs, the BAFs for the individual congeners were assigned weights based on their concentration in salmonids as reported by Oliver and Niimi (1988), as suggested by a commenter. The revised BAF is based on the concentrations of PCBs in salmonids in the Great Lakes and not the concentration of PCBs in the water column since fish are the predominant route of exposure to humans and wildlife. The BAF is based on field-measurements which inherently account for metabolism, bioavailability, growth, concentration in the sediment and rate of uptake. It is necessary to calculate a single BAF in order to derive Tier I human health and wildlife criteria because the corresponding toxicological data are only available for Aroclor 1260, a mixture of congeners. Therefore development of a BAF for lower- and higher-chlorinated PCBs is not appropriate.

The BAF for PCBs was derived using field-measured data for the congeners based on their weighted concentration in salmonids. The BAFs take into account the bioavailability of the chemical in the water column and are lipid normalized. In derivation of the final BAF, the baseline BAF was converted to a BAF based on the total concentration of PCBs in the water column.

EPA acknowledges the commenters' concerns that the trophic level 4 BAF decreased four-fold in the August 30, 1994 Notice of Data Availability (58 FR 44678) as compared to the proposed value. EPA has recalculated the BAF, as described in the above paragraph, which resulted in a baseline BAF value of 116,600,000 for trophic level 4.

EPA lipid normalized the fish tissue concentrations given by Oliver and Niimi (1988) in order to avoid use of unadjusted whole fish values, and calculated the freely dissolved concentration of a chemical in the water column to account for the centrifuged water concentrations. EPA has determined that if these parameters are accounted for, much of the variability is eliminated.

iii. Final Guidance: The baseline BAF for PCBs is based on field-measured BAFs for the congeners of PCBs based on their concentration in fish and thus takes into account the freely dissolved concentration of PCBs in the water column and lipid normalization. The baseline BAFs for trophic level 3 and trophic level 4 are 55,280,000 and 116,600,000, respectively. The BAFs for derivation of Tier I human health criteria for PCBs are 520,900 for trophic level 3 and 1,871,000 for trophic level 4, based on the total concentration of the chemical in the water column and assuming 1.82 and 3.10 percent lipid, respectively. The BAFs for derivation of Tier I wildlife criteria for PCBs are 1,850,000 for trophic level 3 and 6,224,000 for trophic level 4, based on the total concentration of the chemical in the water column and assuming 6.46 and 10.31 percent lipid, respectively.

c. Mercury

i. Proposal: The proposed mercury BAF was 60,000 for trophic level 3 and 130,000 for trophic level 4. Subsequent to the proposal, EPA asked for comment on a recalculated mercury BAF in the August 30, 1994 Notice of Data Availability (59 FR 44678). The recalculated BAF was 28,000 for trophic level 3 and 140,000 for trophic level 4. The derivation of the recalculated BAF differed from the proposed BAF for mercury in the following ways (see EPA-822-R-94-002 for discussion of the data used):

1) The estimated percent of total mercury in water that is methylmercury was changed from 25 percent to 17 percent.

2) The estimated biomagnification factors (BMFs) were changed as follows:

Trophic Level	New BMF	Old BMF
2 to 3	1.26	2.154
3 to 4	5.0	2.154

3) The estimated percent of the total mercury in fish that is methylmercury was changed from 85.3 percent to 97.5 percent.

ii. Comments: Many commenters stated that the derivation of the BAF for mercury is not scientifically valid because the assumptions regarding the bioavailability and fate of mercury in the water column were conservative and EPA had not accurately assessed the sequestration of mercury in the environment, especially in sediment. Other commenters advocated site-specific modifications for mercury, stating that a single BAF is oversimplistic and ignores variations.

Commenters stated that the mercury BAF in the August 30, 1994 Notice of Data Availability (59 FR 44678) did not utilize available field data submitted.

In development of a scientifically-defensible mercury criteria, commenters stated that EPA must consider that fish accumulate the majority of mercury via ingestion of contaminated sediments and food, not by gill uptake of dissolved mercury. Commenters recommended using the BSAF method to recalculate BAF for mercury.

EPA does not agree that the BAF for mercury is not scientifically valid. The assumptions used by EPA regarding the bioavailability and fate, with one exception described below, were based on the best available data including that submitted by commenters. After review of the data, EPA revised the percent of total mercury which is found as methylmercury from 25 percent to 17 percent based on data of Gill and Bruland (1990).

EPA also does not agree that it did not accurately assess the sequestration of mercury in the environment. Sequestration of an inorganic chemical in sediment is generally not important because BAFs are derived based on the relationship between fish tissue concentrations and the water column. For chemicals like mercury, methylation appears to occur in the sediment which releases methylmercury into the water column. This is different from the transfer through the benthic food-chain component that is part of the Gobas model used for organic chemicals. If partitioning to the water column occurs, BAFs based on the bioavailable portion would be higher than the BAFs in the final Guidance which are based on total.

EPA agrees with the commenters that exposure of aquatic organisms to mercury is primarily through food and sediment and has developed a biomagnification factor for mercury based on field data. This was necessary because the 1993 Gobas model is only applicable to organic chemicals. The BSAF method as described in the final Guidance is also applicable to only organic chemicals, and therefore cannot be used in the derivation of the BAF for mercury. Mercury's BAF is derived based on the percentage of methyl mercury and amount of trophic uptake as explained in appendix D of the July 1994 TSD for BAFs (EPA-822-R-94-002). EPA has provided the rationale for the derivation of the BAF in the final TSD for BAFs which is available in the public docket for this rulemaking.

EPA has completed a more comprehensive national analysis of the data concerning the bioaccumulation of mercury by fish, which is being peer reviewed at this time. EPA had intended to use in the final Guidance the baseline BAFs contained in the initial draft of the report but EPA decided to wait until the report has been peer-reviewed and completed. EPA is planning to issue a proposal to revise the mercury criterion in the final Guidance to reflect this new information.

iii. Final Guidance: The baseline BAF for mercury is based on a laboratory-measured BCF and a biomagnification factor. The baseline BAFs for both wildlife criteria and human health criteria and values for trophic level 3 are 27,900 and for trophic level 4 are 140,000.

C. Conformance to the CWA, Great Lakes Water Quality Agreement and Great Lakes Critical Programs Act of 1990

Section 118(c) of the CWA requires EPA to develop, "inter alia," guidance on minimum water quality limits to protect human health, aquatic life and wildlife in the Great Lakes System. The Great Lakes Critical Programs Act of 1990 (CPA) states that the final Guidance shall be no less restrictive than the provisions of the CWA, National water quality criteria and National guidance, and shall conform with the objectives and provisions of the Great Lakes Water Quality Agreement (GLWQA). For reasons set out in the preamble to the final Guidance (see 58 FR 20858), EPA has determined that the final Guidance meets these requirements.

D. Adoption of Water Quality Standards Consistent with the Final Guidance

The final Guidance for deriving BAFs is included in appendix B to part 132. The BAF TSD, which discusses the basis for the final methodology and which sets forth the data and considerations upon which the individual BAFs are based, is available in the docket for this rulemaking. Copies are also available upon written request as described in section XIII of this document.

E. References

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V. HUMAN HEALTH

A. Summary of Final Rule

The methodology for the development of human health criteria and values, as outlined in appendix C of part 132, is identical to the Guidance proposed on April 16, 1993 except for the following changes:

-- When deviations from values presented in the Integrated Risk Information System (IRIS) are anticipated or considered necessary, it is strongly recommended that such actions be communicated to the EPA Reference Dose (RfD) and/or Cancer Risk Assessment Verification Endeavor (CRAVE) work group immediately.

-- To determine the weight of evidence of carcinogenicity for a chemical, and to determine (on a case-by-case basis) whether a Group C chemical should be a Tier I criterion or Tier II value the following data (if available) shall be considered: mutagenicity/genotoxicity (determinations of whether the chemical interacts directly with DNA); structure activity; metabolism and mode of action.

-- Clarification has been added to the discussion on additional uncertainty factors which may be applied to short-term (28-day) study results used in the development of Tier II values. In some cases, an uncertainty factor, from 1-10, may be needed to extrapolate from 28-day study results to subchronic (90-day) results. This decision must be made on a case-by-case basis.

-- If the duration of a cancer bioassay is significantly less than the natural lifespan of the test animal, the slope may be adjusted on a case-by-case basis to compensate for latent tumors which were not expressed during the cancer bioassay. This is a change from the proposal which required an adjustment to compensate for latent tumors if the cancer bioassays were shorter than 78 weeks for mice and 90 weeks for rats.

-- A default relative source contribution factor (RSC) of 0.8 will be applied to all noncarcinogenic chemicals. In the proposed Guidance, an RSC of 0.8 was applied to noncarcinogenic bioaccumulative chemicals of concern (BCCs) and an RSC of 100 percent was applied to noncarcinogenic nonbioaccumulatives. If actual exposure data exists, States and Tribes may use this data, following procedures outlined in the 1980 National Guidelines to calculate an RSC.

-- A fish consumption rate of 15 grams will be applied in the derivation of criteria (3.6 grams for trophic level 3 fish and 11.4 grams for trophic level 4 fish).

-- The minimum data requirements for deriving a Tier I criterion have been changed to include minimum data requirements for bioaccumulation factors as well as minimum toxicological data. For organic chemicals, field-measured bioaccumulation factors (BAFs), predicted BAFs based on the biota-sediment accumulation factor (BSAF), and BAFs less than 125 will be used in calculating Tier I criteria. For inorganic chemicals, either a field-measured BAF or a laboratory-measured BCF can be used to calculate Tier I criteria.

B. Explanation of Final Provisions

The final Guidance for human health is described below. As with the final Guidance for aquatic life discussed earlier, EPA is proposing a two-tier approach for human health. Minimum data requirements for Tier I criteria and Tier II values are discussed later in this section.

Sample human health criteria have been calculated using the proposed methodology for 18 chemicals. The 18 chemicals chosen for criteria development were selected from the Great Lakes Water Quality Initiative (GLWQI) group of chemicals of concern listed in proposed 40 CFR part 132, Table 6, to represent a broad cross- section of the types of chemicals found in the Great Lakes basin. The intent of the chemical selection was to test the final methodology against a broad range of chemicals and to demonstrate how the criteria development process will be carried out. Selection from among the chemicals of concern was made from the perspective of demonstrating the final methodologies' applicability to all types of chemicals, rather than on the basis of health risk priorities.

C. Criteria Methodologies

The final Guidance establishes methodologies to derive human health criteria which will not result in zero risk, but will provide a level of protection likely to be without appreciable risk.

1. Endpoints Addressed

a. Proposal: The proposed Guidance addressed noncancer and cancer effects only. Organoleptic effects (taste and odor), while of concern from an aesthetic standpoint, were not considered a significant health concern and therefore were not included in the proposal. EPA asked for comment on whether EPA should require the Great Lakes States and Tribes to adopt Tier I criteria identical to the existing National guidance for organoleptic substances developed under section 304(a) of the Clean Water Act (CWA).

b. Comments: Several commenters were in favor of the EPA proposal to focus only on cancer and noncancer criteria development. Several other commenters disagreed, stating that existing National guidance for organoleptic criteria should be required to be adopted by the States. If organoleptic criteria are not in place, these commenters argued, people may turn to other sources of drinking water (e.g., bottled) or may turn away from Great Lakes fish (if they are tainted) in favor of other protein sources. The commenters also stated such alternatives may have negative health effects: the quality of bottled drinking water may be unknown and the health implications of eating other sources of protein (or sources of food) such as beef, chicken, pork etc. may reduce one's exposure to bioaccumulated chemicals but may increase one's exposure to higher cholesterol.

c. Final Guidance: The final Guidance will continue to focus on noncancer and cancer effects and will not require the adoption of Tier I organoleptic criteria. While it is conceivable that some people may seek alternative water and food sources due to organoleptic properties of chemicals and such choices may themselves entail a risk of incurring adverse health effects, EPA believes that the human health protection goals reflected in the CWA are best served by focusing on actual, health-related effects (cancer and noncancer effects) due to the exposure to the aquatic resource itself. Moreover, the current National criteria guidance developed for organoleptic effects are available for use by Great Lakes States and Tribes in developing criteria. If States or Tribes want to set criteria based on more stringent organoleptic criteria, as set forth in the 1980 Federal Register Notice of Water Quality Criteria Documents (U.S. EPA,1980), they are free to do so.

2. Mechanism of Action

a. Cancer.

i. Proposal: In the proposal, EPA regarded carcinogenicity generally as a non-threshold adverse health effect. Given that assumption, "no effect" levels for carcinogens (other than zero) were not established, because even extremely small doses are assumed to potentially elicit a finite increase in the incidence of cancer. The proposed Guidance would have provided that a non-threshold mechanism be assumed for carcinogens unless data exist that demonstrate a threshold mechanism. Such a finding would have to weigh all the studies for a particular chemical to determine whether a true threshold effect is occurring across all sensitive test species. The proposal also recommended that States and Tribes confer closely with EPA prior to submitting for EPA approval any criterion for a carcinogen that is based on the assumption that a "safe" threshold dose exists for the chemical. The EPA proposal also stated that the Linearized Multistage Model ("LMS") would be used to extrapolate from actual animal bioassay data to the dose/response relationship expected at low doses, unless it can be established on a case-by-case basis that another model such as the "time-to-tumor" model or ones based on modifications of the LMS model, are more appropriate.

ii. Comments: In response to the EPA-held assumption that carcinogenisis is a nonthreshold event, several commenters stated that EPA relies too heavily on the nonthreshold model of carcinogenicity and rarely factors into the weight of evidence such information as pharmacokinetic data, genotoxicity and mutagenicity data, structure activity and mode of action. With regard to the use of the LMS as a default cancer model, several commenters supported the continued use of the LMS as a default cancer potency model. Other commenters stated that the use of the LMS model is outdated and does not consider all the available mechanistic, pharmacokinetic and other relevant data in assessing cancer potency.

iii. Final Guidance: Based on the rationale below, EPA will continue to include the use of the LMS model as a default model in the final Guidance, unless it can be established on a case-by-case basis that another model is more appropriate. As the 1986 Guidelines for Carcinogen Risk Assessment states: When pharmacokinetic or metabolic data are available, or when other substantial evidence on the mechanistic aspects of the carcinogenesis process exist, a low dose extrapolation model other than the linearized multistage procedure might be considered more appropriate on biological grounds. When a different model is chosen, the risk assessment should clearly discuss the nature and weight of evidence that lead to the choice (U.S. EPA, 1986).

EPA believes the nonthreshold assumption of carcinogenesis is a valid assumption in the absence of data which indicate otherwise. EPA also reiterates that the methodology provides an opportunity to demonstrate a threshold mechanism for a chemical and that on a case-by-case basis another model (threshold or non-threshold) can be applied to the cancer data if it can be established that the other model is more appropriate.

EPA disagrees with the comment that it does not consider all the data in making judgements on potential carcinogens. EPA considers all the available data when conducting a cancer assessment for a chemical, including pharmacokinetic, metabolic, mutagenicity/genotoxic and structure activity data. To ensure that this occurs with regard to development of criteria in the future, EPA has revised the human health methodology in appendix C to part 132 to provide for consideration of each of these specific pieces of evidence when evaluating the potential carcinogenic risk of a chemical.

With regard to the choice of a cancer model, and specifically the appropriateness of continuing reliance on the LMS, EPA believes that, in the absence of adequate information to the contrary (such as information on the mechanism of carcinogenic action), the LMS is the best of the mathematical extrapolation models used for extrapolating from high dose to low dose. As stated in the 1986 Guidelines for Carcinogenic Risk Assessment: When data and information are limited, and when much uncertainty exists regarding the mechanism of carcinogenic action, models or procedures which incorporate low dose linearity are preferred when compatible with the limited information. In the absence of adequate information to the contrary, the linearized multistage procedure will be employed (U.S. EPA, 1986). Because of the uncertainties associated with dose response, animal to human extrapolation, and the serious public health consequences that could result if risk were under-estimated, EPA believes that it is prudent and consistent with public health goals of the CWA to use the LMS to estimate cancer risk for ambient water quality criteria. The LMS has been endorsed by four agencies in the Inter-Agency Regulatory Liaison Group and was characterized as less likely to under-estimate risk at the low doses typical of environmental exposure than other models that could be used (Inter-Agency Regulatory Liaison Group, 1979).

b. Noncancer.

i. Proposal: The proposed Guidance would have provided that a threshold mechanism of action be assumed in deriving criteria for protection against noncancer effects, unless it is demonstrated on a case-by-case basis that there is no threshold with respect to a given chemical's toxicity effect(s). This means there is a dose below which no adverse effects should be observed, or if an adverse effect is observed, the risk of deleterious effect over the span of a lifetime is not appreciable. EPA also recognized that there may be exceptions to this principle: for some non-carcinogenic effects, no identifiable threshold of effects has been demonstrated. Chemicals which may exert non-threshold non-cancer effects include genotoxic teratogens and germline mutagens.

ii. Comments: Several commenters agreed that EPA should allow for a showing that a chemical has no threshold; however these same commenters did not express an opinion regarding the default assumption of a threshold for noncarcinogens. One commenter believed all noncancer effects should be considered nonthreshold events unless proven otherwise. Other commenters believed making such a showing would be difficult and possibly very costly. Some commenters suggested that EPA apply a "weight of evidence" approach to developing an RfD; that we not ignore studies showing no adverse effects while focussing only on studies indicating adverse effects.

iii. Final Guidance: For the reasons stated below, the final Guidance will continue to assume that noncancer endpoints of toxicity exhibit a threshold unless data indicate otherwise. This is consistent with the 1980 National Guidelines which concluded for noncarcinogens that there is a dose below which no adverse effects should be observed. It is also EPA's experience (in developing RfDs) that noncancer effects are regarded almost without exception as threshold events and that nonthreshold noncancer effects are extremely rare and in some cases may be perceived as such due to a lack of toxicological information (e.g., extremely low doses have not been tested or cannot be measured). The possible exceptions to this rule, as stated in the proposal, are genotoxic teratogens and germline mutagens. EPA reiterates that in the rare instances that this type of chemical is encountered, it is recommended that States and Tribes confer closely with EPA prior to establishing a noncancer criterion on the basis of a non-threshold effect. EPA believes the proposed language is adequate in allowing a demonstration of nonthreshold noncarcinogenicity and is adopting this language in the final methodology. EPA has provided additional guidance in "Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values" (EPA 820-B-95-007) (Human Health TSD) on determining whether a chemical demonstrates nonthreshold characteristics.

With regard to the comment that EPA treat all chemicals as if they are nonthreshold chemicals, EPA believes the overwhelming scientific evidence supports the assumption that noncancer endpoints are threshold events. EPA most often assumes that noncarcinogenic and/or nonmutagenic changes have a threshold, that is, a dose level below which a response is unlikely, because homeostatic, compensating and adaptive mechanisms in the cell protect against toxic effects at levels below this threshold. Therefore, in EPA's judgement it would be inappropriate to assume that noncarcinogens act by nonthreshold mechanisms, when the overwhelming evidence suggests otherwise (U.S. EPA, 1991).

With regard to the comment that EPA should apply a weight-of-evidence approach in developing noncancer criteria and values, EPA believes it does employ a weight-of-evidence approach in that it evaluates all the data before choosing a specific study upon which quantification is based. EPA believes its process for evaluating noncancer effects is similar to the cancer weight-of-evidence approach. For example, in developing a noncancer criterion, EPA reviews all the toxicological effects data and determines which study appears to reflect the most critical endpoint. Negative studies (i.e., those that do not elicit a response) as well as positive studies (i.e., those that do elicit a response) are considered. IRIS coversheets describe the critical study which serves as the basis for an RfD but also lists all the critical and supporting studies that were considered in the development of the RfD. EPA agrees that the main focus when evaluating the potential adverse effects of a chemical are on studies that show adverse effects. However, EPA believes this is reasonable to ensure that humans are protected against potential adverse effects. EPA will continue to focus on studies which are most relevant to the consideration of human risk assessment and with the development of more pharmacokinetic data, which can clearly identify metabolic/toxicokinetic differences between species, human risk assessments will become easier.

3. Choice of Risk Level

a. Proposal: The proposal derived criteria which correspond to a plausible upper bound increased incremental risk of developing cancer of one in 100,000 (10^{-5}) over a lifetime of exposure. The choice of 10^{-5} risk level was recommended by the Initiative Committees and is within a range of risk levels (i.e., 10^{-4} to 10^{-6}) that EPA considers to be adequately protective and which EPA has historically considered acceptable in making regulatory decisions. The majority of the Great Lakes States traditionally have used a 10^{-5} risk level in setting their water quality criteria. EPA asked for comment on the choice of risk level, and on alternate risk levels, such as 10^{-6} and 10^{-4}, which could be adopted in the final Great Lakes human health criteria methodology.

b. Comments: Many commenters were in favor of the proposed risk level of one in 100,000, while other commenters were in favor of higher and lower risk levels (one in 10,000 and one in a million). Those who favored one in a million risk believed one in 100,000 was not stringent enough, and that many of the exposure parameters in the criterion equation were not protective of high-end exposed individuals (e.g., high-end fish consumers). That is, many people who eat more than 15 grams of fish per day would be protected at less than 1 in 100,000 risk from cancer (that is, a higher risk). Those that favored a higher risk level, at one in 10,000, believed that EPA's cancer model, and other exposure assumptions are already so conservative that there is no need to set criteria at the one in 100,000 risk level. Other commenters referred to EPA's Superfund program, which uses a risk level of one in 10,000, and cited inconsistency among EPA programs.

c. Final Guidance: The final Guidance continues to derive criteria and values based on a 10^{-5} risk level. EPA believes that this is a reasonable decision in light of the fact that it reflects the policy preferences of most of the Great Lakes States. EPA notes, however, that selection of this risk level does not reflect a judgment that this is the only level of acceptable risk that would achieve the human health protection goals of the CWA. Rather, as noted above, EPA believes that ensuring protection in the range of 10^{-4} to 10^{-6} is acceptable and consistent with the CWA's objectives. Commenters were correct in noting that some identifiable subpopulations or groups consume more fish than 15 grams/day, as assumed in the methodology, and thus such consumers may face a risk that is higher than 10^{-5}. However, EPA believes these consumers will nonetheless be adequately protected. (See section V.B.5.e of this document for detailed information on fish consumption in the Great Lakes basin.)

EPA disagrees with those commenters advocating the use of a one in 10,000 risk level. While the model used to estimate cancer risk has many conservative assumptions that are likely to overestimate actual risks, EPA believes this conservatism is appropriate given the severity of the potential outcome (cancer) and the uncertainties inherent in extrapolating from the high doses administered to laboratory animals to the low doses experienced by humans. Moreover, setting the target risk level at 10^{-4} for average consumers would not include any margin of safety that might be appropriate to ensure the protection of high-end consumers. With regard to the commenter's concern with the conservative nature of the exposure assumptions, EPA attempts to select reasonable assumptions given the need to provide adequate protection to humans.

EPA disagrees with the commenter who asserted that EPA requires the use of a 10^{-4} risk level in the Superfund program, and that the risk level used in the proposed Guidance's human health methodology is therefore inconsistent with the Superfund program. Under EPA's Superfund program, acceptable exposure levels are generally those falling within the 10^{-4} to 10^{-6} risk range. See 40 C.F.R. 330.430 (2)(i)(A)(2).

Finally, EPA disagrees that the final Guidance is inconsistent with other EPA programs regarding the use of a 10^{-5} risk level. As stated above, EPA believes the 10^{-4} to 10^{-6} risk level will provide adequate protection of public health. In any particular regulatory action under its various authorities, EPA targets a level of public health protection that effectively implements EPA's statutory duties and which is tailored to the specific circumstances being addressed by the regulatory action. As stated previously, EPA believes the approach in the final Guidance is consistent with EPA's historical practices in its public health protection programs.

As noted in section II of this document, levels of some pollutants fish tissue in the Great Lakes basin currently demonstrate that applicable criteria are being exceeded, and baseline risks associated with these exposures in some cases exceed the 10^{-4} to 10^{-6} risk range that EPA considers adequately protective. In particular, groups that generally consume more fish on average than the general population (e.g., Native American subsistence fishers and low income minority sport anglers) are at greatest risk, which EPA has estimated may be as high as 3.7×10^{-2} for Native Americans in Lake Michigan due primarily to PCBs. The purpose of the human health criteria and the criteria methodology contained in the final Guidance is to ensure that the adoption of water quality standards that, where they are attained would provide adequate public health protection. Obviously, where standards are not yet attained, actual risk levels will be higher and steps will have to be taken to meet applicable standards. Nonetheless, EPA evaluates the protectiveness of the criteria and the methodology assuming that criteria are met in order to ensure that protective water quality standards will be established in the Great Lakes basin.

With regard to comments that EPA should adopt a lower risk level (i.e., 10-6), EPA notes that States and Tribes are free to adopt a more stringent approach than that contained in the final Guidance. Given that a plurality of States have utilized the 10-5 risk level, EPA believes that the choice of risk level is a reasonable one.

With regard to criteria for protection against non-cancer effects, these criteria are derived so as to prevent hypothetically exposed individuals (i.e., those consuming pollutant-bearing fish and drinking water at the rate assumed in the criteria-derivation formulas explained below) from receiving a dose of the chemical above that which is calculated to correspond to no appreciable risk of adverse effect, based on a threshold model of chemical activity. The issue of risk level is therefore not relevant to such threshold effects (except in these rare instances where a State or Tribe may find, and EPA would agree, that a noncancer effect exhibits no threshold).

For the reasons stated above, the final Guidance will continue to derive criteria and values based on a 10^{-5} risk level.

4. Acceptable Dose

The proposed Guidance used the term risk associated dose (RAD) to represent the dose associated with a one in 100,000 plausible upper bound risk of developing cancer from lifetime exposure to a carcinogen. The term Acceptable Daily Exposure (ADE) was used to represent the dose of a noncarcinogen expected to result in no appreciable risk of adverse health effects from lifetime exposure.

a. RAD.

The proposed Guidance discussed the steps for determining a Risk Associated Dose (RAD) (see 58 FR 20865). EPA also pointed out that many of the steps in developing a RAD may have already been conducted by EPA for a particular chemical and the results made available to the public through EPA's Integrated Risk Information System (IRIS). It was recommended that IRIS be consulted when developing a RAD. (The reader is referred to section V.C.4.c for a description of IRIS and its utility in developing RADs.)

i. Biologically Relevant versus Sensitive Species

(A). Proposal: EPA pointed out that when animal studies are used to estimate effects on humans, data from species most biologically relevant to humans are generally preferred (i.e., a species in which pharmacokinetics and/or toxic mechanisms of action appear closely related to humans). In the absence of data to distinguish the most relevant species, data from the most sensitive animal species tested, i.e., the species exhibiting a carcinogenic response at the lowest administered dose, given a relevant route of exposure, should be used.

(B). Comments: The majority of commenters argued that the most biologically relevant species rather than the most sensitive species should be used. Commenters stated that use of the most sensitive species must be weighed against the assumption that humans are as or more sensitive than the most sensitive species. A minority of commenters agreed with EPA's proposed language to use the most sensitive species as a default, in the absence of data.

EPA agrees that the most biologically relevant species to humans should be used when data is available for the chemical on the mechanism of the carcinogenesis as well as the pharmacokinetics of the test species relative to humans. However, in many cases there will be limited data to assess how well an animal model reflects human toxicological response for a chemical. In these situations, EPA believes it is prudent to use data from the most sensitive species. This is supported by the 1986 Guidelines for Carcinogen Risk Assessment which states: In the absence of appropriate human studies, data from a species that responds most like humans should be used, if information to this effect exists...because it is possible that human sensitivity is as high as the most sensitive responding animal species, in the absence of evidence to the contrary, the biologically acceptable data set from long-term animal studies showing the greatest sensitivity should generally be given the greatest emphasis, again with due regard to biological and statistical consideration (U.S. EPA, 1986).

(C). Final Guidance: For the reasons stated above, the final Guidance is retaining the proposed language that data from species most biologically relevant to humans is preferred. However, in the absence of data to distinguish the most relevant species, data from the most sensitive species will be used. This provision applies to both cancer and noncancer effects.

ii. Less than Lifetime Adjustment Factor.

(A). Proposal: In the proposed Guidance, EPA included a factor $(L/Le)^3$, where L is the natural lifespan of the test species and Le is the duration of the study. This adjustment factor is necessitated when an animal study being used to derive a dose response relationship is not of sufficient duration to measure cancer development over the natural lifespan of the test species. The rationale for such a factor is described in detail in the 1980 National Guidelines (45 FR 79352). Under the proposal, the slope factor adjustment was applied to mouse and rat data if the study duration (Le) was less than 78 weeks for mice or 90 weeks for rats, by multiplying the cancer slope factor by the factor $(L/Le)^3$. EPA requested comment on whether the use of this adjustment factor for studies with less than lifetime duration was appropriate.

(B). Comments: Several commenters agreed that an adjustment factor could be used but disagreed with the choice of the factor proposed and the cutoff (78 and 90 weeks) chosen in the proposed Guidance. These commenters suggested that the adjustment factor should be applied on a case-by-case basis, considering such factors as mechanism of action, and type of tumor and the organ affected.

EPA agrees with the commenters that the best way to evaluate this adjustment factor is on a case-by-case basis since not all carcinogens behave mechanistically the same way (as pointed out by the 1986 Guidelines for Carcinogen Risk Assessment). For some carcinogens, exposure early on (during childhood or adolescence, or the equivalent in test animals) may be critical to tumor expression. For others, exposure of a test animal over a year may result in no more tumors than exposure over a lifetime (two years).

(C). Final Guidance: To allow flexibility in making these judgments, EPA has changed the final Guidance to allow for less than lifetime adjustments on a case-by-case basis. Less than lifetime adjustments to the cancer slope factor are now optional, not required, and should be made on the basis of existing mechanistic data. However, in the absence of data on mechanisms and time to tumor, States and Tribes may continue to use the adjustment factor and the duration cutoffs prescribed in the proposal as a default approach.

iii. Species Scaling Factor.

(A). Proposal: In the proposed Guidance, EPA would have required the use of a "surface area species scaling factor" in deriving a dose response relationship for humans that is based on animal data. The proposed Guidance assumed that exposures in milligrams per kilogram of body weight per day raised to the 2/3 power (also referred to as the two-thirds exponent) would yield equivalent cancer responses in test animals and humans. EPA requested comment on the proposed use of a two-thirds exponent for surface area, and the possible use of a three-fourths exponent for body weight, for scaling animal doses to equivalent human doses. EPA also asked for comment on whether use of some other scaling factor should be used in the final Guidance.

(B). Comments: Several commenters were in favor of the 3/4 body weight scaling factor while others were in favor of the 2/3 surface area scaling factor. Those in favor of the 3/4 body weight scaling factor cited the draft consensus by the Inter-Agency group (U.S. EPA, 1992) and empirical data which supports the scaling on the basis of body weight (Allen et al., 1987). Others suggested flexibility and allowing adjustments on a case-by-case basis, determined by the pharmacokinetics of the chemical.

As cited in the proposed Guidance, an Inter-Agency group comprised of EPA, U.S. Food and Drug Administration and CPSC has deliberated on the issue of appropriate, consistent scaling factors for use by all agencies in developing risk assessments. While the draft recommendation from this group was to apply a 3/4 exponent scaling factor, this undertaking has not been finalized nor adopted as EPA policy to date. The current policy is stated in the 1986 Guidelines for Carcinogen Risk Assessment: In the absence of comparative toxicological, physiological, metabolic and pharmacokinetics data for a given suspect carcinogen, EPA takes the position that extrapolation on the basis of surface area is considered to be appropriate because certain pharmacological effects commonly scale according to surface area (Dedrick 1973, Freireich, et al., 1966; Pinkel;, 1958). As discussed in the preamble to the proposal, there are divergent views among the scientific community regarding whether a body weight or surface area scaling factor provides the best means of extrapolating results from animal studies to humans, and as reflected by the work of the Inter-Agency Pharmacokinetics Group, a consensus among relevant governmental agencies may be reached in the future that the body weight approach is preferable. However, no final consensus has yet been reached. Because EPA's current, longstanding policy calls for use of the surface area scaling factor, EPA is hesitant to change its approach in the absence of a final determination that adoption of the body weight scaling factor is appropriate.

(C). Final Guidance: Consistent with the existing EPA policy, the final Guidance calls for the use of the 2/3 exponent scaling factor (surface area), in the development of cancer slope factor development.

b. ADE.

For non-carcinogens, the proposed Guidance called for a data hierarchy for calculating the ADE. The process outlined is the same one used by EPA's RfD development process but differs in the amount of data required to develop a criterion or value, especially with regard to Tier II ADEs. In some cases, an ADE may be identical to an EPA RfD if the same data and judgments are used. However, since States and Tribes may derive values which may vary based on different interpretations of the supporting data and/or the existence of new data, EPA proposed the term ADE to distinguish the RfD from the ADE.

The proposed Guidance indicated that calculating an ADE for a chemical involves the following steps: 1) determining whether there is evidence from epidemiologic or animal studies that exposure to a chemical may result in adverse noncancer health effects; 2) using available data to determine a threshold dose value that is likely to be without appreciable risk of adverse effect; and 3) reducing this threshold dose value to account for uncertainties inherent in the risk assessment to yield an ADE for humans.

i. List of Deleterious Effects.

(A). Proposal: The proposed Guidance presented a list of adverse effects which the noncancer criteria are protective of, including adverse acute, subchronic and chronic effects and reproductive and developmental effects. EPA solicited comment on whether it should specify in the methodology a longer list of deleterious effects against which noncancer criteria should protect.

(B). Comments: Several commenters agreed with the list of deleterious effects while others requested that EPA expand the list to include such effects as immunotoxicity. Other commenters believed a list was not entirely necessary since the assessment of adverse effects was mostly based on professional judgment.

(C). Final Guidance: EPA believes the list as stated encompasses any effect which can be deemed adverse including immunotoxicity, based on the State or Tribe's professional judgment. Thus, EPA is retaining the proposed list in the final Guidance.

ii. Uncertainty Factors.

(A). Proposal: The proposal provided guidance on the use of uncertainty factors to account for uncertainties in predicting acceptable exposure levels for the general human population. The proposal indicated that the size of the uncertainty factor varies depending on the data available for ADE calculation, including whether the data are from a study on humans or test animals, and on whether the study demonstrates a no observed adverse effect level (NOAEL) or a lowest observed adverse effect level (LOAEL). Under the proposed Guidance a composite uncertainty factor of 30,000 was described as the maximum uncertainty allowed when deriving a Tier I criterion or Tier II value. EPA solicited comments on the uncertainty factors included in the proposal, and particularly on whether other uncertainty factors might offer better assessment of risk, and be more appropriate in deriving water quality values and criteria.

(B). Comments: Many commenters stated that the use of default uncertainty factors of 10 (each) to account for intra-, interspecies variability, and subchronic to chronic adjustments are too rigidly applied. Commenters felt uncertainty factors of less than 10 should be allowed if there is a scientifically sound rationale. Other commenters suggested that EPA add an additional uncertainty factor to the calculation of an ADE to account for the sensitivity of children or other sensitive subgroups.

With regard to the use of uncertainty factors less than 10, EPA agrees that uncertainty factors of less than 10 can be used to account for intra-, interspecies variability, subchronic to chronic adjustments and LOAEL to NOAEL adjustments as long as data exists to justify a lower uncertainty factor. As stated in the proposed Guidance, EPA generally applies uncertainty factors of 10, but is not advocating the rigid application of uncertainty factors of ten in all instances. This is only meant to be a default position when data is lacking to justify a lower uncertainty factor. For example, if pharmacokinetics data shows that a test animal metabolizes a chemical in a fashion identical to humans, a lower interspecies uncertainty factor is probably justified. For information on selecting uncertainty factors less than 10, see appendix A of the Human Health TSD.

With regard to the comment suggesting EPA apply an additional uncertainty factor to protect children and sensitive subgroups, EPA believes an RfD (ADE) should be protective (by definition) of children and sensitive subgroups. In assessing the data base, consideration should be made of these segments of the population. If the overall data base does not yield information on the toxicity of test organisms during all segments of their lifetime (such as infancy, childhood, adolescence), or does not consider sensitive individuals, an additional uncertainty factor may be applied to account for such uncertainty in an incomplete data base. It is important to note that the intraspecies uncertainty factor of 10, which is commonly applied, is designed to account for sensitive individuals in the population. Therefore, the application of another uncertainty factor would be redundant.

(C). Final Guidance: As stated above, the proposed Guidance stated that a maximum uncertainty factor of 30,000 could be applied in deriving a Tier I criterion or Tier II value. In the final Guidance, EPA is clarifying the use of uncertainty factors to include a maximum of 10,000 for Tier I criteria and a maximum of 30,000 for Tier II value development. When deriving a Tier I criterion, the likely maximum composite uncertainty factor applied to a 90-day NOAEL may be 3000. The total of 3000 is based on four separate uncertainty factors: 10 to account for intraspecies variability; a factor of 10 to account for the uncertainty in extrapolating animal data to the case of humans; a factor of 10 to account for subchronic to chronic variability; and a factor of three to account for an incomplete data base. However, in rare cases where an extra uncertainty factor is required to compensate for an incomplete data set or to compensate for the uncertainty associated with a LOAEL (rather than a NOAEL), a composite uncertainty factor of 10,000 may be used. Under this assumption an uncertainty factor of 10 would be applied to account for an incomplete data base or the use of a LOAEL in place of a NOAEL instead of using an uncertainty factor of three. This decision requires the use of professional judgment in determining the adequacy of the data base. For Tier II values, the maximum allowable composite uncertainty factor may be 30,000 which would be applied to a studies with durations greater than a 28-day minimal LOAEL (e.g., 30 days).

The total of 30,000 is based on the three factors of generally 10 each for intraspecies variability, interspecies extrapolation, subchronic to chronic extrapolation, a combined factor of 10 to account for incompleteness of data bases and the difference between a minimal LOAEL and NOAEL (which together result in an overall uncertainty factor of 10,000), and an additional uncertainty factor of 3 to account for the uncertainty in extrapolating from a study greater than 28 days, but sufficiently less than 90 days.

c. IRIS.

i. Proposal: The proposed Guidance indicated that EPA has a process to develop consensus on cancer slope factors (q1*s) and RfDs (referred to as ADEs for the Great Lakes). These values are derived by two EPA work groups called the RfD/RfC and CRAVE work groups and made available as guidance to EPA program offices and the public via a data base called the Integrated Risk Information System (IRIS) which is accessible through the National Library of Medicine's Hazardous Substance Data Base (HSDB). The values (RfDs and q1*s) listed on IRIS are guidance; they are not regulatory in nature.

The proposed Guidance recommended that verified IRIS values (RfDs and cancer slope factors) be considered as a first step in deriving the Great Lakes Human Health criteria. It is also important to note that many chemicals have been reviewed by the RfD or CRAVE Work Groups, have been verified, but have not yet been entered into the IRIS system. A verified RfD or q1* is a value which the RfD or CRAVE Work group has reviewed and officially verified during an RfD or CRAVE meeting. EPA encourages States to call EPA's RfD and CRAVE Work Groups if they are not sure of the current status of a specific chemical. A verified RfD or q1* can be utilized by States and Tribes even though it has not been officially placed into the IRIS system. The proposal also allowed deviation from these values when new data are available or if a different interpretation of the data is made. EPA requested comments on deviating from IRIS values in deriving Great Lakes criteria and values for the reasons highlighted above.

ii. Comments: Many commenters wanted the flexibility to deviate from IRIS while others argued that deviation from IRIS values should not be allowed.

EPA has decided that deviations from IRIS should be allowed since IRIS is only guidance and that other interpretations of the data may be valid. However, to foster consistency between EPA and the States, EPA strongly urges the States/Tribes to communicate any anticipated or necessary deviation from IRIS to the EPA RfD and/or the CRAVE work groups as soon as possible. Following this recommended course of action will allow EPA to discuss the potential deviations with the State or Tribe and could lead to an expedited review of the chemical and data by the EPA work group of concern. In addition, as noted earlier, States may use verified RfDs or cancer potency factors, which have not been entered onto IRIS, for development of Tier I criteria. Finally, when deviating from IRIS, States/Tribes are encouraged to work with the Clearinghouse described in section II, to ensure other States/Tribes are aware of the deviations.

iii. Final Guidance: For the reasons stated above, States and Tribes may deviate from IRIS provided the approach is scientifically defensible.

5. Exposure Assumptions

The proposed Guidance identified seven factors which affect an individual's oral exposure to a chemical: body weight; duration of exposure; recreational exposure; drinking water consumption; fish consumption; bioaccumulation factor and relative source contribution.

a. Body Weight.

i. Proposal: The proposed criteria methodology assumed a mean adult human body weight of 70 kg. This value is consistent with that recommended in the EPA's Exposure Factors Handbook (EPA 600/8-89/043, July 1989). EPA requested comments on the use of the 70 kg body weight assumption and also asked for comments on the issue of using body weights of sensitive subpopulations (such as children) when a chemical's toxicity indicates a specific subpopulation is most sensitive to exposures.

ii. Comments: Several commenters advocated the continued use of the 70 kg body weight assumption. Several other commenters stated that the body weight used in calculating criteria and values should be lower than 70 kg to protect women of childbearing age and children and fetuses. Several of these commenters recommended 55 kg as the body weight. No commenters suggested an actual child weight.which should be used nor did any commenter advocate a higher body weight than 70 kg.

EPA believes 70 kg is an appropriate body weight because it represents a reasonable measurement for the entire population. As stated in the EPA Exposure Factors Handbook (1989), the mean body weights for women and men nationally are 65 kg and 78 kg, respectively, with an overall mean adult body weight of 71.8 kg. The Handbook also indicates that the mean body weight for child bearing women ages 18-45 is 63 kg.) If a State believes that use of a lower body weight is appropriate (which yields a more stringent criterion), the State or Tribe may adopt such an assumption in calculating their criteria and values under their authority to establish more stringent requirements pursuant to section 510 of the Act.

As to whether lower body weights should be used to protect women of childbearing age, children and fetuses, EPA believes that categorically adopting more conservative body weight assumptions may not be appropriate. Each chemical must be addressed separately since some chemicals may be generically toxic to both sexes, while others may be specifically toxic to one sex more than the other. It therefore would not be appropriate to require generally that all criteria be based on conservative body weight assumptions. In the case of mercury, however, a fetotoxic chemical, to be protective of women of child bearing age, EPA has assumed a body weight of 65 kg (as opposed to 70 kg) which results in a Tier I mercury criterion of 1.8 ng/L, which is slightly less than the proposed criterion of 2 ng/L. EPA has set a final Tier I criterion for mercury at 1.8 ng/L.

iii. Final Guidance: Based on the reasons above, the final Guidance retains the 70 kg body weight assumption. States or Tribes may use the female body weight (55-65 kg) or a child's body weight (10-30 kg) or any other more "stringent" assumption on a chemical-by-chemical basis as deemed appropriate based on the properties of a particular chemical. If a child's body weight is assumed, the water consumption rate should also be adjusted for a child to 1 liter/day.

b. Duration of Exposure.

i. Proposal: The proposed Guidance assumed that oral exposure remains constant for a lifetime and assumed a 70 year exposure period in developing criteria and values. EPA requested comments on the use of longer lifetime exposure periods, such as 75 years instead of the currently proposed 70 years, since recent census data indicates that the average lifespan for

Americans is 74.7 years. EPA also requested comments on whether the use of shorter exposure periods (i.e., less than 70 years) would be more appropriate to account for mobility of individuals in and out of the Great Lakes basin.

ii. Comments: Several commenters suggested that EPA increase the lifespan to 75 years or longer to account for women and people who live past 70 years. Other commenters suggested retaining the proposed 70 year value. Other commenters cited the EPA Exposure Factors handbook which identifies nine and 30 years as representative of the average and reasonable upper bound, respectively, of length of time residing in the same house. Commenters also suggested that mobility in the area is high and that individuals in the Great Lakes will not be exposed to contaminants uniformly over their lifetimes.

EPA believes the 70 year lifespan assumption is appropriate because it conservatively assumes a uniform exposure to contaminants over a lifetime. Since consumption patterns may change from infancy to death, EPA is seeking to protect those individuals who may live their entire lives in the Region and those who may encounter similar exposures while outside the region. Without exhaustive analysis, it would be difficult to determine that people who migrate in and out of the region are actually experiencing different exposure patterns. With regard to increasing the lifetime exposure to 75 years or more, EPA believes 70 years is an appropriate assumption as it is still a generally accepted value used by most risk assessors and regulatory agencies.

iii. Final Guidance: For the reasons cited above, the final Guidance retains the 70-year exposure period for developing criteria and values. A State or Tribe may chose to be more stringent and adopt a longer exposure period in its criteria derivation. It should be noted that this assumption does not influence cancer or noncancer criteria and values which are based on animal data since all lifetime animal data is assumed equivalent to a human lifetime, but may have a bearing on criteria and values based on epidemiology studies, depending on other numerical considerations in the calculation. If an epidemiology study is less than lifetime in duration, the dose must be translated into a lifetime human dose based on a specific lifetime duration assumption, either numerically or through the use of an uncertainty factor. In such a case, the assumption regarding the duration of a lifetime would be relevant to determining the human health criterion. In fact, it is relatively rare that epidemiological data is used to derive human health criteria due to limitations in the study which preclude a conclusion of a cause and effect. In the final Guidance there are two cases where epidemiological data were used; in deriving the HCV for benzene and the human noncancer value (HNV) for mercury.

c. Incidental Exposure.

i. Proposal: The proposed Guidance included an incidental ingestion exposure factor which accounted for oral exposures which might occur through recreational activities in or on the water. The factor (0.01 liters/day) was included in the derivation of the GLWQI criteria for those surface waters that are not used as a drinking water source (Nondrinking HNVs and HCVs). This factor was not used in those cases where the waterbody was designated as a drinking water source. EPA requested comments on whether the factor was justified and also requested comments on whether a factor should be included for incidental dermal exposure which occurs through recreational activities. EPA also requested submission of any data that could be used to derive such a factor.

ii. Comments: EPA received many comments stating that the extra factor for incidental exposure was unnecessary since the drinking water assumption of 2 L/day appears overly conservative. EPA also received comment that attempting to account for dermal uptake would be very difficult, if not impossible. No data were received on dermal uptake.

EPA agrees that the extra factor for incidental exposure is not necessary to include in the calculation of criteria and values which are to be used in protecting waters designated as drinking water supplies because such an exposure assumption is of negligible significance when viewed in light of the 2 L/day assumption used in deriving criteria for these waters. (Numerically, the 2.0 liter value in the numerator is so large in comparison to the 0.01 liter value, that it has no numerical effect on the calculated criterion.) However, EPA continues to believe that the inclusion of the incidental exposure factor is appropriate in developing criteria and values for waters designated as non-drinking water (i.e., recreational only).

The effect of using the incidental exposure factor when deriving criteria and values for nonbioaccumulative chemicals can be numerically significant. For example, for nondrinking water sources, when the incidental exposure factor is included, the HNV for methylene chloride is 90 mg/L. When the incidental exposure factor is not included, the HNV is 120 mg/L.

In addition, EPA also believes it is appropriate to account for incidental ingestion in a recreational setting since on an individual or subpopulation basis this exposure may be significant. For example, those people who spend more than an average amount of time recreating in water may exceed the 0.01 liters/day incidental ingestion rate. (The 0.01 value is based on a number of average assumptions for the Great Lakes basin population as a whole.) If States or Tribes want to establish a larger incidental exposure factor for recreational subpopulations (swimmers, waterskiers, rafters, kayakers), they may do so. This factor may become especially important in the future, when criteria for microbiological agents are developed, since very minute amounts of microbially contaminated water can cause adverse health effects.

iii. Final Guidance: The final Guidance retains the incidental exposure factor of 0.01 liters/day for those surface waters that are designated as nondrinking water sources.

d. Drinking Water Consumption.

i. Proposal: EPA proposed that the criteria and values be derived using an assumption of 2 L/day drinking water consumption from untreated surface waters for waters designated as drinking water sources. This represents approximately the 90th percentile ingestion value for the general population. The Exposure Factors Handbook, 1989, states: For the reasonable worst-case value, the 90th percentile rate reported by Gillies and Paulin (1983), 1.90 L/day, suggests that a rate of 2.0 L/day may be a reasonable approximation.

The 90th percentile value suggested by Cantor et al. (1987) is also approximately 2 L/day. This is also supported by a more recent study specifically characterizing tap water intake by Ershow and Cantor (1989) in which 2 L/day represents approximately the 85th percentile value of drinking water consumption. This value, 2 L/day, is recommended as the reasonable worst-case consumption rate. EPA requested comment on whether selection of another value such as 1.4 liters per day, the national average, would be more appropriate. EPA also noted that, since the 2.0 liters value is a conservative assumption (only 10 percent of the population drinks two liters of water a day and considerably less can be expected to drink two liters of untreated surface water) and the 0.01 liter associated with incidental exposure is relatively insignificant in comparison, EPA presumed that 2 L/day is protective of both drinking water and incidental ingestion exposures for waters which may be both a drinking water source and used for recreation. EPA requested comments on whether such an assumption was justified. EPA also requested comments on whether surface water criteria for waters designated for drinking water uses should assume consumption of untreated water, as was proposed.

ii. Comments: Several commenters suggested 2 L/day was too conservative. Others stated that the level of conservatism was appropriate. Those that felt it was overconservative believed that the national average is 1.4 liters/day and that people do not generally drink untreated surface water (in any amount). No commenters suggested that 2 L/day was underprotective. Other commenters stated that some cultural activities conducted by Native Americans, involve the direct consumption of untreated surface water, although the specific nature of these practices was not described.

EPA believes that the consumption rate of 2 L/day, even though conservative, is reasonable given that it will provide a high level of protection for the people in the Great Lakes consistent with the protective goals of the Act. EPA, in determining a water consumption rate, considered adopting the average consumption rate (1.4 liters/day), as discussed in the preamble to the proposal and suggested by commenters. However, in choosing among the available policy options, EPA chose 2 L/day to provide an extra degree of protection for those individuals (which may be a substantial number of persons) who consume more than the population on average. EPA believes that this assumption is reasonable in light of the public health protection goals of the CWA. EPA also believes that it would not be appropriate to dismiss drinking water usages, because as asserted by some commenters, there are expressed cultural practices which include consumption of untreated drinking water. EPA also believes that it would not be appropriate to assume that untreated water is never consumed by users since the CWA requires protection of designated uses. To protect waters designated as drinking water sources, it is important that public drinking water systems not be the only point of clean up and that surface water discharges also share the burden of maintaining the use designation of the water.

iii. Final Guidance: The final Guidance retains the assumption that individuals consume 2 L/day of untreated surface waters when developing criteria/values for waters designated as drinking water sources.

e. Fish Consumption.

i. Proposal: The proposed Guidance included a fish consumption rate of 15 grams per day, which represents the mean exposure level for regionally caught fish for the regional sportfishing population. This value also approximates the 90th percentile for the entire regional population. Thus, a more conservative target population was chosen than is used in the National criteria methodology and the proposed fish consumption value was based on Great Lakes-specific statistical data. The actual value of 15 grams per day was derived from review of several regional studies in Michigan (West, et al., 1989), Wisconsin (Fiore et al., 1989) and New York (Connelly, et al., 1990). Since the proposal, several new pieces of information have emerged that were used in EPA's consideration of the appropriate fish consumption rate: First, an Executive Order on environmental justice was issued February 11, 1994. It requires Federal agencies (to the greatest extent practicable and permitted by law) to "identify and address, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority population and low income populations." Federal agencies are also required, whenever practical and appropriate to "collect, maintain, and analyze information on the consumption patterns of populations who principally rely on fish and/or wildlife for subsistence."

Second, a study conducted by West et al. (1993) for the State of Michigan was provided by the author to EPA during the public comment period. This study is a full year (February 1991 to February 1992) fish consumption survey of 7000 licensed Michigan anglers. The survey found that the average sport fish consumption rate, adjusted for non-response bias, was 14.5 grams/day. The average total fish (all fish, not just Great Lakes sport fish) consumption rate, adjusted for non-response bias, was 24.4 grams/day. This study indicated that fish consumption rates may differ according to race and income level. The lowest income group (< $14,999/year) averaged 21 grams/day sport fish consumption as compared to 14.7 grams/day for those making $40,000 or more/year. The average sport fish consumption rate for minorities was 23.2 grams/day as compared with 16.3 grams/day for non-minority individuals. Lower income ($24,999 or less) minorities averaged the highest consumption rate of all groups in the survey: 43.1 grams/day sport caught fish and 57.9 grams/day total fish; Non-minority individuals of lower income averaged 18.6 grams/day sport fish and 25.8 grams/day total fish. The study also indicated that minorities eat less fish from the Great Lakes and more fish from the inland tributaries than non-minority individuals.

In the proposal, EPA also requested comments how to protect against acute and subchronic effects, the possibility of adverse effects due to binge eating. Specifically, EPA invited comment on the use of 454 grams (one pound) as a reasonable worst-case, one-day fish consumption estimate and 2,240 grams as a reasonable worst case, 10-day fish consumption estimate based on 10 consecutive days of consumption of approximately one-half pounds of fish per day. These values could be used in deriving one-day and 10-day criteria/values protective of acute and subchronic effects. In a Notice of Availability dated August 30, 1994 (U.S. EPA, 1994a) EPA asked for comments on the fish consumption rates identified in the West et al. (1993) study and on the quality of the study itself.

ii. Comments: Many commenters believed EPA's proposed rate of 15 grams/day would not be protective of recreational and subsistence anglers such as the Native American anglers and minority anglers, or women of childbearing age and children. An alternative rate of 50 grams/day was suggested. Others believed the rate of 15 grams/day was too conservative since it is protective of at least 90 percent of the overall population and these commenters suggested a lower rate. With regard to the use of one-day and ten-day worst case rates, comments suggested that this is a worthwhile attempt at dealing with a potential short term risk, but it was not clear how this could be implemented in a water quality standards context. Other commenters stated that one or ten day exposures are not long enough for biouptake and distribution to reach a steady state of chemical concentration in a human high enough to result in a toxic effect.

With regard to comments on the August 30, 1994 Notice of Data Availability (U.S. EPA, 1994a), many commenters were in favor of retaining the proposed fish consumption rate of 15 grams/day, citing the relative conservatism of the entire criterion methodology. Many of these same commenters questioned the validity of the West et al. (1993) study findings. Specifically, they questioned the lower income minority average of 43.1 grams/day since this number was based on a very small sample size and was associated with a large standard deviation. These same commenters acknowledged that there are subpopulations who consume more than 15 grams/day and that the best way to protect these people is to set site-specific fish consumption rates. Several other commenters were in favor of a higher fish consumption rate ranging from 30-60 grams/day. These same commenters supported the findings of the West et al. (1993) study, claiming that the study does show that lower income and minority subpopulations eat more sport caught fish on average, but also pointed out that while the data was presented correctly, many of the opinions presented in the study appeared overly subjective.

One group of commenters suggested that EPA establish in the final Guidance a new approach to establishing fish consumption rates based on default values derived from national data. These commenters argued that regional fish consumption survey data are time-consuming and costly to collect, and consequently are not often available. The commenters recommended that States and Tribes instead utilize default fish consumption rates based upon the particular fish consumption use of the waterbody (i.e., 20 grams/day for average fishing, 45-140 grams/day for sport fishing and 90-165 grams/day for subsistence fishing, with special consideration for Native American subsistence uses). These commenters also argued that use of the proposed fish consumption rate would not be in accordance with Executive Order 12898 addressing Environmental Justice, and would be discriminatory under the Civil Rights laws.

After consideration of the public comments, EPA has decided to retain the 15 grams/day fish consumption rate. EPA does not agree with commenters who argued that this assumption would not provide adequate protection of public health. As stated in the proposal, this value approximates the 90th percentile for the overall population in the Great Lakes basin and the mean value for sport anglers in the basin. EPA believes the results from the West et al. (1993) study (a mean consumption rate of 14.5 grams/day for Michigan sport anglers), along with the studies cited in the proposal (see 58 Fed. Reg. 20870) supports the reasonableness of the fish consumption rate used in the final Guidance.

EPA also believes that attainment of criteria in ambient waters that are derived using the assumed fish consumption rate will result in adequate protection for highly exposed populations. In carrying out regulatory actions under its statutory authorities, including the CWA, EPA generally views an upper bound incremental cancer risk in the range of 10^{-4} to 10^{-6} as adequately protective of public health. As discussed above, the human health criteria methodology is based on a target risk level of 10^{-5}. If fish are contaminated at the level permitted by criteria derived under the final Guidance, individuals eating up to ten times the assumed fish consumption rate (i.e., 150 grams/day) would still be protected at a 10^{-4} incremental risk level, within the range that EPA believes is protective of public health. Thus, while EPA acknowledges that some portion of the population will consume greater than 15 grams/day, the fish consumption rate and the target risk level chosen in the final Guidance combine to ensure that the population as a whole will be adequately protected by human health criteria when the criteria are met in the ambient water.

Available data support the protectiveness of this approach. An analysis of the West study indicates that approximately 99 percent of all persons surveyed in that study consumed less than 150 grams/day and that, even among low-income minorities who as a group consume more fish than the population on average, approximately 95 percent consumed less than this amount. Thus, EPA concludes that full implementation of the final Guidance will result in a high degree of protection for the population as a whole, including those populations that consume greater amounts of fish than the population on average.

The final Guidance requires, moreover, that States and Tribes adopt an additional degree of protection where it is determined to be appropriate for highly exposed populations. Section A.4.a. of procedure 1 in appendix F to part 132 states that "Human health criteria or values shall be modified on a site-specific basis to provide additional protection appropriate for highly exposed populations." Thus, if a State or Tribe determines that a highly exposed subpopulation (e.g., a Tribe of subsistence fishers) would not be adequately protected by criteria or values derived using the final Guidance methodology, the State or Tribe would be required to adopt a more stringent site-specific modification to criteria to provide appropriate additional protection (e.g., to ensure protection at least at the 10^{-4} risk level, or other more stringent degree of protection determined by the State or Tribe to be appropriate). Finally, the final Guidance requires States and Tribes to adopt provisions to ensure that human health is protected from the adverse effects of mixtures of pollutants in the Great Lakes System, including mixtures of carcinogens. <u>See</u> procedure 4 of appendix F to part 132; section VIII.D of this document. Thus, taking into account all relevant portions of the final Guidance -- e.g., the target risk level, site-specific modification procedures, additivity provisions, as well as the many conservative assumptions in the human health methodology discussed elsewhere in this document -- EPA believes that waterbodies meeting criteria developed in accordance with the final Guidance will be protective of all segments of the public, including any more highly exposed populations.

EPA acknowledges the problem identified by commenters that high quality survey data describing fish consumption patterns are often not available. EPA believes, however, that States and Tribes retain substantial flexibility in determining how to address the fish consumption issue should the State or Tribe decide that a more stringent approach than EPA's is appropriate. Where there is an absence of survey data for an area, but evidence of uses that the State or Tribe believe should be specifically reflected in a more stringent fish consumption rate, the State and Tribe could reasonably decide to adopt "default" values to provide a level of protection determined by the State or Tribe to be appropriate for the particular fishing use made of the waterbody. (EPA does not express a view as to the appropriateness of the specific default values suggested by commenters and noted above; such a determination can appropriately be made by the State or Tribe based on its best professional judgment.).

Finally, EPA believes that its action here is fully consistent with the Executive Order on Environmental Justice and civil rights laws because the final Guidance ensures that waterbodies meeting criteria developed using methodologies consistent with the final Guidance will protect the health of all of the public, including more highly exposed populations. Section 1-101 of Executive Order 12898 provides that "[t]o the greatest extent practicable and permitted by law . . . each federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations . . . ." Section 2-2 directs federal agencies to conduct their activities in a manner that ensures that the "activities do not have the effect of . . . subjecting persons (including populations) to discrimination under such programs, policies and activities because of their race, color, or national origin." Finally, section 4-4 of the Order specifically discusses subsistence consumption of fish and wildlife, and provides that "[f]ederal agencies, whenever practicable and appropriate, shall collect, maintain and analyze information on the consumption patterns of populations who principally rely on fish and/or wildlife for subsistence," and that "[f]ederal agencies shall communicate to the public the risks of those consumption patterns."

EPA's action here is consistent with the terms of this Executive Order. In developing the final Guidance, the EPA made a special effort to identify and address the potential risks to highly exposed low-income and minority populations, to maintain and analyze information on these risks, and to communicate risks to the public, as reflected in the August 30, 1994, Notice of Data Availability soliciting public comment on the fish consumption issue and the provisions in the final Guidance specifically targeted to protecting highly exposed populations discussed above. EPA also flatly rejects the notion, advanced by some commenters, that the final Guidance is in any respect discriminatory against persons or populations because of their race, color, or national origin. The final Guidance establishes criteria methodologies and implementation procedures that are expressly designed to ensure full protection of the public, including highly exposed populations. While some groups and individuals, including some low income and minority persons and populations, may face a greater risk of adverse health effects than the general population due to their particular fish consumption patterns, EPA has included in the final Guidance mechanisms that, upon full implementation by States and Tribes, will ensure that these groups will nonetheless receive a level of public health protection within the range that the EPA has long considered to be appropriate in its environmental programs (i.e., 10^{-4} to 10^{-6} incremental cancer risk). Obviously, as long as there is variability in fish consumption patterns among various segments of the population, it would be impossible for EPA to ensure that all groups would face identical risk from consuming fish. Therefore, EPA has sought to ensure that, after attainment of water quality criteria in ambient waters, no group is subject to increased cancer risks greater than the risk range that the EPA has long considered protective.

As noted above, EPA solicited comment on whether EPA should develop short-term criteria to protect against possible effects of worst-case short term exposures. No commenter supported the development of such criteria. Commenters generally did not understand how such short-term criteria could be implemented in the water quality criterion program as now constituted. Commenters did generally support further research into the unanswered questions associated with high, short-term exposure effects, including fetotoxic effects. Several commenters felt that fish advisories were the best way to deal with this issue.

EPA agrees with the commenters that this is an area that needs more research before short-term water quality standards could be set. Research in the area of bio-uptake and whether a steady state can be achieved in a short time period is needed before EPA could determine whether to develop short-term criteria and values that would be sufficiently supported by the available science to serve as sources of regulatory controls. EPA acknowledges that fish intake rates do vary over the course of a lifetime and while EPA believes the 15 grams/day assumption is adequately protective of the Great Lakes population over a lifetime, States have the flexibility to establish criteria specifically targeted to provide additional protection to sensitive subpopulations (e.g., pregnant/nursing women, infants, children) or highly exposed subpopulation (e.g., Native Americans) using adjusted values for exposure parameters for fish consumption, body weight, and duration of exposure. EPA believes the values (short-term, worst-case fish consumption exposure assumptions of 448 grams as a worst-case, one-day fish consumption estimate and 2,240 grams as a worst-case, 10-day fish consumption estimate) provided may be used in setting fish advisories, especially for those chemicals for which acute noncancer effects are most notable.

iii. Final Guidance: For the reasons cited above, the final Guidance uses a fish consumption rate of 15 grams per day when deriving human health criteria. The 15 grams per day is divided into the grams of trophic level 3 fish consumed (3.6 grams) and the grams of trophic level 4 fish consumed (11.4 grams). The grams of fish consumed at each trophic level were estimated using the data in the West et al. (1993) survey. The results of this analysis are discussed in section IV.B.3 of this document. EPA believes separating the quantity of trophic level 3 and trophic level 4 fish consumed better represents the potential exposure to consumers.

f. BAFs.

The proposal included a methodology for deriving BAFs, and technical support documents describing the methodology and BAF derivation for those chemicals for which human health and wildlife criteria are proposed. The BAF methodology in the final Guidance has been modified from the proposal. However, BAFs are still required to be utilized in the derivation of human health criteria.

The new minimum BAF data required to derive Tier I human health criteria for organic chemicals include either: (a) a field-measured BAF; (b) a BAF derived from the BSAF methodology, or (c) a chemical with a BAF less than 125 regardless of how the BAF was derived. For all inorganic chemicals, including organometals such as mercury, the minimum BAF data required to derive a Tier I human health and wildlife criteria include either: (a) a field-measured BAF or (b) a laboratory-measured BCF. For the majority of inorganic chemicals, the BAF is equal to the BCF (i.e., FCM = 1) because there is no apparent biomagnification or metabolism. The basis for these new requirements are discussed in section IV of this document.

g. Relative Source Contribution.

i. Proposal: In the proposed Guidance, EPA assumed an 80 percent relative source contribution (RSC) from surface water pathways (water and fish) for BCCs, and 100 percent RSC for non-BCCs, in deriving noncancer criteria/values. A 100 percent RSC was assumed for all chemicals in deriving cancer criteria/values. The proposal explained the reasoning of the Initiative Committees for choosing each RSC default percentage (see 58 FR 20870).

EPA requested comments on the proposed RSCs and on possible alternatives for derivation of noncancer criteria and values (see 58 FR 20870). EPA also requested public comment on whether any of the options described in the proposal for use of an RSC in deriving noncancer criteria and values should be considered in calculating Great Lakes cancer criteria and values (HCVs).

ii. Comments: Many commenters suggested that EPA not use a default of 100 or 80 percent, but to only derive an RSC when exposure data exists. Other commenters stated that the reason for a different RSC for BCCs and non-BCCs for noncarcinogens was not clear. One commenter suggested we use an RSC of 40 percent for all chemicals, but also acknowledged that this value was chosen arbitrarily, not based on any specific data set. Many other commenters believed that no RSC should be derived at all; that the RSC should be 100 percent for BCCs and non-BCCs. Several commenters stated that EPA should not apply an RSC to the development of cancer criteria and values but did not provide reasons for this opinion.

EPA agrees with the commenters who suggested that actual data should be used in developing an RSC when available. As stated in the 1980 National Guidelines, to account for exposures from other sources, actual exposure data can be subtracted from the RfD (ADI, as it was called in 1980) to account for contributions of the pollutant from diet and air (ADI - (DT + IN) where DT is the estimated non-fish dietary intake and IN is the estimated daily intake by inhalation (U.S. EPA, 1980). Therefore, where data are available, if States or Tribes want to use actual data in developing their RSC, they may do so, following the procedure outlined in the 1980 National Guidelines. It is important to note, however, that EPA's policy on how to use exposure data in developing an RSC is now under review. Once EPA has finalized its policy review on the RSC, EPA will address the application of the RSC during the triennial review of Water Quality Standards under section 303 of the CWA. Until such time, the EPA has decided to apply an RSC of 80 percent to all noncarcinogenic chemicals (both BCCs and non-BCCs).

After further consideration and review of public comments, EPA does not support the reasoning of the Initiative Committees that there is a clear difference in RSC development for BCCs as opposed to non-BCCs. While it may be true that surface water may be the major route of exposure for bioaccumulatives (through fish consumption), even though a pollutant is not bioaccumulative, it does not preclude the possibility that there may be other significant sources of exposure.

With regard to the use of a 80 percent default value, EPA believes that the assumption helps to provide some measure of protection against the possibility that exposures from other sources may contribute to the overall exposure of the public to a particular contaminant. Available data for indicate that non-water sources contribute varying amounts to overall exposure to a particular chemical (U.S. EPA 1982; U.S. EPA 1983). Such exposures can occur through air and the diet. Since available data indicate that such exposures can and do occur, but these data are often limited in their ability to predict with precision the relative source contribution, EPA believes it is prudent not to assume that all exposure to a pollutant occurs from one medium. The 80 percent default was chosen because it reflects the approximate contribution from surface water pathways (fish consumption) to the overall exposure to BCCs such as PCBs in the basin (see section III., Relative Source Contribution, in the Human Health TSD).

For nonbioaccumulatives, 80 percent was also chosen as a default value to account for the other possible non-water sources which may contribute to the overall exposure of the chemical. However, actual exposure data may also be used in the final Guidance by States and Tribes to calculate a relative source contribution. EPA recognizes that the choice of a default value of 80 percent in these cases is fundamentally a policy judgment that criteria development should reflect the fact that exposures to a pollutant occur through other media, rather than an empirically-based calculation of the precise proportion of exposure via water versus non-water sources, since such values vary on a case-by-case basis. EPA also acknowledges that use of a 80 percent default for non-BCCs is a conservative measure, however, if other significant exposures are not accounted for, the criteria could underestimate overall exposure to the chemical and thus could underestimate the risk of adverse health effects. In addition, in the absence of data, it is prudent and consistent with the health protection goals of the CWA to include a margin of safety in the event that there are exposures from other sources. The important fact, EPA believes, is to take some accounting of other possible exposure pathways.

With regard to the concern raised by some commenters that point sources should not be expected to compensate for the failure to address other pollutant sources, EPA does not believe that the relative source contribution factor in the final methodology unduly burdens point source dischargers. It is common practice in EPA programs (e.g., in establishing maximum contaminant level goals under the Safe Drinking Water Act) to take into account other routes of exposure to a chemical when establishing health-based standards for a particular route of exposure. If this step is not taken, and EPA were always to assume that no exposures occurred through other media (in spite of evidence to the contrary), then the totality of exposures could obviously result in adverse health effects, contrary to EPA's goal of establishing standards that insure that such effects do not occur. EPA agrees, however, that it is important to take steps to address all routes of exposure to pollutants in order to achieve the greatest overall public health protection at the least cost.

iii. <u>Final Guidance:</u> The final Guidance provides for the application of a 80 percent RSC for all noncarcinogenic chemicals. This is a change from the proposal, which provided for the application of the 80 percent RSC to noncarcinogenic BCCs only. The rationale for the change is explained above.

6. <u>Minimum Data Requirements/Tier I and Tier II</u>

In the proposal, EPA established a two tier system, each tier with a different set of minimum data requirements. This was established to facilitate interpretation of State narrative standards and to lead to development of as many criteria and values as possible. EPA stated that the data base necessary to derive Tier I criteria was fairly extensive and could preclude the development of a permit limit for a chemical of concern, if the minimum data was not available. In the absence of Tier I criterion, the permitting authorities needed some mechanism with which to interpret and ensure that the narrative prohibition against the discharge of toxic substances in toxic amounts is reflected in water quality-based effluent limitations. To address this issue, a Tier II methodology, which requires a less extensive data base (similar to the Tier II methodology for the development of aquatic life values), was proposed for the development of human health values.

In the proposal, Tier I criteria and Tier II values for human health were differentiated based on the quantity and quality of toxicological data only. There was no differentiation based on the quantity or quality of BAFs. After reconsideration, EPA has decided to differentiate the Tier I criteria and Tier II values for humans based on both the quantity and quality of toxicological and bioaccumulation data. The minimum BAF data required to derive a Tier I human health criterion for non-polar organics include either a field-measured BAF, a BAF predicted from a field-measured BSAF, or a chemical with a BAF less than 125 regardless of how the BAF was derived. For inorganic chemicals including mercury, BAFs derived based on field-measured BAFs or laboratory-measured BCFs are considered adequate for derivation of Tier I criteria because there is little concern with metabolism for the majority of inorganics. The rationale for establishing the minimum data requirements for BAFs is included in section IV.2.b of this document. Based on this change, the minimum data to derive Tier I criteria must include both the minimum toxicological data, discussed below, and the minimum BAF data. If these data are not available, then a Tier II human health value must be developed.

a. Carcinogens.

i. Proposal: Under the proposal, the methodology for deriving Tier I criteria and Tier II values for carcinogens (the human cancer values or HCVs) was identical. The only difference between Tier I and II was the weight of evidence, and the amount and quality of data that was required for use in deriving the criteria or values. The major issue regarding the two Tiers was how to address Group C chemicals. The proposal would have provided that Tier I criteria be set for those types of Group C chemicals which are well characterized and supported by a well-conducted study. For those Group C chemicals in which the cancer study (or studies) indicate(s) a significant increase of cancer in test animals but are limited by either: a marginal statistical correlation between chemical and tumors due to high control tumor incidence; a weak dose-response relationship; or an incidence of benign tumors rather than malignant tumors, Tier II cancer values were to be derived (if enough data is available to conduct a quantification). If a cancer quantification could not be conducted due to lack of data (number of test animals, and/or only one dose group of animals has responded, making it impossible to determine a slope factor) then the chemical was to be assessed on a noncancer basis and a Tier I or Tier II human noncancer criteria or value (HNV) should be developed, if available data exists.

EPA requested comments on: the procedures proposed for derivation of Tier I criteria and Tier II values for possible carcinogens (Group C); the alternative of using an additional uncertainty factor (up to 10) on a noncancer endpoint for Group C chemicals to provide protection from possible carcinogenicity; and the alternative of deriving criteria and values for Group C only through noncancer assessments without an added uncertainty factor for possible carcinogenicity.

Another option, which EPA requested comments on, was whether a Tier II value could be set for an unquantifiable Group C chemical, whether endpoints other than malignant tumors such as benign tumors or other precursors to malignant tumors (such as hyperplastic nodules or peroxisome proliferation) could be used to set a value.

ii. Comments: With regard to how Group C chemicals should be addressed, several commenters believed EPA should set criteria and/or values for Group C chemicals on a case-by-case basis since the variability in quality of the data base which is used in establishing Group C status can be so wide. Others were split on whether Group C chemicals should be regulated at all under Tier II. Several commenters believed the data supporting Group C chemicals was much too minimal to support Tier II value development. Other commenters supported the development of Tier II values for Group C chemicals citing the need to protect the public from potential carcinogens even when the supporting data base is minimal.

With regard to the use of uncertainty factors to account for potential carcinogenesis, commenters were split on this issue. Many found the practice of using an extra uncertainty factor indefensible from a scientific viewpoint;

others felt it was a sound policy which should be continued in the Drinking Water Program and also used in the final Guidance.

In response to the use of precursors, such as hyperplastic nodules or peroxisome proliferation, to set a value, some commenters stated that their use in setting criteria or values was controversial and could be difficult to defend. They cited examples where precursors such as hyperplastic nodules or peroxisome proliferation were not associated with the onset of cancer.

With regard to how Group C chemicals should be addressed, EPA agrees with commenters that Group C chemicals should be dealt with on a case-by-case basis and has changed the final Guidance to reflect this. As the final Guidance is written, States and Tribes have the discretion to develop criteria or values for Group C chemicals based on the overall toxicological data base. The final Guidance directs that this case-by-case determination be made taking into account information including data on mutagenicity, genotoxicity, structure activity, and mode of action. EPA believes that those Group C chemicals which act via a genotoxic mechanism (that is through direct interaction with DNA), may be most appropriately dealt with through use of a linearized multistage model (LMS) or other models which appropriately reflect this type of mechanism of action (nonthreshold). If the chemicals does not interact with DNA, it may be best dealt with as a noncarcinogen and an RfD should be developed. (See the updated Human Health TSD, section II - Tier designations - for guidance on determining whether an agent interacts with DNA directly. Several assays which are key to making such a determination are listed.)

With regard to the use of uncertainty factors to account for potential carcinogenesis, EPA believes the use of an extra uncertainty factor of up to 10 can be justified if there is concern of potential carcinogenesis (i.e., equivocal bioassay and genotoxicity results) and that the State or Tribe should make this determination on a case-by-case basis. However, as stated above, a clear determination should be made whether the chemical interacts directly with DNA. If this is a clear cut decision (i.e., the genotoxicity data is not equivocal), then the use of an extra uncertainty factor may not be necessary: either the chemical can be addressed as a carcinogen and quantified using an LMS or other appropriate model or it can be addressed as a noncancer agent and an ADE is set. The determination whether to use an extra uncertainty factor can also be based on which data set is more reliable or convincing. If the cancer data is marginal in terms of testing protocol and statistics, but the noncancer data is well-conducted and unambiguous, it may be preferable to use the noncancer data in setting a criterion with an extra uncertainty factor of up to 10 to account for possible carcinogenicity. EPA stresses that the entire data base should be used in developing an overall weight of evidence for human carcinogenicity before choosing a course of action with regard to selecting a Tier or a risk assessment approach (cancer or noncancer).

With regard to the use of precursors in developing Tier II values, EPA agrees that the use of precursors as an endpoint may be controversial and difficult to defend unless a clear determination of mechanism of action is made implicating a precursor to an eventual tumor incidence. However, if a chemical is well studied and the mechanism of carcinogenesis is well established indicating a clear procession from precursor to malignant tumor, such endpoints can be used by States/Tribes in developing a Tier I criterion or Tier II value.

iii. Final Guidance: The final Guidance provides for a case-by-case determination of carcinogenicity for Group C chemicals with an emphasis on evaluating the entire data base.

b. Non-carcinogens.

i. Proposal: The proposed Guidance also made a clear distinction between Tier I and Tier II for noncarcinogens. Human Noncancer Values (HNVs) for the Tiers I and II are again distinguished on the basis of the available data base. The minimum acceptable data base for derivation of a Tier I criterion is at least one well-conducted subchronic mammalian study. The duration of the study must be at least 90 days in rodents, or 10 percent of the lifespan of other appropriate species. The preferred minimum data point for decision making is a NOAEL; however, the proposal also allowed the use of a LOAEL involving mild, reversible effects, which may be considered acceptable from longer term studies where a NOAEL may not be available. In developing Tier II values, the proposal stated that the minimum acceptable data base was a well conducted repeated dose mammalian study of at least 28 days. However, the proposal also maintained that the minimum acceptable data point for decision making on such short term exposure data was a NOAEL. In addition, the proposal stated that the study ideally should be designed to observe all possible systemic effects and include examinations for histopathology. Data from studies of longer duration (greater than 28 days) and LOAELs from such studies were also allowed in some cases for derivation of Tier II values. EPA did not want to preclude the use of LOAELs from studies slightly longer than the required 28-day studies (such as 30 day tests) if the LOAEL from such a study represents an effect which is mild, reversible, close to a probable or actual NOAEL, and is representative of effects observed over chronic exposures.

EPA also recognized in the proposal that when the Tier II methodology is used to derive a HNV, an additional uncertainty factor of up to 10 may be applied in deriving the ADE to account for the difficulties in extrapolating from a short term NOAEL to a long-term NOAEL. Structure activity relationships (SARs), and all other available data on the chemical should be used to determine the appropriate additional uncertainty factor.

EPA requested comments on several issues including: the use of a 28-day, or other subacute study with the use of additional uncertainty factors; whether the use of the Tier II human health methodology was appropriate; whether or not even shorter term studies, such as 14 day studies, might effectively be used in a Tier II HNV approach; and the appropriateness of using surrogate chemicals employing an SAR evaluation to develop Tier II values and the use of SAR as a screen for requiring additional toxicity information.

ii. Comments: The majority of commenters opposed the use of 14 day studies, while they were divided on the use of 28-day data for developing Tier II values. Many commenters stated the 28-day minimum was scientifically indefensible since a 28-day study is not designed to characterize subchronic or chronic risk (it is less than 10 percent of most test mammals' lifespan) and that EPA should only develop Tier I criteria using the data base specified for Tier I. Other commenters believed the 28-day study was the minimally acceptable test but they also cautioned that the values derived with 28-day study data be used only on an interim basis in order to encourage the development of longer term data. Other commenters stated that the use of a LOAEL should not be allowed. With regard to comments on the overall Tier II methodology, several commenters supported the Tier II process but indicated that resulting values should only serve as an interim risk assessment on a chemical. Other commenters opposed the Tier II process stating that if good data does not exist for a chemical, it is unreasonable to regulate it on such a basis.

With regard to the use of SAR in the development of Tier II values, many commenters were in favor of using SAR to evaluate Tier II chemicals but not to develop surrogate chemical values. Commenters believed that SARs are very theoretical in nature, without solid data foundation, and could not form the basis for a permit limit.

EPA believes the use of 28-day data is supportable in the context of Tier II development. While such short term studies typically do not reveal evidence of possible adverse effects resulting from longer term exposures, there is some evidence that the data can be correlated to longer term studies (Wiel and McCollister, 1963).

EPA acknowledges that the certainty in the overall risk assessment is not as high as with 90-day study results since it is necessary to extrapolate from a short term study to lifetime exposures, and the correlatability of short term study results to long term study results is not definitive and quantitative. However, EPA believes that the number derived using the 28-day data and an extra uncertainty factor will be adequately protective (since the uncertainty factor will further reduce the final value) and will serve as motivation to obtain longer term data to develop Tier I criteria. For these same reasons, EPA believes the Tier II process is a sound approach to developing interim regulatory values for pollutants with minimal data bases.

In addition, EPA believes that for the majority of chemicals that will be found in discharge effluents, there is already adequate data to develop Tier I criteria. This is based on a review of the toxicological data bases for the 138 pollutants of initial focus. These are the chemicals identified by the Steering Committee to be known or suspected of being of primary concern in the Great Lakes basin (see 58 FR 20843). Of the 138, EPA estimates that about 120 have enough data to derive Tier I criteria. This leaves about 20 chemicals with either insufficient data to calculate a Tier I criterion or no data to calculate either a Tier I criterion or Tier II value. Thus, EPA believes the number of chemicals with Tier II values will be minimal. (See section II.C.5 for a more complete discussion.)

With regard to the use of SAR, EPA agrees that SAR may be useful in assessing the potential effects of a chemical and may be valuable in selecting the uncertainty factor for a Tier II value. However, it is a process which requires a great deal of scientific judgement and can be open to differing interpretations. Because of these concerns, EPA has decided to not require the use of SAR as the basis for II values. EPA believes the expertise or the resources may not exist in many States to use SAR for routine regulatory purposes. In addition, the interpretation of SAR data may lead to inconsistent values among the Great Lake States. With further research and a greater confidence in the process, SAR may be used in the future to derive surrogate chemical Tier II values.

iii. <u>Final Guidance:</u> For the reasons stated above, EPA is maintaining the methodology for developing Tier II values, which relies upon the use of 28-day study results as the basis of value development and the use of SAR for the selection of uncertainty factors.

D. Criteria Derivation

The final Tier I human cancer criteria or Tier II value are calculated as follows:

$$HCV = \frac{RAD \times BW}{WC + [(FC_{TL3} \times BAF_{TL3}) + (FC_{TL4} \times BAF_{TL4})]}$$

Where:

HCV = Human Cancer Value in micrograms per liter (μg/L).

RAD = RAD in milligrams toxicant per kilogram body weight per day (mg/kg/day) that is associated with a lifetime incremental cancer risk equal to 1 in 100,000.

BW = Body weight of an average human (BW = 70kg).

WC = average per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies (WC_d = 2 L/day) and average per capita incidental daily water exposure for surface waters not used as public water supplies (WC^r = 0.01 liters/day)

FC_{TL3} = mean consumption of trophic level 3 fish by regional sport fishers = 0.0036 kg/day

FC_{TL4} = mean consumption of trophic level 4 fish by regional sport fishers = 0.0114 kg/day

BAF_{TL3} = BAF for trophic level 3 fish

BAF_{TL4} = BAF for trophic level 4 fish

The Tier I human noncancer criteria or Tier II value is calculated as follows:

$$HNV = \frac{ADE \times BW \times RSC}{WC + [(FC_{TL3} \times BAF_{TL3}) + (FC_{TL4} \times BAF_{TL4})]}$$

Where:

HNV = HNV in micrograms per liter (µg/L).

ADE = ADE in milligrams toxicant per kilogram body weight per day (mg/kg/day).

RSC = RCS factor of 0.8 for all chemicals of concern. This is used to allow for potential exposure via sources other than consumption of contaminated water and fish recreational exposure. States may develop an RSC using actual exposure data following the procedures specified in the 1980 National Guidelines.

1. Proposed Criteria and Values

40 CFR part 132, Table 3, sets forth HCVs and HNVs for 18 chemicals which have been derived using the final human health methodology. Note that for each HCV and HNV, two criteria are provided. The first is that which applies when exposure is from recreational activities and consumption of aquatic organisms. The second is that which applies when exposure is from consumption of aquatic organisms, drinking water and recreational activities. EPA requested comments on the proposed HCVs and HNCs in Table 3 of proposed 40 CFR part 132. The docket for the final rulemaking contains technical support documents describing the details of derivation of each criterion and value.

The criteria for the chemicals in Table 3 of part 132 have been modified from the proposal to reflect changes in the BAFs and the use of a default RSC of 80 percent for all noncarcinogens not just those noncarcinogens that are bioaccumulative chemicals of concern (BCC). The rationale for the changes in the BAFs are discussed in section IV of this document. The change in the RSC is discussed in section V.C.5.g above.

The criterion for heptachlor and pentachlorophenol are not included in Table 3 of part 132 because the BAFs for the chemicals were estimated using a laboratory predicted BCF multiplied by a food chain multiplier and their BAFs were greater than 125. Consequently, they did not meet the minimum BAF data requirements for deriving a Tier I human health criterion as discussed in section V.C.6 above.

The noncancer criterion for trichloroethylene and toxaphene are not included in Table 3 of part 132 because the RfDs needed to derive a human noncancer criterion are currently under review by EPA. In the proposal, the noncancer criterion were derived using RfDs that had not been verified by EPA.

EPA has decided that it would not be appropriate to include criterion in Table of part 132 that do not have a RfD verified by EPA. For this reason, the final Guidance does not include a human noncancer criterion for toxaphene or trichloroethylene. However, even if the noncancer criterion used in the proposal were retained, the cancer criterion for the two chemicals would be lower (toxaphene - cancer criterion is 6.8 x 10^{-5} μg/L and noncancer criterion would be 2.1 x 10^{-2} μg/L; trichloroethylene - cancer criterion is 29 μg/L and noncancer criterion would be 470 μg/L).

The ADE (RfD) for chlordane was modified to correct an error in the uncertainty factors used in the proposal. The ADE in the proposal was 5.50 x 10^{-4} mg/kg/day. This was based on a NOAEL of 5.5 x 10^{-2} mg/kg/day and an uncertainty factor of 100 to account for interspecies variability and intraspecies variability. An additional uncertainty factor of 10 should have been included to account for the lack of an adequate reproduction study and adequate chronic study in a second mammalian species and the generally inadequate sensitive endpoints studied in existing studies. The resulting uncertainty factor of 1000 is recommended by EPA in its IRIS data base. The resulting ADE is 5.50 x 10^{-5} mg/kg/day and the noncancer criterion for chlordane is 1.4 x 10^{-3} μg/L. The cancer criterion for chlordane is 2.5 x 10^{-4} μg/L.

The NOAEL for hexachloroethane in the proposal was adjusted from 1.0 mg/kg/day to 0.71 mg/kg/day to account for the fact that the test animals were fed only 5 days a week. Upon further review of the study used to estimate the NOAEL, it was determined that the test animals were fed every day of the week and not 5 days per week as assumed in the proposal. An adjustment of the NOAEL in the proposal to account for the 5 day feeding week was therefore not justified. Thus, the final Guidance uses a NOAEL of 1.0 mg/kg/day.

The NOAEL used for deriving noncancer criterion for methylene chloride in the proposal was 6.47 mg/kg/day. This was based on a study in which the NOAELs were 5.85 and 6.47 mg/kg/day for male and female rats, respectively. The NOAEL for the female rat was used in the proposal as the basis for deriving a noncancer criterion. Based on further review, EPA believes that the NOAEL of the male rats should be used in deriving a noncancer criterion. EPA decided to use the male NOAEL because it will provide slightly greater protection and is consistent with the NOAEL used in IRIS. In either case, the cancer criterion for methylene chloride is more stringent than the resulting noncancer criterion. The noncancer criterion using the female rat study would be 1.8 x 10^3 μg/L, the criterion using the male rat study would be 1.6 x 10^3, and the cancer criterion is 47 μg/L.

a. PCBs (Human Cancer Value).

i. Proposal: The proposed criterion document for PCBs set a HCV of 3 pg/L for both drinking water sources and non-drinking water sources. These criteria were based on a slope factor of 7.7 (mg/kg/day)-1 derived from the rat bioassay of Norback and Weltman (1985). This study utilized large numbers of Sprague Dawley rats (70/sex/dose) in a chronic Aroclor 1260 feeding study. Animals were administered 100 ppm for 16 months, followed by a 50 ppm diet for an additional eight months, then a basal diet for five months. Among the test animals that survived for at least 18 months, females exhibited a 91 percent incidence of malignant liver tumors. In males, corresponding incidences were four percent for liver tumor and 11 percent for neoplastic nodules.

ii. Comments: Several commenters were critical of the PCB criterion and made the following comments: there is no evidence that congeners other than those found in Aroclor 1260 are carcinogenic; EPA should pool the data from all Aroclor studies and develop a geometric mean from these studies; the re-evaluation of tumors in the Norback and Wellman (1985) study by IEHR results in a substantially lower cancer potency; and the epidemiology data on PCBs indicates that the current animal based cancer potency is overly conservative.

With regard to the comment that congeners other than those found in Aroclor 1260 are not carcinogenic, as stated on IRIS: "Although animal feeding studies demonstrate the carcinogenicity of commercial PCB preparations, it is not known which of the PCB congeners in such preparations are responsible for these effects, or if decomposition products, contaminants or metabolites are involved in the toxic response." Nominally, it appears that animal studies with Aroclor 1260 are the only studies indicating carcinogenic response. However, there are indications that Aroclor 1254 may also be carcinogenic. A study by NCI (1978) reported carcinomas of the gastrointestinal tract in Fischer rats treated with Aroclor 1254, however the incidence was not statistically significant. While it is not statistically significant, the presence of such a response still raises the concern regarding the carcinogenicity of PCB mixtures other than Aroclor 1260. The EPA believes it is not reasonable to develop a criterion for each PCB Aroclor mixture. PCBs are mixtures of chlorinated biphenyls. Each mixture may contain up to 209 possible individual compounds. Each of the mixtures would be expected to contain all combinations of chlorinated compounds even though some of them only in small or trace amounts. Since it is not known which compound of the 209 is clearly responsible for eliciting a cancer response, to conservatively protect against the potential for carcinogenicity associated with all PCB mixtures, EPA has chosen to base criteria on study results using Aroclor 1260.

EPA disagrees with the commenters who suggest EPA should pool all the cancer data from all the available congener studies in developing a criterion for PCBs for following reasons: The Norback and Wellman (1985) study is judged by EPA as acceptable in design and conduct compared to other available studies. As stated on IRIS, "The estimate (slope factor) based on the data of Norback and Weltman (1985) is preferred because Sprague Dawley rats are known to have low incidence of spontaneous hepatocellular neoplasms. Moreover, the latter study spanned the natural life of the animal, and concurrent morphological liver studies showed the sequential progression of liver lesions to hepatocellular carcinomas." Normally EPA will pool study data only if available studies are considered of marginal quality. The Norback and Wellman study is considered a good study and therefore the pooling of studies is not needed.

In response to the reevaluation of the tumor data by IEHR, the IEHR potency factor was 5.1 (mg/kg/day)-1 as compared to the EPA derived cancer potency factor of 7.7 (mg/kg/day)-1. The IEHR reevaluation was a reread of the histopathology slides from Norback and Wellman study, in which several lesions which were originally interpreted as malignant lesions were reinterpreted as non-malignant lesions (neoplastic nodules). The EPA is currently reviewing the IEHR data for PCBs. Until the EPA can fully assess the validity of the conclusions drawn in the IEHR reevaluation, it would be premature to make the suggested changes in the criterion.

In response to the epidemiology data indicating that humans are less sensitive than test species to PCBs, EPA does not believe the epidemiological results are as conclusive as the animal results from the Norback and Wellman study. As presented on IRIS, the human carcinogenicity data is considered inadequate. Although there are many epidemiological studies, the data are inadequate due to confounding factors. The factors noted in IRIS are: population differences in alcohol consumption, dietary habits, ethnic composition, contamination of PCBs by dibenzofurans, and exposure of workers to other known carcinogens. It is EPA's longstanding practice to rely upon studies in animals for risk assessment in the absence of adequate human data.

iii. Final Guidance: For the reasons stated above, EPA continues to believe that the study by Norback and Weltman is the best available study to use for deriving a human health criterion for PCBs.

b. TCDD.

In the proposal, EPA stated that it is currently conducting a major new dioxin research and analysis effort, the results of which could not be reflected in the proposed Guidance. EPA also stated that if the results of this study became available prior to the finalization of the rule, EPA expected to publish a notice of availability and solicit comment on whether the rule should be modified to reflect this new information. EPA invited comment on the approach it should take to establishing dioxin criteria pending completion of its ongoing dioxin studies.

Many commenters stated that EPA should not develop criteria for dioxin until the dioxin reassessment is final. Other commenters stated that EPA should not delay the publication of dioxin criteria until the reassessment is finalized.

EPA agrees with commenters that it is important that EPA develop a dioxin criterion regardless of the status of the dioxin reassessment. Dioxin, from all indications, is one of the most potent carcinogens and must be regulated with the most recent available data at hand. Once the dioxin reassessment is final, EPA will revisit the dioxin criterion, and make changes if needed. EPA's proposed dioxin reassessment was made public on September 13, 1994. The final dioxin reassessment is anticipated sometime in late 1995.

i. TCDD - Noncancer Criterion

(A). Proposal: In the proposal, EPA developed a Tier I criterion of 0.1 pg/L for drinking water and nondrinking water sources based on a reproductive study by Bowman et al. (1989) on rhesus monkeys which indicates a LOAEL based on behavioral effects at 25 ppt (0.67 ng/kg/day) and a NOAEL at 5 ppt (0.13 ng/kg/day). The ADE was developed by dividing the NOAEL of 0.13 ng/kg/day by an uncertainty factor of 100 (10X for intraspecies variability and 10X for interspecies extrapolation).

(B). Comments: Several commenters believed the intra- and interspecies adjustment of 10 was unjustified since the rhesus monkey data was used. They argued that the rhesus monkey is very close to humans in terms of pharmacokinetics and therefore an interspecies uncertainty factor of three is warranted instead of the usual uncertainty factor of 10 which is applied for interspecies differences between humans and less similar mammals such as rodents.

(C). Final Guidance: With regard to the noncancer criterion, it is EPA's judgement to apply an intraspecies uncertainty factor of 10 to account for variability and sensitivity within the human population. EPA also believes that the interspecies uncertainty factor of 10 is justified because the study groups were very limited in size and the statistical and biological significance of the findings are unclear. In addition, metabolic and pharmacokinetics parameters for humans and rhesus monkeys may be sufficiently different. For these reasons, EPA believes an interspecies uncertainty factor of 10 is justified.

ii. TCDD - Cancer Criterion

(A) Proposal: The proposed criterion document for dioxin presented a human cancer value of 0.01 pg/L for drinking and nondrinking water sources. These criteria were based on a slope factor of 7.5×10^4 (mg/kg/day)-1 based on the pooled significant tumors in female rats of Kociba, et al. (1978) with the liver tumor reevaluation of the Pathology Working Group (Sauer, 1990).

(B). Comments: Commenters stated that the dioxin criteria should reflect the 1986 cancer guidelines (U.S. EPA, 1986), not the draft EPA cancer guidelines which EPA is in the process of revising.

(C). Final Guidance: EPA agrees that the 1986 cancer guidelines are appropriate for use in developing the dioxin criterion, and believes this is appropriate until the revised cancer guidelines are peer reviewed, publicly reviewed and finalized.

c. Mercury.

i. Proposal: EPA proposed a criterion of 2 ng/L for mercury for both drinking water and nondrinking water sources. This criterion was based on a LOAEL of 3 μg/kg/d and an uncertainty factor of 50. The LOAEL was based on several studies that have shown neurological symptoms of mercury toxicity in adults at blood levels of mercury in the range of 200 to 500 ng/ml. The 200 ng/ml mercury levels in blood have been associated with an oral intake in adults of 3 μg/kg/d of mercury and with adult hair concentrations of 50 μg/g. The uncertainty factor of 50 is composed of a 10-fold factor to adjust the LOAEL to a NOAEL and an additional 5-fold factor to ensure the criterion will provide protection from the potential fetal effects of mercury exposure via maternal ingestion of mercury contaminated fish.

ii. Comments: Several commenters agreed with the EPA criterion and the choice of the study and uncertainty factors. Other commenters agreed with the mercury criterion but disagreed with the basis for developing the criterion. These commenters stated that the LOAEL should be based on studies indicating fetal effects on the central nervous system occur at a LOAEL of 10 μg/g in maternal hair. They argue that if the 10 μg/g LOAEL is used, the 5-fold uncertainty factor to ensure the criterion will provide protection from potential fetal effects would not be needed.

iii. Final Guidance: EPA continues to believe the adult LOAEL of 3 μg/kg/d should be used in the derivation of criterion instead of the 10 μg/g maternal hair concentrations suggested by the commenter. EPA believes the adult effects are more clearly delineated from the available data than the fetal effects and thus the use of a LOAEL of 3 μg/kg/d (50 μg/g adult hair concentrations) is appropriate. The LOAEL of 10 μg/g maternal hair concentrations is predicted and therefore can be viewed as a somewhat less reliable endpoint upon which to base a criterion than the adult endpoints. EPA continues to believe the 5-fold uncertainty factor is justified to protect central nervous systems development during the sensitive fetal life stages. In addition, as discussed in section 5.a. above, EPA has assumed a body weight of 65 kg (as opposed to 70 kg) for mercury. The resulting Tier I mercury criterion is therefore 1.9 ng/L, which is slightly less than the proposed criterion of 2 ng/L.

Since the proposal, EPA's RfD work group has recently revised the RfD, using an effect level of 1 μg/kg/d and using an uncertainty factor of 10 to account for within-human variability and for an insufficient data base. The resulting RfD is 0.1 μg/kg/d which is higher than the proposed RfD (ADE) of 0.06 μg/kg/d. However, because the new RfD of 0.1 μg/kg/d was not verified until early February 1995, it was not possible to publish the data, request comment, and revise the final Guidance, if needed, prior to promulgation of the final Guidance. Consequently, EPA plans to publish a Notice of Data Availability after the publication of the final Guidance with the new mercury assessment for human health and will change the final mercury criteria for human health if appropriate.

E. Relationship of the Great Lakes Initiative Guidelines to National Guidelines Revisions

1. Proposal: As stated in the proposal, much of the Great Lakes methodology for deriving human health criteria was based on the 1980 methodology and advances in the science since 1980. Concurrent with the development of the final Guidance, EPA is also in the process of reviewing and revising the 1980 National Guidelines which would apply to development of EPA National water quality criteria under section 304(a) of the CWA. It is

expected that a proposed revision to the National guidelines will be published in the Federal Register in 1995 and that there will be a separate opportunity for public comment on that proposal. In the proposal, EPA discussed the possibility of making no change from the current 1980 methodology. Accordingly, EPA requested comments on the possibility of retaining the approach set forth in the 1980 National Guidelines with respect to each individual component of the proposal that differs from the current National guidelines.

2. Comments: A few commenters stated that EPA should retain the 1980 methodology but these commenters did not discuss why EPA should take such an approach. The majority of commenters were in favor of EPA using the best science in conducting any risk assessment which becomes the basis for water quality criteria. Other commenters stressed that EPA must strive for consistency between the methodology presented in the proposal and the revised national methodology.

3. Final Guidance: EPA believes it has presented a methodology which reflects the best science to date. EPA also believes it is essential to revise the 1980 National Methodology to reflect the latest science and policy of the EPA and the scientific community. Prior to revising the Guidelines EPA will request comments on the latest developments in draft EPA policy such as the draft revised Cancer Guidelines, the proposed policy on body weight to surface area scaling, and the proposed RSC policy. Until EPA's revised policies are finally adopted, after consideration of public comments, EPA believes it would be premature to adopt such revisions as part of the final Guidance.

With regard to fish consumption, EPA has not yet revised its national policy on developing a fish consumption rates However, in the final Guidance, EPA believed it was appropriate to develop a regional fish consumption rate for the protection of the population of the Great Lakes basin and therefore adjusted the national fish consumption rate accordingly with regional consideration in mind.

F. Comparison with the CWA and Great Lakes Water Quality Agreement

The Great Lakes Critical Programs Act of 1990 (CPA) states that the proposed Guidance shall be no less restrictive than the provisions of the CWA and national water quality criteria and guidance. The CPA also specifies that the final Guidance is to conform with the objectives and provisions of the Great Lakes Water Quality Agreement (GLWQA). The discussion below addresses conformance of the final human health methodologies and criteria with these requirements.

1. Tier I Criteria/Methodology

a. Comparison with the CWA.

Under the authority of section 304(a)(1) of the CWA, EPA established the 1980 National Guidelines, to be used in deriving National human health criteria. EPA believes that although the final Tier I human health criteria methodology and the criteria are not identical to the 1980 National Guidelines and individual National criteria in all details, they are generally no less restrictive.

First, as discussed above in this section of the document, EPA finalized Tier I human health criteria for 18 pollutants for which National criteria exist. These pollutants include a broad selection of pollutants of initial focus proposed by the Initiative Committees to test the proposed methodology. Although the final Guidance includes only these 18 pollutants while National human health criteria are currently available for 91 pollutants, EPA believes that this approach will not result in less stringent levels of control. This is because under the implementation scheme presented today, Great Lakes States would be required to derive criteria and values for these pollutants and for all other pollutants except those listed in Table 5 of part 132 whenever sufficient data exist to meet Tier I or Tier II minimum data requirements and the State determines that it is necessary to control these pollutants. Thus, the scope of the final Guidance in terms of pollutants covered is actually broader than the current National guidance.

Furthermore, because the Tier I criteria for human health assume a higher fish consumption rate than the national criteria, use BAFs rather than BCFs to calculate fish tissue residues, and include relative source contributions for all noncarcinogens the final numeric criteria are equivalent to, or more restrictive than, the current national criteria.

b. Conformance with the GLWQA. For the reasons stated in section III.D (Aquatic Life) of this document, EPA believes that the final Guidance conforms to the General Objectives of the Agreement regarding the elimination or reduction of discharges into the Great Lakes System. For the 18 pollutants for which Tier I human health criteria have been derived, the final Guidance criteria are more stringent than the water quality criteria presented in the Agreement, except for lindane. The GLWQI criterion for lindane is based on noncancer effects. EPA is currently reviewing the carcinogenicity of lindane. EPA believes that a cancer criterion for lindane would be lower than the GLWQA for lindane.

2. Tier II Criteria/Methodology

a. Comparison with the CWA. EPA's current guidance and regulations for water quality standards contain nothing directly analogous to the two-tier approach proposed today for human health. States currently have very broad discretion when regulating pollutants that are subject only to narrative criteria. EPA believes that the final Guidance is more rigorous than the current National requirements in this area because the Tier II methodology derives generally more conservative values for non-cancer criteria to compensate for greater uncertainty in the data base. Based on studies done to date, EPA expects that Tier II values will be more stringent than existing standards for these pollutants in most cases. Further, this approach imposes a structure to the process of translating narrative criteria into numeric values. Finally, the final Guidance will result in more uniform control of pollutants lacking National standards in the Great Lakes States.

b. Conformance with the GLWQA. EPA believes that the Tier II methodology is consistent with the General Objectives of the Agreement. Moreover, it serves as a translator mechanism of the States' narrative water quality standards. The Tier II methodology will enhance regulatory efforts in the Great Lakes basin, will serve its purpose of promoting consistency in the regulation of toxics in the Great Lakes basin, and is therefore also in conformance with the Agreement.

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VI. WILDLIFE

A. Introduction

For the purposes of the final Guidance, "wildlife" is defined as all non-domesticated species in the taxonomic classes Aves and Mammalia (birds and mammals). The final Guidance for deriving wildlife criteria is provided in appendix D to part 132. The final Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria (EPA 820-B-95-009) (Wildlife TSD) and the final Great Lakes Water Quality Initiative Criteria Documents for the Protection of Wildlife: DDT and Metabolites; Mercury; 2,3,7,8 TCDD; and PCBs (EPA 820-B-95-008) (Wildlife Criteria Documents), which provide the data and the derivation of each individual criterion, are available in the docket for this rulemaking.

As stated in the proposal and in section I (Background) of the final Guidance, wildlife in the Great Lakes are at risk from contaminants in Great Lakes water. To address this problem, the proposal presented a methodology for deriving criteria and values that would likely be protective of wildlife within the Great Lakes basin. EPA requested comments and asked for additional information on several topics relating to the methodology. Described below is a summary of the proposal for that topic, significant comments received (with EPA's response to each), and the requirements of the final Guidance. Responses to all comments received are provided in the Response to Comments Document, which is included as part of the docket for the final Guidance.

Currently, there is no National methodology for the development of water quality criteria for the protection of wildlife comparable to the proposed Guidance; however, there is a mechanism for consideration of wildlife impacts within the 1985 National aquatic life criteria guidelines (Stephan et al., 1985). While the aquatic life methodology provides a mechanism to protect against bioaccumulation of a compound within a food web, it has several limitations. The current approach in the national aquatic life guidelines to provide protection to wildlife is the use of the final residue value (FRV), which represents the highest prey tissue concentration of a toxicant which will not produce an adverse effect in the consumer organism. The FRV is derived through one of three approaches: either from a Food and Drug Administration (FDA) action level; a long-term wildlife field study; or a chronic wildlife feeding study. Because an FDA action level is intended to protect humans, and not wildlife, an FRV derived from an FDA action level for a specific contaminant does not ensure protection of wildlife species which may consume contaminated aquatic organisms as a larger portion of their diet or exhibit a greater sensitivity than humans. While an FRV may be more adequate based on a long-term wildlife field study or a chronic wildlife feeding study, there are very few chemicals for which these studies are available. In addition, such studies are frequently only conducted after the chemical has been theorized to be responsible for a problem in the environment.

In cases where no FRV is available, biomagnification of a chemical into the higher trophic levels of a food web, and potential impacts on these wildlife species, is not considered in the derivation of the aquatic life criterion.

EPA has begun a separate effort to derive National wildlife criteria. Following the release of the 1987 General Accounting Office (GAO) report entitled "National Refuge Contamination is Difficult to Confirm and Clean Up," (GAO, 1987), EPA began to work cooperatively with the U.S. Fish and Wildlife Service to develop methods for deriving National wildlife criteria. The wildlife criteria efforts carried by the Initiative Committees have been coordinated with the on-going National efforts. Because the effects on wildlife may not be accounted for in other methodologies for deriving water quality criteria, the proposed methodology was developed to address this deficiency. The proposed methodology contained both an effect and an exposure component to account for varying species susceptibility to chemical intoxication, and dissimilar feeding and drinking behaviors and natural histories.

B. Scope of Methodology

1. Proposal: The proposed wildlife methodology was based largely on the noncancer human health paradigm described in appendix C to part 132. The methodology, like the aquatic life and human health methodologies, included a two-tiered approach for deriving wildlife criteria and values, as described in the proposal (58 FR 20878). The main difference between the two tiers in the proposed Wildlife methodology was the extent of the data base needed to generate a final wildlife criterion or value. In order to generate a Tier I criterion, data from both mammals and birds were required. Separate values for mammals and birds were developed with the lower of the two values being the final Tier I criterion. In order to generate Tier II values, data from either mammals or birds were required. This value was modified by an interclass uncertainty factor (UF) to account for sensitivities between taxonomic classes, and was then applied as the Tier II wildlife value. Because the rationale behind Tier II values was that they were to be typically more stringent than Tier I criteria, due to the smaller data set available, it was expected that the magnitude of some of the UFs applied in the derivation would be larger.

2. Discussion of Comments

Comment: Some commenters believed that the focus of the wildlife methodology is misdirected because other factors, such as habitat destruction and exotic species, are more important than toxic contaminants in affecting species' viability in the Great Lakes System.

Response: EPA disagrees that the wildlife methodology focus is misdirected. As discussed in section I of this document, research on wildlife species resident in the Great Lakes indicates that some wildlife populations remain threatened in areas of high contamination by toxic chemicals. In the Great Lakes, reproductive impairment of numerous wildlife species has been correlated with the presence of polychlorinated biphenyls (PCBs), p,p'-dichlorodiphenyltrichloroethane (DDT) and its metabolites, and other contaminants (58 FR 20806).

Because many wildlife species are at the top of the aquatic food web, current water quality criteria derived to protect fish may be inadequate to protect wildlife who consume contaminated fish. Wildlife are especially at risk from chemicals which biomagnify because they are frequently exposed to very high levels of these contaminants because many species feed primarily from aquatic food webs. For this reason, emphasis was placed on selecting piscivorous wildlife species (i.e., those which eat fish) for the derivation of wildlife criteria as to represent species likely to experience significant contamination through an aquatic food web. Wildlife species may also be uniquely susceptible to some chemicals, as compared to aquatic species.

EPA acknowledges that other factors, such as habitat destruction and introduction of exotic species are impacting species viability in the Great Lakes System. EPA has programs in place that are attempting to address many of these problems; however, this does not mean that toxic chemical discharges into the Great Lakes basin are not also adversely affecting species viability. As discussed in section I, and in U.S. EPA (1995b), effects of toxic chemicals on wildlife species continue to be a problem.

Comments: Many commenters expressed general concerns over the scientific soundness of the proposed methodology. In particular, some were critical of the use of the noncancer human health paradigm as a model for ecological risk assessment (which might include an assessment of all ecological stressors on all components of the ecosystem). Those commenters were also concerned that the effect component of the noncancer human health paradigm methodology is based on individual-level, rather than population-level measurement endpoints. Some commenters recommended either delaying implementation of the methodology, or making the methodology just guidance.

Responses: EPA agrees that the use of the noncancer human health paradigm does not consider all potential stressors on an ecosystem. However, the final wildlife methodology is not designed to be a comprehensive model for assessing all ecological risk to the entire Great Lakes ecosystem. Instead, the intent of the methodology is to initially focus attention on those avian and mammalian species in the System which are likely to experience significant exposure to contaminants through aquatic food chains. The methodology specifically excludes reptiles and amphibians because there is currently insufficient toxicity data for these species and insufficient understanding of exposure routes to estimate risks from toxic contaminants to include these groups in the methodology. While it would be better to provide a comprehensive ecological risk assessment approach for chemical and non-chemical stressors to the System, it is currently not possible given the many data gaps and enormous resources required to develop such an approach. As explained below, EPA finds the noncancer human health paradigm to be appropriate for the avian and mammalian species on which the method focuses.

EPA considered not including the methodology in the final Guidance until a more comprehensive multi-stressor risk assessment approach could be designed. However, this option was rejected because such a program will take many years to develop and a sound wildlife methodology was available at this time to provide protection to those species at greatest risk from persistent, bioaccumulative pollutants. EPA selected a reasonable approach to address the adverse ecological effects from toxic contaminants in the Great Lakes System. In addition, based on the results from the two National meetings and the April 1994 EPA Science Advisory Board (SAB) (U.S. EPA, 1994a) commentary (discussed below), EPA concludes that the paradigm is a scientifically reasonable approach to address impacts from bioaccumulative compounds on avian and mammalian species in the Great Lakes at this time.

During the development of the wildlife methodology, EPA hosted two public meetings held in December 1989 and April 1992, (U.S. EPA, 1989, 1994b) as part of a national effort to develop methodologies to protect wildlife criteria. During both of these meetings, there was general consensus that the proposed Guidance methodology was fundamentally sound from bioaccumulative contaminants. In addition, other concepts developed for the national program were extensively used in the development of the wildlife portion of the final Guidance.

Finally, EPA discussed the use of the proposed paradigm for developing water quality criteria to protect wildlife with EPA's SAB in February 1992 and April 1994 (U.S. EPA, 1992, 1994a). The report from the February 1992 SAB (U.S. EPA, 1992) meeting indicated concern with the wildlife criteria concepts being formulated around the perceived requirements of the noncancer human health paradigm, which might be inadequate for wildlife. In response to the SAB's commentary, EPA made several changes that were discussed in the proposed Guidance (see 58 FR 20882). The April 1994 SAB commentary (U.S. EPA, 1994a) stated that, while the use of the noncancer human health paradigm for the development of wildlife criteria is in the early stages of development, it promises to be an innovative and valuable new method for understanding the fate and effects of contaminants in the environment. Based on the changes made to the methodology in response to the February 1992 SAB commentary (U.S. EPA, 1992) and the support for the use of the methodology expressed by the report from the April 1994 SAB commentary (U.S. EPA, 1994a), the paradigm being pursued is appropriate for the species and stressors EPA is currently addressing.

EPA also does not agree that the wildlife methodology focuses too extensively on the protection of individuals. The methodology focuses on population-level impacts by restricting the toxicological measurement endpoints on which a criterion is based to those that are likely to adversely affect populations. If these toxic responses were observed in wildlife populations in the Great Lakes System, the continuation of breeding populations of the wildlife species could be jeopardized. The SAB (U.S. EPA, 1994a) endorsed the basis of the wildlife criteria on the protection of wildlife populations from the direct effects of chemical stressors.

There are two distinctions between the noncancer human health paradigm and the wildlife approach used in the proposal. Because the wildlife approach is designed to protect populations and not individuals, the wildlife paradigm does not include an intraspecies UF (although exceptions can be made in cases where toxicological or exposure data suggest that species listed pursuant to section 4 of the Endangered Species Act will not be protected by system-wide criteria) to ensure better protection of toxicologically sensitive members of a given population. Further, the selection of toxicological endpoints in the wildlife methodology is restricted to gross endpoints likely to adversely affect population dynamics (i.e., reproductive or developmental effects). This approach is consistent with the recommendation from the SAB (U.S. EPA, 1994a), but is different from the human health methodology which focuses on the effects on individuals. This is illustrated by comparing the Human Health criteria documents with the DDT section in the final Wildlife Criteria Documents. Both documents reference the same study, but the same dose level considered a No Observed Adverse Effect Level (NOAEL) for wildlife criteria derivation, based on reproductive endpoints, is cited as a Lowest Observed Adverse Effect Level (LOAEL) in the noncancer human health criteria document, based on liver lesions as an endpoint. Examples of acceptable endpoints are made available in the final Wildlife Criteria Documents, as well as in the proposal (58 FR 20882).

Comments: The use of Tier II wildlife values was generally criticized by many commenters who believe there were technical weaknesses with the methodology and because of insufficient data being used to derive these values. Some commenters were concerned with the resource requirements to derive wildlife criteria or values for the entire universe of pollutants. Some commenters supported the use of Tier II values for wildlife.

Responses: The methodology for deriving Tier II values is sound. EPA agrees, however, with commenters that the data for deriving wildlife values is currently limited. In addition, EPA agrees with those commenters who cautioned against advancing too rapidly with a new methodology before additional field validation can be made. Therefore, during review of comments received on the proposal, EPA reconsidered the scope of application of the wildlife methodology. EPA decided to limit the methodology to bioaccumulative chemicals for which the determining route of exposure is through the diet. EPA still agrees, however, that the methodology can be modified to derive reasonable wildlife values where other exposures become significant. For non-bioaccumulative chemicals, it may be more appropriate to select different representative species which are better examples of wildlife species with the greater exposure for a given chemical.

In addition, EPA decided to limit the methodology to require developing only Tier I criteria for several reasons, including concerns that a Tier II value, which is based on toxicity data from only one taxonomic class, could not be protective of wildlife species in other taxonomic classes when there is evidence of wide differences in sensitivities across classes. Further, a Tier II value is based on an interclass UF that is not used in deriving a Tier I criterion, making the uncertainty inherent in the value potentially unreasonably greater. Finally, the proposed wildlife methodology was a new approach to ecological risk assessment for wildlife. EPA believes, however, that the taxonomic class-specific wildlife values provide adequate protection for species of that class, even where toxicity data from other classes are missing.

3. Final Guidance: Based on the above discussion, the use of the proposed methodology is appropriate and the methodology does not emphasize on individual effects.

However, EPA has decided to modify the scope of the final wildlife methodology. The final Guidance requires the States or Tribes to use the methodology to derive Tier I numeric wildlife criteria for only the bioaccumulative chemicals of concern (BCCs) listed in Table 6-A of part 132. EPA considered making the methodology optional for all chemicals, as advocated by some commenters, but decided that the methodology was advanced enough to use for those chemicals of greatest concern (BCCs) to the higher trophic level wildlife species feeding from the aquatic food webs in the Great Lakes basin.

For the development of Tier II wildlife values for all pollutants, use of the proposed Tier II methodology is encouraged, but not required. To derive Tier I numeric wildlife criteria for chemicals not listed in Table 6-A of part 132, the methodology contained in the final Guidance is also encouraged, but not required. While States or Tribes may develop and implement additional Tier I criteria or Tier II values as deemed necessary, any derived Tier I criterion remains subject to EPA review and approval at 40 CFR part 131. In the event that the methodology is used to derive Tier I criteria for pollutants not listed in Table 6-A of part 132 or to derive Tier II values, States and Tribes are also encouraged to use the methodology for deriving bioaccumulation factors (BAFs), described in appendix B to part 132.

C. Effect Component

As with the noncancer human health methodology, the wildlife methodology consists of both an effect and an exposure component. The effect component is determined by the toxicity data and the UFs used to account for uncertainties in predicting an appropriate test dose (TD) for wildlife species.

1. Minimum Data Requirements

a. Proposal: The effect component of the proposed methodology was defined by the NOAEL, which is the maximum concentration of the toxicant in the food of the test species which did not cause adverse effects to those test organisms. A NOAEL is derived from published studies from which dose-response curves can be developed. EPA proposed that the NOAEL selected must be based on studies of adequate length (i.e., a minimum of 90 days for mammals, and 28 days for birds) so that chronic effects may be reasonably expected to be expressed. The use of a LOAEL, adjusted by an UF, could be used to derive criteria where an acceptable NOAEL was not available. A LOAEL is defined as the lowest concentration of the toxicant in the diet of the test species which produces an adverse effect on the test organisms.

The acceptable observed endpoints in these toxicity studies were those that are directly or indirectly related to maintaining viable wildlife populations. Examples of endpoints which would reasonably be expected to be related to the reproductive or developmental success of the species included the number of viable young per female, or hatching or whelping success.

The proposal also established an order of preference for selecting the appropriate NOAEL or LOAEL to be used to calculate individual wildlife values for each taxon. Field study data were preferred over laboratory data, but the latter could be used in place of field study data if best professional judgement deemed it to be of better quality. Examples of circumstances where laboratory data may be more appropriate than field study data include cases where: dose-response curves or cause-effect relationships cannot be established for the field study because of the design of the field study; because the effects of other stressors cannot be identified or controlled; where laboratory data are determined to be more consistent with other published data than are field data; or, where there are quality control concerns.

b. <u>Comments:</u> Many commenters argued that the minimum exposure durations required for toxicity studies were too short to adequately evaluate the potential reproductive effects of chemicals. Other commenters either supported or challenged the use of field studies in the development of wildlife criteria. Commenters in support argued that field studies provide a reasonable estimate of the impact of chemicals in a natural setting, incorporating actual exposures and metabolic impacts of the chemicals. Commenters opposed to the use of field studies believed that current studies were not constructed to provide quality data or adequate controls to satisfy the intent of the final Guidance. In addition, EPA received comments recommending that existing field studies be used to validate criteria as they are derived.

<u>Responses:</u> The endpoints of concern, as defined in the proposed methodology, were those expected to impact adversely the reproductive or developmental success of a species. The intent of establishing the minimum study duration was to limit the use of short-term acute toxicity information because it may not fully reflect potential impacts on the endpoints of concern (i.e., reproduction and development), and, therefore, could result in an under-protective criterion. EPA agrees that longer-term studies, including multi-generational studies, are desirable and should be used where available. It is also important not to make the study duration requirements so long that most available data, which could be used to derive wildlife criteria or values, was eliminated.

The study duration of 90 days for mammals is consistent with the minimum requirements established in the 1980 Human Health National Guidelines (45 FR 79347) and in the final Guidance for developing noncancer human health criteria (Appendix C.II.1 to part 132). In that guidance, "subchronic" toxicity tests are defined as continuous or repeated exposures for a period of 90 days, or approximately 10 percent of a rat's lifespan. EPA acknowledges that the test species used for development of wildlife criteria could have significantly different life-spans than a rat, and therefore permit some flexibility in the selection of an appropriate study. However, rat data are allowed to be used in deriving wildlife criteria with the proper use of UFs; therefore, it is reasonable to use a minimum 90-day study duration for wildlife.

The minimum study duration for bird taxa was changed from 28 days to 70 days. The 70-day period was selected to conform with established EPA test protocols for reproductive effects on avian species, described in U.S. EPA (1986). If a study evaluates impacts on growth or mortality of chicks, post-hatching, 28 days may be an adequate exposure duration.

EPA continues to support the use of field studies in the development of wildlife criteria because such studies can be used to predict the impacts of chemicals in the environment, by integrating food web, dietary preferences, and metabolic considerations. EPA cautions that both field study data and laboratory study data must be carefully reviewed and evaluated for their usefulness and adequacy in deriving wildlife criteria. Where appropriate, and based on best professional judgement, EPA supports the use of laboratory data over field study data when it has been determined that the laboratory data are of better quality and are more likely to predict impacts on wildlife species. EPA also supports the use of any other appropriate data to validate not only the derived criterion, but any and all UFs and exposure parameters used in the derivation of that criterion.

The final Wildlife TSD provides further guidance on the appropriate selection of toxicity data, including proper evaluation of studies.

c. Final Guidance: A Tier I criterion is based on toxicological data of sufficient duration (generally 90 days or more for mammals and 70 days or more for birds) from which a dose-response curve may be developed. Assuming a dose-response or a cause-effect relationship can be established, field studies remain the preferred type of data for deriving a TD, although laboratory data continues to be allowed if it is determined to be of better quality and more appropriate, or where field data are lacking.

2. UFs

a. Proposal: EPA proposed to allow the use of UFs to address uncertainty in any extrapolation of toxicity data to an appropriate endpoint. For chemicals lacking an acceptable NOAEL, the LOAEL could be substituted, with the application of an UF (ranging from 1 through 10) to extrapolate to an estimated NOAEL. The minimum test durations for the use of LOAELs were the same as for NOAELs (28 days for birds, and 90 days for mammals); these differ from the noncancer Human Health methodology for Tier I criteria, which requires a LOAEL to be based on a one year or longer rodent study. The one-year requirement provides a level of conservatism which is not needed for the protection of wildlife populations, where species typically have shorter life-spans and reproductive cycles (see 58 FR 20879).

In cases where a chronic endpoint was not observed, but subchronic effects were expressed which could reasonably be expected to lead to chronic effects in a longer study, these data could be used with the application of a subchronic-to-chronic UF. The range proposed for this factor was 1 through 10 (see 58 FR 20879).

Because the species tested may not necessarily reflect the sensitivities of a representative wildlife species in the Great Lakes System, an additional UF, the species sensitivity factor, could be applied to extrapolate to protect species of greater sensitivity than the test species. In the proposal, this factor ranged from 0.01 through 1 and was applied as a multiplier, rather than a divisor, as were the other UFs described above (see 58 FR 20880).

Finally, in the proposal (58 FR 20881) EPA requested comment on an alternate formula. This formula was functionally the same as the proposed formula, except that each of the UF_S was explicitly included in it.

b. Comments: Several commenters considered the use of UFs inappropriate because it could result in overly conservative criteria because the factors are multiplicative in nature, thereby resulting in large uncertainties being applied. Commenters also suggested that there is an insufficient data set available to evaluate the appropriateness and range of these factors. Other commenters complained that there was insufficient guidance to choose appropriate UFs in the ranges provided. A number of commenters expressed a preference for using the alternate equation described in the proposal. They believed this equation more clearly described the application of the UFs in the methodology.

Responses: EPA believes that the use of UFs is appropriate. Wildlife UFs are needed for several reasons, including the limited amount of available toxicological data, test duration, observed endpoints, and differences in the sensitivities among wildlife taxa. All of these factors introduce uncertainty into the criterion derivation process, making the precise determinations of the effect of ambient concentrations of specific chemicals on wildlife populations difficult.

EPA agrees that any UF must be applied with careful consideration of the magnitude of the factor; however, the ranges for the UFs proposed for the wildlife methodology are reasonable. In the proposal, the data to support the appropriateness and range of specific UFs was, in most cases, from work that had been completed for human health.

Subsequent to the proposal, EPA performed work that confirms the ranges of the UFs used for wildlife. The analysis to support the range of interspecies UFs of 1 to 100 involved examinations of acute and chronic toxicity data. The analysis compared median lethal doses for numerous species for a variety of chemicals. The results indicate that approximately 90 percent of the median lethal doses among the species for the same chemical tested were within a factor of 20. The chronic toxicity analysis involved a review of data for four chemicals (including DDT and mercury). It was determined that 90 percent of the chronic endpoints for each species were within two orders of magnitude of the corresponding NOAELs for the other species tested.

Regarding the basis of the LOAEL-to-NOAEL UF, results indicate that 95 percent of the ratios of LOAELs to NOAELs for birds and mammals are less than 10. Finally, the recommended range of the subchronic-to-chronic UF is supported by previous reviews on the toxicity of chemicals to laboratory mammals, and a new analysis of toxicity to birds. In two separate reviews more than 95 percent of the ratios of the NOAELs for subchronic exposures (approximately three months) to NOAELs for chronic exposures (approximately two years) were less than 10 (Weil and McCollister, 1963; McNamara, 1976). More detailed information is provided in the final Wildlife TSD and in U.S. EPA (1995b).

Although a cumulative UF of 10,000 is possible, the range of the combined UFs for the four chemicals listed in Table 6-A of part 132 range from six to 10. In comparison, the Human Health methodology, section V.C.4.b.ii, estimates a likely maximum composite UF of 3,000. Therefore, while it is possible to use a large cumulative UF for a chemical, in practice the magnitude of the UFs in the final criteria are likely to be small. EPA considers it unlikely that a State or Tribe will derive cumulative UFs that are significantly higher. To ensure that UFs remain reasonable, EPA recommends that States or Tribes consider a cap on the maximum composite UF of 1,000 because composite UFs greater than 1,000 may indicate a level of uncertainty that is unacceptable.

EPA believes it has provided sufficient guidance on the selection of UFs. Even so, it is important to note that the selection of UFs will, in many situations, be based on best professional judgement. EPA anticipates that the Clearinghouse described in section II of this document will provide a forum for assisting in selecting appropriate UFs for chemicals.

EPA agrees that the alternate equation is preferred because it eliminates the potential confusion of having to multiply the TD by the species sensitivity factor, while at the same time dividing the subchronic-to-chronic and LOAEL-to-NOAEL factors into the TD. Instead, all UFs are divided directly into the TD. In addition, the term "species sensitivity factor" has been changed to "interspecies UF" to reduce potential confusion regarding its use.

Several changes were made to the alternate equation as proposed. The intraspecies UF was removed, which was to be applied when additional protection of the individual or more sensitive members of a species was deemed appropriate. Guidance for modifying the criteria to provide for this added protection is provided in procedure 1 of appendix F to part 132, and in the final Wildlife TSD. In addition, the subscripts for the three remaining UFs were changed to be consistent with U.S. EPA (1991). Finally, several of the representative species feed at two or more trophic levels, which was not readily apparent in the proposed equation. To more clearly characterize uptake through food, the food ingestion rate for each trophic component has been separately calculated, and these are presented in Table 1 (discussed below). Contaminant uptake through the food is calculated by summing all the products of the trophic level-specific food ingestion rates and the appropriate BAF.

During its review of the UFs, EPA considered including in the equation (described in the final Guidance section, below) an allometric scaling factor to derive doses which would be more toxicologically equivalent when extrapolating from test animals to the representative species, based on differences between the species' body weights and metabolic rates. This is because the current state of the science indicates that some of the variability in sensitivity across species can be related to general physiological and anatomical differences observed across organisms within the same taxonomic class (e.g., mammals). The rates of such processes, such as basal metabolic rates, cardiac output, renal clearance, oxygen consumption, food consumption, and water consumption, tend to vary across species according to allometric scaling factors that can be expressed as a non-linear function of body weight. The relationship of these and other physiological processes to toxicokinetics has led to the explicit use of allometric scaling for estimating more toxicologically equivalent doses in EPA's human health cancer methodology and its implicit use in the human health noncancer methodology. EPA recommends that in the determination of an interspecies UF, States or Tribes apply the equation below to assess the allometric scaling factor for each representative species and to consider that assessment as one component in the determination of an appropriate interspecies UF. This equation was endorsed by EPA in 1992 (57 FR 24152). In the derivation of wildlife criteria, allometric scaling is useful in adjusting for some of the toxicokinetic differences across species. However, it may not accurately reflect the toxicokinetics of all chemicals nor encompass all the toxicodynamic differences among species. Therefore, in determining an interspecies UF, allometrically-derived TDs should be considered in conjunction with chemical class-specific information on sensitivity, toxicokinetics, and toxicodynamics across species. This is consistent with the guidance provided in the SAB commentary (U.S. EPA, 1994a) which stated that allometric relationships should not be the sole basis for selecting an interspecies UF.

$$TD_R = TD_T * \left(\frac{Wt_T}{Wt_R}\right)^{1/4}$$

where: TD_R = Test Dose scaled for the given representative species in question (mg/kg-d).

TD_T = TD for the test species (mg/kg-d).

Wt_T = Body Weight of the test species (kg).

Wt_R = Body Weight of the given representative species (kg; presented in Table 1).

c. <u>Final Guidance:</u> The use of the LOAEL-to-NOAEL, subchronic-to-chronic, and interspecies UFs described in the proposal (58 FR 20879) remain in the final Guidance, although they are applied as divisors in the equation, consistent with the preferred alternate equation, as well as for clarity as to their application. Their ranges remain as in the proposal, 1 through 10, except for the interspecies UF which ranges from 1 through 100 (the mathematical inverse of its counterpart, the species sensitivity factor, contained in the proposal).

In addition, the alternate equation, as modified in accordance with the above discussion, has been selected for the final Guidance:

$$WV = \frac{\frac{TD}{UF_A \times UF_S \times UF_L} \times Wt}{W + \sum (F_{TLi} \times BAF_{TLi}^{WL})}$$

Where:

WV = Wildlife Value in milligrams of substance per liter (mg/L).

TD = TD in milligrams of substance per kilograms per day (mg/kg-d) for the test species. This shall be either a NOAEL or a LOAEL.

UF_A = UF for extrapolating toxicity data across species (unitless). A species-specific UF shall be selected and applied to each representative species, consistent with the equation.

UF_S = UF for extrapolating from subchronic to chronic exposures (unitless).

UF_L = UF for LOAEL to NOAEL extrapolations (unitless).

Wt = Average weight in kilograms (kg) for the representative species.

W = Average daily volume of water consumed in liters per day (L/d) by the representative species.

F_{TLi} = Average daily amount of food consumed from trophic level i in kilograms per day (kg/d) by the representative species.

BAF_{TLi}^{WL} = BAF for wildlife food in trophic level i in liters per kilogram (L/kg), developed using guidelines for wildlife presented in appendix B to part 132, Methodology for Development of Bioaccumulation Factors. For consumption of piscivorous birds by other birds (e.g., herring gulls by eagles), the BAF is derived by multiplying the trophic level 3 BAF for fish by a biomagnification factor (BMF) for biomagnification from fish to birds.

D. Exposure Component

The proposed exposure component of the wildlife methodology consisted of three general areas: selection of the representative species; exposure parameters for those representative species; and use of BAFs specific for wildlife diet. The first two areas will be discussed below. For a discussion on the BAFs refer to section IV of this document.

1. Representative Species

a. Proposal: During the development of the proposed methodology, EPA considered using a hypothetical model wildlife species on which to base the derivation of wildlife criteria or values. EPA decided, however, to use actual Great Lakes System species representing various foraging behaviors at upper trophic levels and, therefore, greater exposure than other wildlife species inhabiting the Great Lakes System. In addition, the use of representative species allowed a basis for deriving an appropriate interspecies UF in cases where it is known that there are more sensitive species than the species from which the NOAEL was derived. This would have been difficult to determine if a hypothetical model wildlife species was used.

Five species were proposed as the representative species: two mammals, the mink (Mustela vison) and river otter (Lutra canadensis); and three birds, the belted kingfisher (Ceryle alcyon), osprey (Pandion haliatus), and bald eagle (Haliaeetus leucocephalus). These species were proposed based on geographic distribution, dietary habits, and the trophic level of their prey. EPA did not consider routes of exposure other than through the aquatic food web in selecting representative species because of the focus on bioaccumulative pollutants.

b. Comments: While some commenters expressed support for the selection of the five representative species, other commenters argued that these species are not ecologically representative of the Great Lakes wildlife species because they may not be widespread throughout all parts of the Great Lakes System, nor are they resident in all ecological habitats. Other commenters recommended replacing or adding species, such as gulls, cormorants, or the raccoon.

Responses: EPA agrees that the proposed species selected may not be ecologically representative of all the possible wildlife species in the Great Lakes System, but they were not selected for this reason. Rather, EPA's intent was to select disparate species most likely to be exposed to environmental contaminants from aquatic ecosystems to serve as surrogates of wildlife species that are highly exposed to toxicants from the aquatic food chain. The representative species are not necessarily the most toxicologically sensitive species, nor do they represent species most likely to be exposed to bioaccumulative environmental contaminants from terrestrial ecosystems, or through other routes of exposure. It was not EPA's intent to select species to account for every available niche.

After reviewing comments which suggested the use of different representative species, EPA decided to replace the osprey with the herring gull (Larus argentatus) based on a re-evaluation of the exposure parameters of Great Lakes wildlife species, including species identified by commenters for inclusion on the list (e.g., raccoons, herring gulls, common terns, and double-crested cormorants). EPA first re-evaluated all five of the proposed species to determine if they are truly representative of the species that are the most likely to be exposed to environmental contamination through the aquatic ecosystem. EPA showed that, although the osprey is one of the more highly exposed piscivorous birds, it is not one of the most exposed and that the gull is potentially more exposed. In addition, the osprey's foraging behavior is similar to the bald eagle's and a bird with foraging behaviors different from the kingfisher and eagle would be preferred. The herring gull was selected because its body weight is roughly in between the eagle and the kingfisher, its food ingestion rate is greater than the osprey, and the trophic levels at which it feeds are higher (72 percent at trophic level 3, 18 percent at trophic level 4 and 10 percent terrestrial prey, compared to 100 percent at trophic level 3 for the osprey).

EPA also considered replacing the kingfisher with the common tern; however, the estimated exposure parameters for the two species were essentially the same, and either species could be used. Distribution attributes of the common tern that may make it appear a more representative of the Great Lakes ecosystem do not affect the derivation of the a wildlife criterion by the methodology in the proposed or final Guidance. EPA, therefore, retained the kingfisher as a representative of a small piscivorous bird feeding entirely on trophic level 3 fish.

No changes were made to the mammalian representative species because all other appropriate species in the Great Lakes System have much lower rates of consumption of aquatic organisms (e.g., raccoon) than either the mink or otter. (See U.S. EPA, 1995a.)

c. Final Guidance: Elements of the exposure component remain largely the same as the proposal: the use of five representative species, as described in the proposal, with the replacement of the osprey by the herring gull. The focus on the food and water uptake routes of exposure remains as in the proposal.

2. Exposure Parameters

a. Proposal: The routes of exposure to wildlife considered in the proposal were uptake through drinking the ambient water and uptake through dietary consumption of prey in the aquatic food web. EPA presumed that other routes of exposure (e.g., inhalation or trans-dermal uptake) were insignificant for these two taxonomic classes where bioaccumulative chemicals are concerned as in the case for the final Guidance. Exposure parameters were derived for each representative species, consisting of body weight, and food and water ingestion rates. In each case, the "average" individual was assumed. Where the ingestion rates could not be determined from published literature because of the lack of available data, use of allometric equations from Nagy (1987) were proposed. Additional information on the food and water ingestion rates selected may be found at 58 FR 21005.

The degree of accumulation of a contaminant at different steps in the aquatic food chain was determined through the application of BAF calculated pursuant to the proposed BAF methodology (58 FR 21022).

b. Comments: Several commenters criticized the use of the allometric equations to determine food and water ingestion rates because rates change throughout the life of the organism; others criticized the values of the rates presented in the proposal. Some commenters stated that the bald eagle diet consists in part of herring gulls, and that the methodology should be modified to reflect that route of exposure, taking into account the proper trophic level of the gull.

Responses: Where available, EPA continues to support the use of empirically-derived ingestion rates. EPA conducted a review of the available literature to re-evaluate ingestion rates used for the representative species. In this re-evaluation, EPA used empirical data (where available) or allometric equations to determine basal metabolic rates for free-living animals. Food ingestion rates were determined from the basal metabolic rates so different caloric contents of wildlife food could be considered. The revised exposure parameters are presented in Table 1, below.

TABLE VI-1. Exposure parameters for the five representative species identified for protection.

Species	Adult Body Weight	Water Ingestion Rate	Food Ingestion Rate of Prey for Each Trophic Level	Trophic Level of Prey
Units	kg	L/day	kg/day	Percent of diet
Mink	0.80	0.081	TL3: 0.159 Other: 0.0177	TL3: 90 % Other: 10 %
Otter	7.4	0.600	TL3: 0.977 TL4: 0.244	TL3: 80 % TL4: 20 %
Kingfisher	0.15	0.017	TL3: 0.0672	TL3: 100 %
Herring gull	1.1	0.063	TL3: 0.192 TL4: 0.0480 Other: 0.0267	Fish: 90 % TL3: 80 % TL4: 20 % Other: 10 %
Bald eagle	4.6	0.160	TL3: 0.371 TL4: 0.0929 PB: 0.0283 Other: 0.0121	Fish: 92 % TL3: 80 % TL4: 20 % Birds: 8 % PB: 70 % non-aquatic: 30 %

Note: TL3 = trophic level 3 fish
TL4 = trophic level 4 fish
PB = piscivorous birds
Other = non-aquatic birds and mammals

Because ingestion rate data, however, are very limited, EPA considers the use of the allometric equations presented in the methodology to be adequate when more specific measured values or more appropriate allometric equations are not available. In addition, EPA also supports the use of the estimation methods described in U.S. EPA (1993a) or the information contained in U.S. EPA (1988). The States or Tribes can at their discretion use any of the estimation methods or the allometric equations to derive ingestion rate data.

In the sensitivity analysis sections for each pollutant in the proposed Wildlife Criteria Documents, EPA considered the ingestion of mammals, non-fish eating birds, and fish-eating birds by the eagle. To define better the magnitude of the ingestion of these prey, EPA conducted an analysis described in the final Wildlife TSD and in U.S. EPA (1995a), which characterized the diet of all five representative species, including the eagle and other birds in the Great Lakes basin. Based on this analysis, the composition of the eagle's diet for the Great Lakes basin was modified. The method also incorporates the use of chemical-specific biomagnification factors to account for the accumulation of contaminants in piscivorous birds which serve as prey for the eagle. The final Wildlife TSD and the final Wildlife Criteria Documents further discuss this method for incorporating the biomagnification factor into the criteria.

c. Final Guidance: For use where ingestion data are lacking, the final methodology retains the use of the allometric equations from Nagy (1987) or the estimation methods contained in U.S. EPA (1993a).

EPA also made modifications to the body weight, and food and water ingestion rate exposure parameters for each of the five representative species. These modifications were based on the continued review of the technical literature, and as requested by commenters (see Table VI-1).

EPA also reviewed the dietary composition of each of the five representative species. EPA found that aquatic organisms comprise virtually all of the prey for two of the species: the river otter and kingfisher; however, the mink, herring gull, and eagle obtain a significant portion of their diets from mammals and birds. The contribution of these aquatic organisms to the uptake of the contaminant from the aquatic system by these three species is reflected through an appropriate weighting of the energy intake through the aquatic and terrestrial components of the diet, and by assuming zero uptake of the contaminant through the terrestrial component of the food chain.

To properly account for the exposure through the food chain, the portion of fish-eating prey in the diet must be quantified, and an appropriate adjustment factor (a BMF) for the fish-eating birds (prey) must be determined. The derivation and application of the BAF and BMF, and examples of how these calculations can be made are described in the final Wildlife TSD and in the final Wildlife Criteria Documents.

E. Protection of Individual Members of a Population

1. Proposal: The proposed methodology also made allowance for the protection of individuals in cases where decreasing population size or density threatened the continuing existence of the species in the Great Lakes System. An intraspecies UF, ranging from 1 through 10 could be applied in the effect component of the methodology, in a manner similar to the LOAEL-to-NOAEL, interspecies, or subchronic-to-chronic UFs.

2. Comments: Several commenters were concerned that the wildlife criteria did not allow enough flexibility in making site-specific modifications to existing criteria. Some commenters argued that the criteria should be waterbody-specific, and other commenters believed that site-specific modifications less restrictive than the System-wide criteria should be

allowed. EPA's response to this issue is addressed in section VIII.A. of this document.

F. Wildlife Criteria

1. Proposal: The proposed Guidance presented Tier I wildlife criteria for four pollutants: mercury (including methylmercury); PCBs; 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD); and DDT and its metabolites. A discussion of the TD, UFs, and other assumptions were fully described in the Wildlife Criteria Documents. No Tier II values were derived in the proposal.

2. Discussion: The four Tier I criteria listed in the proposal have been modified based on reconsideration of the applicable UFs, on revised exposure parameters for the final five representative species, and recalculation of the BAFs pursuant appendix B to part 132 of the final Guidance. Additional changes from the proposal, including changes to the UFs and the BAF used to account for uptake from piscivorous birds to the eagle are discussed below..

In general, values of one, three, or 10 were used as the UFs, to reflect relative degrees of conservatism. Theoretically, the UF_A could range to 100, but that did not occur in the derivation of these four criteria. A value of one for any of these UFs indicates that there is reasonable certainty that the TD portrays the expected toxicological condition (i.e., the result is a true chronic condition with an adequate duration, the test species is reasonably expected to be among the most sensitive, and the endpoint reflects a reasonable NOAEL); a value of 10 indicates that there is significant uncertainty that the TD portrays the expected toxicological condition; and a value of three indicates an intermediate level of certainty.

Additional justification for the toxicological and exposure data used in the derivation of the four wildlife criteria may be found in the final Wildlife Criteria Documents.

a. Mercury.

Comments: Several commenters stated that the proposed mercury criterion of 180 pg/L is significantly below natural background, and therefore, is erroneous. These commenters cite natural background levels averaging 1 ng/L, with upper bounds of near 7 ng/L. Other commenters stated that the proposed mercury criterion is too stringent and that it is orders of magnitude below the level of detection. These commenters believed compliance with the criterion would be impossible. Some commenters believed that the avian LOAEL for mercury should be based on the ingestion rates of the test animals, not the ingestion rates of the controls.

Responses: EPA revised the numeric criterion for mercury to reflect adjustments made to the exposure parameters for the five final representative species and modifications to the BAFs (particularly the trophic level 3 BAF). A re-evaluation of the interspecies UF for the avian class was also made. The resultant value is 1300 pg/L, approximately the same as the natural background concentrations cited by commenters.

EPA conducted a study to determine the natural background levels of mercury (U.S. EPA, 1993b). In general, there is an unfortunate lack of reliable data because the global transport of mercury from anthropogenic sources has created concern over whether pristine areas receive significant loads of mercury from atmospheric deposition into freshwater ecosystems.

Data contained in Noreheim and Forslie (1978), Wren (1983), and Vermeer et al. (1973) indicate a BMF range of three to 12 between fish and piscivorous birds (i.e., bird prey species for the eagle). The value 10 was selected as being a reasonable BMF.

The dose-response curve from the studies from which the avian TD was based (Heinz, 1974, 1975, 1976a, 1976b, and 1979) indicate that the TD level was close to the NOAEL. In addition, the UF_L selected in the proposal was two. For these reasons the UF_L remains at two. The UF_A was changed for all three representative species from 10 to three because reconsideration of the ranges of sensitivities of various avian species to wildlife indicates that the mallard is relatively sensitive, but not the most sensitive species. The avian LOAEL was modified from 64 μg/kg-day to 78 μg/kg-day to accurately reflect the ingestion rate of the test animals, rather than the controls as had been done in the proposal.

The mammalian UFs were not changed from the proposal. EPA notes that the UF_S was set to 10 because of the test length; in the study selected (Wobeser et al., 1976) there was histopathological effects observed at the low doses and the authors indicated that if the exposure period was longer death may have resulted.

EPA considered the concern on the level of detection in ambient systems, and the impact on compliance monitoring by discharging facilities. The final Guidance sets forth an appropriate mechanism to describe reasonable compliance goals in cases where the criterion is below the level of detection. Section 303(c)(2)(A) of the Clean Water Act states that water quality standards are to be adopted which are protective of the uses designated for the waters affected. In compliance with this provision, aquatic life criteria for metals have been promulgated in recent years by several states in the Great Lakes System that are more restrictive than the level of detection. Implementation of the water quality standards, however, does take into account the ability to detect the pollutant in the waste stream. Procedure 8 of appendix F to part 132 provides that the water quality-based effluent limit must be derived from the water quality criterion; compliance with that limit, however, may be based (at the State's discretion) on the level of quantification, defined in procedure 8 of part 132.

EPA agrees that the ingestion rates of the test animals, not the controls should be used in deriving a LOAEL for the avian value. The LOAEL was revised to account for the different ingestion rate.

b. DDT.

Comments: Several commenters argued against the use of the Anderson et al. (1975) study from which the avian wildlife value for DDT was derived. They argued that a dose-response curve could not be generated from the data presented in that study. Another commenter argued that the different toxicities of the various DDT congeners should be accounted for in the Tier I criterion.

Responses: The Anderson et al. (1975) study used to derive a NOAEL represents an adequate basis from which to derive an effect level for use in deriving a wildlife water quality criterion for DDT and its metabolites. The study analyzed DDT concentrations in the food items of West Coast pelicans over several years and correlated those concentrations to reproductive effects, including hatching success, egg shell thinning, and fledgling success. From these data a dose-response curve can be developed, with the appropriate application of a UF_L to account for uncertainties in extrapolating to a NOAEL and for uncertainties in time lags for eliminating the toxicant from the parents.

The Anderson et al. (1975) study did not differentiate the effects of DDT and those of its metabolites, and therefore, the avian value is based on total DDT (DDT, DDE, and DDD) at a near steady-state condition in an aquatic system. It is important to account for the differences in bioaccumulation of each metabolite through the food web and establish appropriate BAFs for the DDT mixture in the Great Lakes. Based on data from Oliver and Niimi (1988), EPA derived composite DDT and metabolite BAF values for aquatic trophic levels

3 and 4, based on weighting the BAF for DDT, DDE, and DDD (derived for the dissolved fraction), in accordance with the fraction of each compound in the Great Lakes fish species (see section IV). The values for the two BAFs for trophic levels 3 and 4, respectively, are 1,687,000 and 9,357,000 L/kg.

Data contained in Braune and Norstrom (1989) indicate a value of 85 for a BMF for DDE for trophic level 3 fish to herring gulls is a reasonable, yet conservative value. The BMF used in the calculation for DDT and metabolites was 63 (see appendix K of the GLWQI TSD for the Procedure to Determine Bioaccumulation Factors for a discussion on how the BMF of 63 was derived). This value was obtained from weighting the proportions of DDT, DDE, and DDD in the tissues of the organisms, and was used in assessing that portion of the eagle's diet that is comprised of piscivorous birds. Additional information may be found in the final Wildlife Criteria Documents.

The avian UF_L was changed from 10 to three because of the relatively low level of response noted in the study as the LOAEL (Anderson et al., 1975). A value of one is inappropriate because there is a clear indication of an adverse impact at the TD. The UF_A was also changed from 10 to one for each of the representative species because published data indicate that the test species used, the pelican, is among the most sensitive birds in terms of available LOAELs, particularly when compared to the three avian representative species.

The mammalian test dose value was changed from 0.5 mg/kg/day to 0.8 mg/kg/day, based on a recalculation of the food ingestion rate of the test animals. Further the contaminant used in the mammalian study was DDT, not a mixture of DDT and metabolites. Therefore, the BAFs used to derive the mammalian wildlife value were based on DDT only, not the mixture weighted BAF used for birds. The mammalian UFs were not changed from the proposal.

The criterion is reported for DDT and its metabolites because the criterion is based on the avian wildlife value, which used a test dose that included DDT, DDD, and DDE.

c. PCBs. Data contained in Braune and Norstrom (1989) indicate a value of 90 for a BMF between fish and piscivorous birds (i.e., bird prey species for the eagle) is reasonable, yet conservative.

The UF_L for birds was changed from 10 to three because a re-evaluation of the dose-response relationship suggested that a factor of 10 was overly conservative.

The UF_S for mammals was adjusted from 10 to one because the duration for the study selected (Aulerich and Ringer, 1977) was 300 days which was considered of sufficient length for manifestation of chronic effects.

d. 2,3,7,8 TCDD. Data contained in Braune and Norstrom (1989) indicate a value of 30 for a BMF between fish and piscivorous birds (i.e., bird prey species for the eagle) is reasonable, yet conservative.

The avian UF_S was adjusted from one to 10 because the test duration of 10 weeks (Nosek et al., 1992) was only a small fraction of the reported half-life for TCDD elimination in non-egg laying adult pheasants (U.S. EPA, 1993c). The UF_A was adjusted from 10 to one for each representative species because other species showed only slightly greater sensitivities than the test organism, particularly when compared to the three avian representative species.

No changes were made to the values selected for the UFs for mammals. EPA notes that the UF_A value for each representative species was selected based on a comparison of single-dose lethality data for the rat and mink.

3. <u>Final Guidance:</u> The final values for each of the four Tier I criteria, modified as discussed above, are presented in Table 2. States and Tribes must adopt criteria for these four pollutants that are no less stringent than EPA;s final criteria. Additional information may be found in the final Wildlife Criteria Documents.

G. <u>Comparison of Wildlife Criteria and Methods to National Program and to Great Lakes Water Quality Agreement</u>

The proposal at 58 FR 20884 contained a discussion of the relationship of this methodology to both the National Program and to the Great Lakes Water Quality Agreement (GLWQA). The final Guidance largely supports that discussion, including the statement that the four wildlife criteria continue to be more restrictive than existing aquatic life values.

The proposal described that the wildlife criterion for DDT and metabolites at 0.87 pg/L was more stringent than the corresponding GLWQA Annex 1 value of 3.0 pg/L. The final criterion is now 11 pg/L, which is slightly less stringent than the Annex 1 value. For the reasons described in the aquatic life section of this document, EPA continues to believe that the DDT criterion adequately conforms to the GLWQA.

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Table 2. Final Tier I Wildlife Criteria.

Pollutant	Criteria (μg/L)
mercury (including methylmercury)	1.3×10^{-3}
PCBs	7.4×10^{-5}
2,3,7,8-TCDD	3.1×10^{-9}
DDT and metabolites	1.1×10^{-5}

VII. ANTIDEGRADATION

A. General Discussion/Background

This document explains the intent of the final Guidance on antidegradation and EPA's expectations of the Tribes and States in the development and implementation of antidegradation policies and procedures. This document also includes guidance to Tribes and States in the implementation of the agreement entitled "A Bi-National Program to Restore and Protect the Lake Superior Basin." (September, 1991) Tribes and States may extend additional protection to the waters of the Lake Superior Basin through the use of the special designations contained in the final Guidance if they so choose.

1. History of the Great Lakes Antidegradation Guidance

The history of the Federal policy on antidegradation is discussed in detail in the preamble of the proposed Guidance; readers are referred there for a complete discussion of the origins and evolution of the Federal antidegradation policy. EPA's Water Quality Standards Handbook (September, 1993) also contains useful background information.

Current national policy is found in the Federal regulations at 40 CFR 131.6 and 40 CFR 131.12. Federal regulations at 40 CFR 131.6 specify that Tribal or State water quality standards must include an antidegradation policy. Federal Regulations at 40 CFR 131.12 identify the elements of an acceptable antidegradation policy. The Federal antidegradation policy is composed of three levels of protection commonly referred to as tiers. The first element identified at 40 CFR 131.12(a)(1) protects the minimum level of water quality necessary to support existing uses and applies to all waters. This element establishes the ultimate limit on the extent to which water quality can be lowered in a water body. Lowering of water quality to the point where existing uses are impaired is prohibited. The second element is found at 40 CFR 131.12(a)(2), and protects water quality where water quality is better than that needed to support fish and aquatic life and recreation in and on the water. Where these conditions exist, the water body is considered high quality and water quality must be maintained and protected unless lowering water quality is necessary to support important social and economic development. The third element at 40 CFR 131.12(a)(3) involves the protection of water quality in water bodies that are of exceptional ecological, aesthetic or recreational significance. Water quality in such water bodies, identified as Outstanding National Resource Waters (ONRW), must be maintained and protected.

The protection of high quality waters under antidegradation causes considerable confusion and controversy. It is often interpreted incorrectly as an absolute prohibition on lowering of water quality in high quality waters. Such a prohibition would amount to a "no growth" policy which is not consistent with EPA's position as expressed in the regulations. Neither the existing Federal regulations nor the final Guidance prohibit activities that would lower water quality in high quality waters. The antidegradation provisions contained in the final Guidance provide a structure for the systematic evaluation of activities that are expected to lower water quality. Implementation of antidegradation allows Tribes and States to arrive at a decision that considers all the available information regarding the social, economic and environmental impacts of lowering water quality. Review of such activities under a Tribe's or State's antidegradation policy is intended to ensure that any lowering of water quality is necessary, that the lowering of water quality is minimized and that desirable economic and social benefits accrue to the area affected by the lowered water quality as a result of the lowering of water quality.

The applicability of antidegradation to nonpoint sources is also a source of confusion. EPA policy is that water quality standards, including antidegradation, are applicable to any activity that might affect water quality (see "Interpretation of Federal Antidegradation Regulatory Requirement," memorandum from Tudor Davies, Director, Office of Science and Technology, to Water Management Division Directors, dated February 22, 1994). However, despite the broad applicability of water quality standards, mechanisms to implement water quality standards may not exist in all circumstances. Neither the antidegradation provisions contained in the final Guidance, nor existing regulations, confer any additional authority upon States, Tribes or EPA to regulate nonpoint sources of pollution. However, where independent regulatory authority over nonpoint sources exists requiring compliance with water quality standards, compliance with the antidegradation provisions of the final Guidance is required.

From the inception of the joint State-EPA effort to develop consistent water quality standards for the Great Lakes, the participants recognized antidegradation guidance was an essential element of such an effort. The Great Lakes Critical Programs Act of 1990 also recognized this by requiring that the final Guidance published by EPA include antidegradation provisions at least as stringent as existing Federal requirements.

2. <u>Summary of the Proposed Guidance</u>

The proposed Guidance consisted of four components each of which were to be adopted by Tribes and States:

a. An Antidegradation Standard;
b. Antidegradation Implementation Procedures;
c. An Antidegradation Demonstration; and
d. An Antidegradation Decision.

Each of the components is discussed in detail below.

a. <u>The Antidegradation Standard</u>

As proposed, the Great Lakes antidegradation standard was derived from the existing Federal antidegradation policy at 40 CFR 131.12. The proposed Guidance provided additional detail on antidegradation to assist Tribes and States in implementing the standard and to encourage consistency across the basin.

The protection of existing uses contained in the proposed Guidance refers to the definition found at 40 CFR 131.3. The intent of this reference was to make clear that water quality necessary to support existing uses, as well as designated uses, is protected under antidegradation. The proposed Guidance prohibited lowering water quality if, as a result, either existing or designated uses would be impaired.

The proposed Guidance and existing regulations at 40 CFR 131.12 provide similar protection for high quality waters. The proposed Guidance expanded upon Federal regulations, however, in that it specified that high quality waters should be identified on a parameter-by-parameter basis, whereas existing Federal regulations do not specify a particular method for identifying high quality waters. The parameter-by-parameter approach was selected for the proposed Guidance because it was considered the most reasonable and workable way of identifying high quality waters and because it ensured that water quality improvements would be protected. Also, a parameter-by-parameter approach allows a water body to be considered high quality for one pollutant even if the criteria for another is exceeded, as is the case in many water bodies within the Great Lakes basin. Finally, this approach is consistent with how waters are assessed and regulated in other aspects of States' and Tribes' water quality programs.

The final major element of the standard is the protection of Outstanding National Resource Waters (ONRWs). The standard contained in the proposed Guidance is identical to existing Federal regulations.

b. Antidegradation Implementation Procedures

The implementation procedures contained in the proposed Guidance were intended to provide direction to States and Tribes on how the antidegradation standard should be applied. The implementation procedures included definitions of key terms and descriptions of how the Tribes and States were to carry out the requirements of the Great Lakes antidegradation standard. The proposed Guidance stated explicitly that designated uses must reflect existing uses and that where designated uses are impaired, water quality may not be lowered at all with respect to the pollutant or pollutants causing the impairment.

For high quality waters, the proposed Guidance defined the concepts of de minimis lowering of water quality and significant lowering of water quality. The implementation procedures recognized that considerable variation was possible in the effects of different activities on water quality. The proposed Guidance included a mechanism for distinguishing between activities based on the extent to which water quality was anticipated to be lowered. Small reductions in water quality were identified as de minimis and not subject to antidegradation review, whereas larger reductions were identified as significant and subject to antidegradation review. Both concepts were intended as mechanisms to allow Tribes and States to differentiate between activities that are likely to have an inconsequential effect on water quality and those that are likely to have significant effects and to focus their efforts on those that are of the most consequence to water quality. The definition of de minimis in the proposed Guidance provided criteria to be used by Tribes and States to identify when a lowering of water quality could be considered de minimis. The proposed Guidance also provided criteria for identifying when an activity would result in a significant lowering of water quality subject to antidegradation review.

The proposed Guidance recognized that the significance of a potential lowering of water quality depended not just on the magnitude of the lowering of water quality, but also on the types of pollutants involved. In keeping with the emphasis of the Guidance on BCCs, the proposed Guidance established a more restrictive threshold of significance for BCCs than for non-BCCs. The concept of existing effluent quality (EEQ) was specified in the proposed Guidance as the means to implement antidegradation for BCCs. EEQ served as the basis for either permit limits or notification requirements which, if exceeded, triggered antidegradation review. Each of these concepts is discussed in greater detail below.

It should also be noted that for high quality waters and ONRWs, the implementation procedures in the proposed Guidance allowed short-term and temporary lowering of water quality without review under the antidegradation provisions of the Guidance. This is consistent with existing national policy as described in USEPA's Water Quality Standards Handbook (August, 1994) and allows Tribes and States greater flexibility in how they use the antidegradation procedures as regulatory tools.

c. Antidegradation Demonstration

When an action is considered that could lower water quality in a high quality water, Federal regulations require that a determination be made that the action is necessary to support important social and economic development {40 CFR 131.12(a)(2)}. The proposed Guidance explained the process for evaluating such activities and the information a discharger considering such an action must provide to the regulatory agency making the determination. The antidegradation demonstration process consisted of two sub-demonstrations:

1. a demonstration that the significant lowering of water quality is necessary and,

2. a demonstration that the significant lowering of water quality will support important social and economic development.

Under the proposal, the two demonstrations were intended to be performed sequentially, with performance of the social and economic development demonstration contingent on a successful demonstration that the significant lowering of water quality was necessary. To assess the need for a significant lowering of water quality, a person proposing an action that would lower water quality would first determine whether or not existing treatment, pollution prevention, additional treatment or some combination within a defined cost range could avoid the need to lower water quality. If this was the case, the significant lowering of water quality would not be permitted. If not, the discharger would be required to demonstrate that important social benefits, economic benefits or both would accrue to the community as a result of the activity responsible for the significant lowering of water quality.

The proposal also included special requirements applicable to RCRA and Superfund actions. In addition, requirements for implementing optional special designations for Lake Superior were included.

d. Antidegradation Decision

The proposed Guidance described how Tribes and States should evaluate the data provided by a discharger in making a decision concerning whether or not to allow a significant lowering of water quality. The specifics of this section are discussed in greater detail below.

B. Overview of the Final Guidance

The final Guidance includes Great Lakes-specific antidegradation requirements for BCCs only. A lack of specific requirements in the final Guidance for non-BCCs should not be construed as relieving States and Tribes of their responsibilities under the CWA and Federal regulations to adopt water quality standards consistent with the CWA and Federal regulations. As stated at 40 CFR 131.6, antidegradation provisions consistent with 40 CFR 131.12 are compulsory elements of any State's or Tribe's water quality standards; States and Tribes must adopt antidegradation policies and implementation procedures just as they must adopt designated uses and criteria. For non-BCCs, the antidegradation policy and implementation procedures developed by States and Tribes must define key terms,, specify what types of information will be required to demonstrate that a significant lowering of water quality is both necessary and will support important social and economic development, how that information will be used to arrive at a final decision regarding a request to lower water quality, and how public participation will be factored into the final decision consistent with the antidegradation standard and 40 CFR 25. This SID includes EPA's recommendations as to how antidegradation should be implemented for non-BCCs.

For BCCs, States and Tribes must adopt specific provisions consistent with the antidegradation standard and implementation elements contained in appendix E. Special requirements for BCCs are necessary because of the demonstrated sensitivity of the Great Lakes System to such pollutants. Consequently, imposing these requirements on Great Lakes States and Tribes is warranted to protect the shared resources of the Great Lakes System.

A second major change to the final Guidance is that the final Guidance does not require the use of existing effluent quality (EEQ)-based limits to implement antidegradation for BCCs. EEQ-based limits are not included in the final Guidance because EPA believes that it is possible that the use of EEQ-based limits to implement antidegradation could have unintended effects contrary to the goals of the CWA and the intent of antidegradation.

The final Guidance retains the overall structure of the proposed Guidance, that is, it contains an antidegradation standard, implementation procedures, demonstration requirements, and a final decision. Very few changes were made to the antidegradation standard between the proposal and the final Guidance. An implementation framework, consisting of implementation procedures, demonstration requirements and the requirement for a final decision is provided in the final Guidance. However, many of the details contained in the proposed Guidance, such as specific benchmarks for assessing affordability of alternative treatment technologies, are included elsewhere in this document as guidelines only.

C. Detailed Discussion of the Final Regulation

1. The Antidegradation Standard

The antidegradation standard contained in the final Guidance differs little from either the proposed Guidance or existing regulations on antidegradation at 40 CFR 131.12. The section pertaining to the protection of high quality waters was reworded to cross-reference the definition of high quality waters at 40 CFR 131.3 (See discussion below). States and Tribes are required to adopt an antidegradation standard consistent with the Standard contained in appendix E applicable to increased loadings of BCCs to the Great Lakes System. States and Tribes may adopt the antidegradation standard as applicable to all waters and pollutants. As required by 40 CFR 131.6, water quality standards adopted by a State or Tribe must include an antidegradation policy consistent with 40 CFR 131.12.

2. Antidegradation Implementation Procedures

The antidegradation implementation procedures were the second major component of the proposed Guidance. The implementation procedures consisted of definitions of key terms and the processes to be used by Tribes and States in applying antidegradation. The proposed Guidance provided procedures for protecting existing uses, high quality waters and ONRWs. In addition, the implementation procedures included methods for applying optional special protection designations to waters in the Lake Superior Basin.

a. De Minimis Lowering of Water Quality

i. Background

The proposed Guidance made provision for identifying certain small increases in loading as de minimis and not subject to the requirements for antidegradation review. The "de minimis test" identified three criteria to be used in classifying an increased loading as de minimis. These were:

1. only non-BCCs will be released as a result of the proposed activity responsible for the anticipated lowering of water quality;
2. the proposed lowering of water quality uses less than 10 percent of the available assimilative capacity; and
3. for pollutants included in 40 CFR 132.2, Table 5, at least ten percent of the total assimilative capacity remains unused following the lowering of water quality.

The proposal also required that any decision to allow a de minimis lowering of water quality comply with the requirements in the TMDL section of the implementation procedures to maintain a margin of safety (MOS). Finally, the proposal specified how and when the total and unused assimilative capacity of a water body should be calculated.

EPA's intent in including the de minimis test in the proposed Guidance was to recognize that certain activities, although they may result in some lowering of water quality, will not lower water quality to such an extent as to result in a significant lowering of water quality. EPA's goal in allowing States and Tribes to identify certain increases as de minimis was to provide a means of reducing the administrative burden on all parties associated with activities of little or no consequence to the environment. De minimis determinations were made at the discretion of the State or Tribal Director; the Director could choose to treat as significant any lowering of water quality that would otherwise be de minimis where the circumstances of a particular discharge warrant more thorough review.

ii. Discussion of Significant Comments

EPA received a number of comments on the proposed de minimis provisions. Significant comments are discussed below. For responses to specific comments, see the comment response document in the docket of this rulemaking.

Comment: Some commenters stated that the de minimis provision is too broad and should be narrowed to include fewer activities.

Response: De minimis provisions are not part of existing regulatory requirements, nor are they authorized for BCCs under the final Guidance. For non-BCCs, States and Tribes may include de minimis provisions in their antidegradation policy at their discretion. Although de minimis provisions do involve non-conservative assumptions, the de minimis provisions included in the proposed Guidance are not likely to seriously undermine the protection afforded a high quality water body through antidegradation.De minimis provisions provide a means for States and Tribes to differentiate between actions that will result in an increased loading of a pollutant to a receiving water that is likely to have a significant impact on water quality and those that are unlikely to do so and focus review efforts on actions that will degrade water quality. It is reasonable to assume that loading increases of non-BCCs that will use less than ten percent of the remaining assimilative capacity in a water body will have a negligible effect on ambient water quality.

Comment: Some commenters felt that the de minimis provisions are too narrow and should be broadened to reduce the number of activities subject to antidegradation review.

Response: Given that existing Federal regulations are silent on the concept of de minimis and that allowing any de minimis provision involves non-conservative assumptions about the effects of increased loadings on water quality, an expanded de minimis provision would be incompatible with the antidegradation standard that States and Tribes are required to adopt under 40 CFR 131.6. De minimis provisions must be narrow in order for antidegradation to function as it was intended. Some activities or actions have a negligible impact on water quality and may be exempted appropriately from antidegradation review through a de minimis provision; however, allowing loading increases that use more than ten percent of the remaining assimilative capacity of a water body to be considered de minimis strains the credibility of a State's or Tribe's antidegradation implementation procedures and increases the chance that a significant lowering of water quality could occur without antidegradation review.

Comment: The de minimis provisions should be extended to include BCCs.

Response: EPA does not agree that even small increases in the loadings of BCCs to the Great Lakes Basin can be considered de minimis. Low levels of BCCs in the Great Lakes have adverse impacts on the organisms that inhabit them. Further, because BCCs are both resistant to degradation and hydrophobic, they tend to accumulate in sediments and biota, amplifying their effects. For these reasons, even small increases in loadings of this type of pollutant must be considered significant.

Comment: There is no need to reserve a portion of the unused assimilative capacity as a MOS for either the pollutants included in the final Guidance or those listed on Table 5 and excluded from the Guidance.

Response: EPA does not agree with this comment. A MOS is essential to preserve high quality waters in their high quality state. It is inconsistent with the intent of antidegradation to allow such waters to be degraded without scrutiny to the point where criteria are only just achieved. Consequently, a de minimis provision must include a MOS to ensure that such a situation does not occur. When a State or Tribe chooses to define de minimis as a percentage of the remaining assimilative capacity, there will always be an opportunity for a de minimis increase, albeit a smaller and smaller one. Absent a MOS requirement, this could lead to a situation where the water quality in a water body is reduced to the point where the water body is effectively no longer high quality, without antidegradation review. To prevent this, a MOS similar to the requirements contained in the final Guidance should be a part of a State's or Tribe's antidegradation implementation procedures if the procedures include a de minimis provision.

Comment: Many commenters felt that EPA should either do more to account for the cumulative effects of multiple de minimis lowerings of water quality or, conversely, that special protection against such cumulative effects is not necessary.

Response: EPA agrees with those commenters concerned over the cumulative impacts of a State's or Tribe's de minimis provisions. MOS requirements ensure that in no case will the water quality of a high quality water body be degraded to the point where the water body is no longer high quality without review and should be a part of a State's or Tribe's antidegradation implementation procedures.

MOS requirements, however, address only the more extreme cumulative effects of de minimis increases. Several commenters expressed concern that a single discharger could request numerous de minimis increases resulting in a significant impact on water quality that would not be subjected to antidegradation review. Similarly, several dischargers to the same water body could receive permission for de minimis increases leading to a significant lowering of water quality. Such concerns are inherent in any decision to allow for de minimis provisions. However, the benefits of the de minimis provisions in allowing States and Tribes to reduce administrative burdens and prioritize their efforts outweigh the possibility for abuse, especially given the MOS requirements and Tribal, State and EPA oversight of water quality program implementation. Abuse of the de minimis provisions can also be prevented if States and Tribes adopt a definition of significant lowering of water quality that allows the Director to identify any lowering of water quality as significant on a case-by-case basis.

iii. The Final Guidance

Because the final Guidance does not address non-BCCs, it also does not make provision for de minimis lowering of water quality. Where a State or Tribe wishes to include a de minimis provision in the State's or Tribe's antidegradation policy and procedures for non-BCCs, EPA recommends adopting an approach based on the proposed Guidance. Any de minimis provision should be based on a percentage of the unused assimilative capacity to protect against over-allocation of the water body. In addition, the de minimis provision should include a MOS based upon a percentage of the total assimilative capacity such that once more than a certain percentage of the total assimilative capacity is used, any further lowering of water quality is subject to antidegradation review. If a TMDL is in place, total assimilative capacity and loading capacity are functionally equivalent; it is not necessary to recalculate the total assimilative capacity of a water body where loading capacity has already been calculated. Unused assimilative capacity must account for background loading and should be determined based on permitted rather than actual discharge levels at point and nonpoint sources. As written in the proposal, unused assimilative capacity could have been overestimated if background loadings were not considered or if dischargers to the water body were discharging below permitted levels. Finally, the unused assimilative capacity must be recalculated prior to each request for a lowering of water quality to ensure that it reflects current conditions in the water body.

b. High Quality Waters

i. Background

As explained above, existing Federal regulations at 40 CFR 131.12 establish a framework for antidegradation consisting of three levels of protection. The second level creates the category known as high quality waters and defines high quality waters as those water bodies with water quality better than minimum levels necessary to support fish and other aquatic life and recreational uses. Federal regulations provide that where water quality is better than that needed to support propagation of fish, shellfish, and wildlife and recreation in and on the waters, that water quality shall be protected unless lowering of water quality is necessary to support important social and economic development.

The proposed Guidance followed closely the provisions contained in the Federal regulations. In addition, the proposed Guidance specified that the level of protection afforded a water body under antidegradation be determined on a parameter-by- parameter basis, considering each individual pollutant separately from the others present in a water body. Under the proposed Guidance, a discharger contemplating an action that would result in an increased loading would identify the constituents of its effluent that would increase as a result of the action. Then, the ambient level of the pollutants of interest would be determined and compared to the applicable criteria. Where ambient concentrations of the pollutants in question are less than criteria concentrations, the water body would be considered high quality for those pollutants and increases in those pollutants would be subject to the requirements applicable to high quality waters.

EPA selected this method of identifying high quality waters for the proposed Guidance for several reasons. First, it establishes a clear, easily evaluated criterion for determining whether or not a water body is high quality. The proposed method is also consistent with existing EPA guidance on the subject of identifying high quality waters for purposes of antidegradation (see "Application of Antidegradation Policy to the Niagara River," memorandum from Martha G. Prothro, Director, Office of Water Regulations and Standards, to Richard L. Caspe, Director, Water Management Division, Region II, dated August 4, 1989, available in the docket for this rulemaking) and the current approach taken by many States in the Great Lakes basin to implementing antidegradation. Also, the parameter-by parameter approach ensures internal consistency between the mechanisms used in the final Guidance to identify impaired waters and those used to identify high quality waters. Finally, identifying high quality waters on a parameter-by-parameter basis protects high quality water wherever it exists in the basin, even when individual criteria may not be met and ensures that the water quality of the Great Lakes System will not degrade below that necessary to support fish and other aquatic life and recreation in and on the waters.

ii. Discussion of Significant Comments

Comment: A number of commenters stated that factors other than just the ambient pollutant concentration should be considered in determining whether or not a water body is high quality.

Response: EPA does not agree with this comment as a general matter. The language of the final Guidance conforms with existing Federal regulations that refer to ambient water quality as the measure of whether or not a water body is high quality. In addition, ambient water quality provides a quantitative measure for identifying high quality waters with regard to a specific pollutant that is compatible with implementation through a permit to discharge or other control document. Finally, in general, the water bodies found in the Great Lakes basin are, or should be, able to support fish and aquatic life and recreational uses. Therefore, where water quality is better than necessary to support fish and aquatic life and recreation, that water quality should be protected.

Comment: Some commenters stated that the parameter-by-parameter approach to identifying high quality waters should be required for BCCs only.

Response: The commenter does not provide any compelling reasons for employing a different approach to identify high quality waters for non-BCCs than is used for BCCs. On the contrary, the rationale for using a parameter-by-parameter approach is equally valid for both BCCs and non-BCCs. While the final Guidance requiring the pollutant-by-pollutant approach pertains only to BCCs, EPA believes that consistent with current EPA policy, States and Tribes should implement antidegradation on a parameter-by-parameter basis for non-BCCs, and identify high quality waters on this basis.

Comment: The identification of high quality waters for purposes of antidegradation should consider the attainability of fishable/swimmable uses as well as ambient water quality.

Response: Given that final Guidance applies only to increased discharges of BCCs, and given the properties of BCCs, it is not reasonable to assume that there exists anywhere in the Great Lakes System a water body where an increased loading of BCCs does not have the potential to ultimately affect water quality in the a water body where fish and aquatic life uses and recreation in and on the water occur. Consequently, there is no basis for distinguishing between different water bodies within the Great Lakes System for purposes of antidegradation. In order the protect the Great Lakes System as a whole, any water body where water quality is better than the minimum necessary to support fish and aquatic life and recreation in and on the water is considered high quality and subject to full protection under antidegradation.

Attainability of a use should not be confused with impairment of a use. In some instances, a designated use may be impaired due to pollution resulting from historic activities, such as fish consumption advisories due to PCB contamination, and yet the use may be considered attainable with control of the contamination. Identifying high quality waters on a parameter-by-parameter basis provides Tribes and States the flexibility to both encourage restoration by prohibiting increased loadings of the pollutant causing the impairment, and at the same time provide antidegradation protection for otherwise high quality waters. As a result, water quality problems will be kept from worsening through the protection of existing and designated uses while new water quality problems will be prevented through the protection of high quality waters.

Comment: The definition of high quality waters should recognize that some waters that meet the requirements on a parameter-by-parameter basis may not be high quality resources. The final Guidance should allow for less rigorous review for activities affecting such waters.

Response: As stated above, any release of BCCs to the Great Lakes System has the potential to affect water quality throughout the system, because of their persistence and tendency to bioaccumulate. In order to maintain the Great Lakes System as a whole in a high quality condition, all water bodies within the system must be treated as high quality. However, EPA agrees with the concerns raised by this comment with respect to non-BCCs. EPA may approve implementation procedures for non-BCCs which include an exemption from the requirements for identifying high quality waters on a parameter-by-parameter basis for non-BCCs for water bodies that are of limited ecological, recreational and aesthetic significance.

iii. The Final Guidance

Much of what was included in the proposed Guidance is incorporated in the final Guidance. For BCCs, the final Guidance requires States and Tribes to identify high quality waters on a parameter-by-parameter basis. For pollutants other than BCCs, EPA recommends that, in general, high quality waters be identified on a parameter-by-parameter basis in the same manner as for BCCs.

The final Guidance includes one additional change to improve its consistency and clarity. A detailed definition of high quality water is included in the definition section. In the proposed Guidance, the definition was found only in the antidegradation standard.

c. Lake Superior Basin - Outstanding International Resource Waters

The final Guidance includes a definition of the term "Lake Superior Basin - Outstanding International Resource Waters." This term, which was not defined in the proposed Guidance, is defined in the document, "A Bi-National Program to Restore and Protect the Lake Superior Basin," (September, 1991) available in the docket to the rule. A definition is included in the final Guidance in response to comments requesting the inclusion of the definition.

d. Outstanding National Resource Water

i. Background

The proposed Guidance included a definition of Outstanding National Resource Water (ONRW). The definition was derived from existing Federal regulations at 40 CFR 131.12(a)(3). The definition specified that designation of ONRWs is at the discretion of States and Tribes. The definition also included examples of the types of waters that might be afforded ONRW status by States and Tribes.

ii. Discussion of Significant Comments

Comment: Some commenters stated that the proposed Guidance broadened the definition of ONRW beyond existing Federal regulations. The commenters stated that the examples of types of waters that could be considered for ONRW designation could encompass any water body within the Great Lakes basin and that this could lead to delays in the permitting process as disagreements arose over whether or not a water body was or should be an ONRW.

Response: EPA does not agree with this comment. The final Guidance does not contemplate any additional requirements beyond existing Federal regulations for ONRWs. The types of waters subject to listing were included in the proposal as examples of what States and Tribes should consider in designating ONRWs. Identification of an ONRW is inherently site- and case-specific and depends not only on the water body but also on its importance as a resource to the State or Tribe. Any cold water stream may be an ONRW where such resources are rare; elsewhere, where they may be more common, the presence of a cold water community may not in itself be sufficient to warrant designation as an ONRW. Designation of ONRWs occurs through the normal water quality standards review process and should not delay permit issuance.

iii. The Final Guidance

The content of the final Guidance was not changed from the proposal. The definition included in the final Guidance represents accurately what is intended by an ONRW designation.

e. Significant Lowering of Water Quality

i. Background

The proposed Guidance identified criteria for determining when a lowering of water quality is significant. For all regulated discharges of BCCs, any increase in loading to a high quality water, measured as a change in EEQ, was considered significant and subject to antidegradation review. For point source discharges of non-BCCs to high quality waters, a significant lowering of water quality was defined generally as an increase in applicable permit limits greater than a de minimis increase. For nonpoint sources of non-BCCs, a significant lowering of water quality was defined generally as an increase in the rate of mass loading authorized by the governing nonpoint source program. Increased mass loadings of non-BCCs that would not change the concentration of the pollutant outside of a designated mixing zone were not required to undergo antidegradation review. Finally, there was a "safety provision" that allowed the Director to consider any action as significant on a case-by-case basis.

ii. Discussion of Significant Comments

Comment: Several comments stated that there is a need for a succinct definition of an action in the definition of a significant lowering of water quality.

Response: EPA takes the term "action" or "activity" to have a broad meaning with respect to determining what may or may not be subject to antidegradation. Although the final Guidance includes examples of actions and activities, it is not possible to anticipate each activity or action that might result in an increased loading of pollutants or otherwise lead to a deterioration of water quality. Anything more than a broad definition could constrain States and Tribes from requiring antidegradation reviews where appropriate. Therefore, EPA does not agree that including a definition of the terms "action" or "activity" would be appropriate; States and Tribes need to retain a measure of flexibility to adapt their antidegradation policies and implementation procedures to the circumstances encountered in the day-to-day operation of a water quality management program. However, based on comments received, EPA has determined that some commenters believe certain activities to be potentially considered an "action" which EPA believes do not constitute an action, accordingly, EPA has listed these activities in the final rule, and noted that they are not subject to antidegradation review.

Comment: A number of commenters stated that it is inaccurate to assume that an increase in the loading of a pollutant to a water body will result in a lowering of water quality in that water body.

Response: An antidegradation review is required whenever a "significant" lowering of water quality is considered. For BCCs, because of their persistence and ability to exert profound impacts through accumulation in the food chain, the final Guidance defines any increased loading of such pollutants as a significant lowering of water quality.

Comment: A number of commenters stated that the "catch-all" provision allowing any action to be considered significant is too broad.

Response: As stated above in the discussion of the term "action," States and Tribes need a certain amount of flexibility to be able to respond to all the various types of situations that may arise as they attempt to implement this Guidance. The "catch-all" provision gives them the ability to consider whether individual actions that might lower water quality and are not covered explicitly by the final Guidance are of concern, and to require an antidegradation review, as appropriate. This flexibility is important and is therefore retained in the final Guidance. However, EPA has revised this provision to clarify that it applies to deliberate activities.

Comment: A number of commenters stated that the term "significant" is ambiguous and should be deleted.

Response: The term "significant" does not stand alone, but is rather a part of the term "significant lowering of water quality." EPA has provided, in the final Guidance, additional language to the definition of the term so that the perceived ambiguity is minimized.

iii. The Final Guidance

The final Guidance differs from the proposed Guidance in several important ways. First, the EEQ provisions contained in the proposed guidance for identifying significant lowering of water quality for BCCs were dropped in favor of requirements that facilities provide notification and an antidegradation demonstration in support of actions that are expected to result in any increase in loading of BCCs prior to taking the action. Although the underlying concept that any increase in loadings of BCCs to the Great Lakes System warrants review under antidegradation remains intact, the mechanism for triggering reviews was modified. This change addresses comments received and is discussed in greater detail in the section of this document addressing antidegradation implementation.

With respect to non-BCCs, the most significant change is that States and Tribes are no longer required to adopt a definition of significant lowering of water quality that is consistent with the definition contained in the final Guidance States and Tribes are only required to adopt definitions as needed to support their implementation procedures, consistent with their antidegradation standard and implementation procedures. At a minimum, EPA recommends that any activity that is expected to increase loadings of pollutants such that relaxed permit limits are required, or which will result in a new discharge of pollutants, should receive an antidegradation review.

If a State or Tribe chooses to link antidegradation review to changes in permit limits for pollutants other than BCCs, the State or Tribe must also ensure that when an action at a point source increases the loading of a pollutant that was not subject to a previous permit limit, that increase is subject to antidegradation review. Examples of activities that could receive an antidegradation review include installation of a new source, a change in process at an existing source that results in the addition of new pollutants into the waste stream or the tie-in of a new industrial user to a municipal treatment plant. Similarly, for loadings of non-BCCs from nonpoint sources, antidegradation review could be required when a new project seeks authorization from the State or Tribe. The revisions discussed above make the implementation of antidegradation more equitable by subjecting both new and existing dischargers to the same requirements.

Antidegradation review is not required when a new limit is imposed as a result of new monitoring data, improved monitoring techniques or a change in a wasteload allocation or TMDL that results in no increase in loading or a de minimis increase in loading. Under the final Guidance, antidegradation review for new limits is only necessary when there is or will be a significant lowering of water quality.

f. Deleted Definitions

Two definitions were included in the antidegradation section of the proposed Guidance that are not included in the final Guidance. These were the definitions of "bioaccumulative chemical of concern" and "pollutant." Definitions for these terms are included in the general definition section of the final Guidance at section II B, making it unnecessary to include them in appendix E.

g. Implementation Procedures

i. Background

The proposed Guidance required that, for all waters, the level of water quality necessary to protect existing uses be maintained. The proposed Guidance also specified that the uses designated by Tribes and States must include existing uses. Where water quality criteria for a particular parameter are not attained, the proposed Guidance prohibited further degradation of water quality for the parameters in question.

For high quality waters, the proposed Guidance restricted when significant lowering of water quality could occur to those instances where the discharger demonstrates that the significant lowering of water quality is both necessary and will support important social and economic development. Different measures of significance were proposed for BCCs and non-BCCs.

For BCCs, the proposed Guidance defined any increase in loading as significant. EEQ was selected to serve as the baseline against which increased loadings would be measured. EEQ was structured so as to track effluent quality and could be reduced in subsequent permits to reflect load reductions or increased to reflect loading increases approved under antidegradation. Tribes and States were given the option of either imposing EEQ-based effluent limits in discharge permits or including provisions in discharge permits requiring an antidegradation review if an EEQ value were exceeded. Tribes and States were also required to prohibit actions by dischargers that would increase loadings of BCCs without prior approval of the Director pursuant to section IV of the proposed Guidance.

Where the proposed increase involved non-BCCs, a significant lowering of water quality was defined as an increase in permit limits greater than de minimis. If a discharger was able to operate below permit limits such that an increased loading from the discharger would not exceed existing permit limits, no antidegradation review would be required. Similarly, if the proposed increase in permit limits was less than a de minimis amount, no antidegradation review would be required.

For ONRWs, the proposed Guidance stated that water quality must be maintained and protected. The proposed Guidance did not permit permanent degradation of water quality in ONRWs. Short-term and temporary degradation, replacement of a failing septic system for example, could be permitted at the discretion of the Director.

The proposed Guidance also included provisions for Lake Superior if Tribes and States wished to adopt special protection designations for the lake. Two special protection designations were included in the proposed Guidance, Lake Superior Basin - Outstanding National Resource Waters (LS-ONRW) and Lake Superior Basin - Outstanding International Resource Waters (LS-OIRW). The LS-ONRW designation could be used by Tribes and States to prohibit new or increased discharges of certain listed pollutants, known as Lake Superior bioaccumulative substances of immediate concern (BSICs), to portions of the Lake Superior basin so designated. The LS-OIRW designation could be used by Tribes and States to require more stringent treatment for new or expanding sources of BSICs.

In addition, the implementation section included a description of the circumstances under which the proposed implementation procedures would not apply. These included short-term and temporary lowering of water quality, bypasses not prohibited at 40 CFR 122.41(m) and certain actions under the Comprehensive Environmental Response, Compensation and Liability Act.

ii. Discussion of Significant Comments

The majority of the comments received on the antidegradation implementation procedures addressed EEQ. The comments received are summarized below.

Comment: Use of EEQ is a disincentive to optimal waste water treatment beyond the minimum necessary to achieve permit limits. Dischargers that do so will be "penalized" by receiving more stringent permit limits, whereas dischargers that do the bare minimum receive less stringent effluent limits.

Response: EPA modified the final Guidance to address this concern. Effluent limits are no longer required as the mechanism for implementing antidegradation. Instead, the final Guidance builds off of existing reporting requirements and requires an antidegradation review prior to commencement of any activity that has the potential to result in an increased loading of BCCs to waters within the Great Lakes System. There are a number of advantages to the mechanism included in the final Guidance for identifying when a significant lowering of water quality will occur over what was in the proposal. First, the mechanism included in the final Guidance requires consideration of antidegradation at the appropriate point in the process, before the lowering of water quality occurs and while the project is still in the planning stages. EEQ, on the other hand, serves a mechanism for identifying failure to consider antidegradation and thus has a punitive rather than preventative function. Second, unlike EEQ, the mechanism contained in the final Guidance does not expose dischargers to enforcement actions solely as a result of unusual effluent variability. Also, by linking antidegradation requirements to actions taken by a discharger, there is no danger of a discharger being forced to undergo spurious antidegradation reviews to justify apparent increases in loadings. Finally, since antidegradation is independent of effluent limits, there is no disincentive to efforts by dischargers to optimize waste water treatment.

Comment: A significant number of commenters stated that use of EEQ deprives dischargers of compliance benefits of improved waste water treatment. Dischargers frequently achieve better effluent than is required by their permit limits in order to ensure compliance with effluent limits and account for process variability. The EEQ provisions in the proposed Guidance eliminated this option and exposed dischargers to greater enforcement liability.

Response: Revisions to the implementation procedures in the final Guidance address this concern. Under the final Guidance, antidegradation considerations for BCCs are uncoupled from effluent limits. As a result, if dischargers wish to reduce loadings to improve compliance, they may do so without a corresponding change in applicable effluent limits. Consequently, dischargers will be able to build as large a margin between the limits contained in their control documents and their actual effluent quality as they choose.

Comment: EEQ is burdensome to dischargers and regulators. The EEQ requirements in the proposed Guidance will necessitate increased monitoring by dischargers. In addition, the need to analyze data and recalculate EEQ at each permit reissuance will be difficult for regulators and slow the permit issuance process.

Response: The final Guidance does not require calculation of permit limits to implement antidegradation for BCCs. Thus, no additional monitoring or reporting is likely to be necessitated by the final Guidance. Although the final Guidance does specify monitoring requirements for discharges that are known or suspected containing BCCs, this requirement should not be onerous as in most case, regardless of the antidegradation provisions, monitoring would be necessary to assess compliance and provide data for States' and Tribes' reasonable potential procedures.

Comment: Many commenters felt that the EEQ provisions create uncertainty, making it difficult for dischargers to anticipate regulatory requirements.

Response: The changes in the antidegradation implementation procedures incorporated in the final Guidance should reduce the uncertainty of dischargers regarding future discharge limits. Dischargers will receive limits for BCCs based on the reasonable potential and limit calculation procedures adopted by States and Tribes consistent with the final Guidance. For BCCs, antidegradation will be administered separately from numeric limits on BCCs. Further, the procedures contained in the final Guidance remove the uncertainty associated with the proposed approach that resulted from limits that became tighter over time as a result of antidegradation. As a result, dischargers will have greater certainty about what future control document requirements will be. For a discussion of the anticipated costs of implementing the final Guidance, see the discussion of Costs and Benefits, section IX of this document.

Comment: Commenters believed that monitoring associated with an EEQ-based approach will be excessive.

Response: While it could be argued that the proposed approach would have led to increased monitoring, under the final Guidance monitoring requirements for dischargers should not be increased significantly as a result of the antidegradation provisions. In most cases, the requirement to monitor for BCCs that is included in the final Guidance will be met through normal monitoring to measure compliance with control document requirements and support control document reissuance. No unusual or more sensitive monitoring is envisioned as a result of antidegradation.

Comment: A number of commenters stated that the EEQ provisions are inconsistent with the TMDL process and the watershed approach. Commenters stated that the antidegradation procedures undermined the TMDL process and EPA's watershed protection goals by allowing limits more stringent than those derived through the TMDL process, making the TMDLs irrelevant.

Response: EPA does not agree that antidegradation is incompatible with TMDLs. First, TMDLs and antidegradation address different and complementary components of the water quality program and both are necessary and required for the protection of water quality in the Great Lakes System. TMDLs, in the simplest sense, establish the maximum amount of a pollutant that may be discharged into a water body without exceeding water quality criteria necessary to protect designated uses. Antidegradation, on the other hand, protects existing water quality where water quality is better than the criteria. Thus, conceptually, protection of high quality waters under antidegradation is concerned with water quality that is better than the minimum required by a TMDL. Second, TMDLs and antidegradation are likely to address different subsets of water bodies. At present, TMDLs are only required to be calculated for threatened or impaired water bodies and result in imposition of water quality-based effluent limits sufficient to ensure compliance with water quality standards. In contrast, the effects of the final antidegradation Guidance will be felt most strongly by dischargers to waters that attain water quality standards and whose effluent limits are technology-based. Finally, unlike the proposed Guidance, in the final Guidance, antidegradation is not implemented through effluent limitations for BCCs. In practice, antidegradation and TMDLs each reinforce the other, and either one or the other of the two processes will be the important controlling mechanism in a given water body for a given pollutant.

iii. The Final Guidance

The final Guidance incorporates a number of changes in response to comments received during the public comment period on the proposed Guidance. These include revisions to the treatment of BCCs in high quality waters.

EPA received a significant number of comments on the use of EEQ in the proposed Guidance as a means of controlling loadings of BCCs. Numerous comments opposed the use of EEQ in the proposal on the grounds that it would be a disincentive to optimal waste water treatment and would deprive dischargers of any "cushion" they create between their effluent limits and actual effluent quality to ensure compliance. However, other commenters supported the reasoning in the proposed Guidance that led to the proposed use of EEQ, namely that the environmental risk from BCCs is so great that any increased loading should be considered significant.

To reconcile these two positions, the final Guidance employs an approach that, while not linked to specific, numeric limits, requires an antidegradation review any time a discharger undertakes an activity that could result in an increased loading of BCCs. The new approach will be implemented through notification requirements in a discharger's control document. Antidegradation review will occur when an action is proposed that is likely to result in an increased loading of BCCs. No regulated facility would be permitted to take an action that would result in an increased loading of BCCs without completing an antidegradation demonstration and receiving approval from the State or Tribe with jurisdiction over the affected waters. Taking an action without receiving approval would be a violation of the applicable control document and would be subject to enforcement. EPA selected this approach because it eliminates perceived problems with EEQ and yet is consistent with defining any increase in loadings of BCCs as a significant lowering of water quality. Also, it places greater emphasis on the prevention and minimization of any significant lowering of water quality and less on use of antidegradation as punitive measure against dischargers. As envisioned by the final Guidance, antidegradation is a tool to be used by States and Tribes to make rational, well-supported decisions regarding activities that affect water quality. For dischargers, antidegradation should be viewed as a reality check on a proposed project, that all possible opportunities to minimize impacts on water quality have been considered and implemented, as appropriate. States and Tribes may employ EEQ as a means of implementing antidegradation if they so choose.

A further benefit of the approach taken in the final Guidance is that it does not require quantifiable effluent concentrations for implementation. Where the available data are insufficient to calculate a loading level but BCCs are known to be discharged, as in the case where discharge concentrations are below levels of quantification, increased loadings of BCCs are controlled by a requirement in the control document prohibiting a discharger from taking any deliberate action that would increase loadings of BCCs without first providing an antidegradation demonstration and receiving approval for the increase from the Director. Thus, where loadings of BCCs are occurring, but are not quantifiable, increases are still subject to antidegradation.

It should be noted that requiring a discharger to receive approval prior to taking an action that will result in a lowering of water quality is not a new requirement. The intent of the antidegradation policy contained in the Federal regulations at 40 CFR 131.12 is that antidegradation review of an activity that will lower water quality occur before the activity takes place, when the antidegradation review will be most effective in identifying ways that degradation of water quality may be minimized.

For non-BCCs, EPA recommends that, at a minimum antidegradation review be required any time a permit limit is made less stringent. States and Tribes must also ensure that the antidegradation policy and procedures they adopt address new sources and increasing sources where no permit limit currently exists for a pollutant. States and Tribes may also include a provision in their procedures that allows them to review any action that is not specifically addressed to provide the flexibility to respond to unforeseen circumstances.

3. Antidegradation Demonstration

a. Background

Existing Federal regulations at 40 CFR 131.12 require that water quality in a high quality water be maintained and protected unless a lowering of water quality is necessary to support important social and economic development. The phrase "antidegradation demonstration" is used as shorthand for the information gathered for review by the permitting agency to show whether or not an action proposed by a discharger that will result in a significant lowering of water quality both is necessary and will support important social and economic development.

The proposed Guidance required an antidegradation demonstration be performed prior to any significant lowering of water quality. The proposed Guidance interpreted the Federal regulations at 40 CFR 131.12 as requiring two distinct demonstrations; first, that the significant lowering of water quality was "necessary," meaning the proposed activity could not occur without a concomitant significant lowering of water quality, and second, that the proposed activity would result in social and economic development. Consistent with Federal regulations, the proposed Guidance organized the antidegradation demonstration into a hierarchy of three separate demonstrations to be made by the discharger. The discharger was required to demonstrate that the significant lowering of water quality could not be reduced or prevented through the application of prudent and feasible pollution prevention alternatives, that the significant lowering of water quality could not be prevented through the application of alternative or enhanced treatment within a defined cost range and finally, if, as a result of the preceding demonstrations, a significant lowering of water quality was shown to be necessary, that the proposed activity would result in social and economic development. Each of the demonstrations included certain required elements to be considered by dischargers conducting an antidegradation demonstration.

b. Discussion of Significant Comments

Comment: Tribes and States lack the technical expertise required to review antidegradation demonstrations.

Response: The final Guidance identifies the broad areas that should be a part of any antidegradation demonstration. This document identifies key areas that should be considered in evaluating an antidegradation demonstration, which will assist Tribes and States in their reviews. Using the final Guidance, Tribal and State water quality personnel should be capable of determining whether or not an antidegradation demonstration prepared by a discharger considers all of the essential elements.

It should also be noted that preparing a demonstration may in and of itself be useful to the proponent of an activity that would significantly lower water quality. In order to request a significant lowering of water quality to accommodate a particular activity, a discharger must investigate alternatives to lowering water quality. This investigation may lead the discharger to cost-effective alternatives to lowering water quality.

Comment: More detailed guidance is needed on all aspects of the demonstration.

Response: In reviewing the comments received, EPA is convinced that it is not possible to write guidance that would cover adequately every possible situation. In addition, including great detail would hinder efforts by Tribes and States to adapt the final Guidance to existing regulatory structures and thereby slow its ability to respond to requests to lower water quality. Consequently, the final Guidance provides a framework within which Tribal and State programs must operate with respect to BCCs. This general approach will also prove more versatile as new circumstances arise that were not foreseen when the Guidance was developed. Further, general guidance allows Tribes and States to tailor antidegradation reviews, including level of detail and documentation, to the specific circumstances encountered.

Comment: A number of commenters noted that the costs of pollution prevention need to be considered.

Response: The final Guidance has been revised to require that a discharger identify "cost-effective" pollution prevention alternatives that will eliminate or greatly reduce the extent of the significant lowering of water quality. Alternatives that would cause the proponent of the activity to incur excessive costs would not be considered cost-effective; however, pollution prevention can be the most cost-effective and environmentally benign approach to protecting the environment.

EPA's intent in having pollution prevention figure so prominently in the antidegradation demonstration is to focus attention on alternatives that will not lead to the release of pollutants to the environment rather than on those that depend upon treating the pollution after it is generated. Such an emphasis is consistent with the hierarchy outlined in EPA's National Pollution Prevention Policy (see discussion in section I of this document).

Comment: Several commenters stated that the ten percent mandatory expenditure requirement for enhanced and/or alternate treatment is arbitrary.

Response: EPA agrees that the ten percent mandatory expenditure requirement may limit the ability of States and Tribes to consider individual circumstances in reviewing antidegradation demonstrations. As a result, the ten percent additional cost benchmark is included in this document as guidance only. EPA realizes that the determination of what represents affordable treatment options is specific to the case in question. Therefore, a strict cut-off at ten percent additional costs is not realistic. Greater costs may be affordable in some cases; in others, ten percent may be too expensive. In the final Guidance, the determination of what treatment alternatives are practicable is left to Tribes and States. EPA is developing additional National guidance on a variety of issues related to economic considerations in water quality standards that will provide direction to Tribes and States as they implement their antidegradation policies. It is important to note that the affordability measures discussed above are separate and distinct from any determination of penalties or ability to pay within the context of an enforcement action.

Comment: Some commenters suggested that the cost-effectiveness alternative described in the preamble to the proposal is preferable to the approach taken in the proposed Guidance.

Response: Although EPA considers the ten percent additional cost benchmark to be the easiest measure of affordability to implement, the final Guidance does not mandate any one approach to identifying available treatment options. Tribes and States are free to use any approach they choose that is appropriate to the specific situation under consideration. The increased flexibility of the antidegradation requirements of the final Guidance will make it more sensitive to the circumstances of each individual situation. Any benchmark chosen by a State or Tribe to determine whether or not additional or alternative treatment is affordable is relevant only within the context of an antidegradation demonstration for purposes of evaluating information provided in support of a request to lower water quality in a high quality water.

Comment: Some commenters believed that expenditures should be required even if improvements are only incremental.

Response: The final Guidance does not preclude Tribes or States from granting only partial approval of requests to lower water quality. Where a Tribe or State believes that a project may occur with a less extensive lowering of water quality than was requested, control documents may be issued with limits that reflect the lowering of water quality necessary to accommodate the activity.

Comment: Several commenters stated that the antidegradation demonstration should establish a direct link between the degradation of water quality and the social and economic development.

Response: EPA agrees with this comment in principle. In the final Guidance, a demonstration of the important social and economic development that will result from the proposed significant lowering of water quality is a precondition to approving a significant lowering of water quality. The other components of the antidegradation demonstration, the cost-effective pollution prevention analysis and the enhanced and alternate treatment analysis are intended to ensure that social and economic development takes place with a minimum of environmental impact. However, it is not always possible to quantify exactly how much degradation is associated with a certain activity that will produce social and economic development.

c. The Final Guidance

The final Guidance retains the framework contained in the proposed Guidance, but with less detail. The demonstration is divided into pollution prevention, alternative and enhanced treatment and social and economic development components that are performed in series. States and Tribes are required to adopt the demonstration elements contained in the final Guidance for purposes of regulating new and increasing discharges of BCCs. For non-BCCs, States and Tribes may either adopt the procedures contained in the final Guidance, or develop their own antidegradation demonstration requirements provided they are consistent with the requirements of 40 CFR 131.12.

The first two components of the demonstration, the pollution prevention alternatives and the enhanced and alternative treatment demonstrations, address the question of whether or not water quality must be lowered to accommodate the proposed activity (i.e., is the significant lowering of water quality necessary). EPA's intent in mandating these tests is to ensure that, when they are available, feasible alternatives that would allow an activity to occur with little or no degradation of water quality are identified and implemented and the lowering of water quality is minimized. In keeping with EPA's preference for source reduction over waste treatment, dischargers are first directed to identify any and all cost-effective pollution prevention alternatives that might eliminate or reduce the proposed significant lowering of water quality. If the significant lowering of water quality cannot be eliminated entirely through pollution prevention, then alternative or enhanced waste water treatment should be considered. Only after pollution prevention and alternative and enhanced treatment are examined and no feasible alternative to the significant lowering of water quality is found can it be considered necessary. A more detailed discussion of the components follows.

i. Identification of Cost-Effective Pollution Prevention Alternatives to Prevent or Reduce the Significant Lowering of Water Quality

This is the starting point for the antidegradation demonstration. The proponent of the activity should consider five broad categories of pollution prevention activities in determining whether or not alternatives exist that would reduce or eliminate the anticipated significant lowering of water quality. These include:

-- Substitution of non-bioaccumulative or non-toxic chemicals for BCCs. The primary objective of this evaluation is to determine if the source of a BCC, which would otherwise cause or contribute to a significant lowering of water quality, can be eliminated in favor of a less environmentally problematic substance, especially one that is not a BCC.

-- Application of water conservation methods. The objective of this portion of the pollution prevention analysis is to determine whether or not reductions in the overall volume of waste water are possible and would reduce pollutant loadings so that the proposed activity could occur without a significant lowering of water quality.

-- Waste source reduction within process streams. The objective is to evaluate all waste streams involved in the process affected by the proposed activity. Opportunities to control more carefully the use of raw materials and reduce waste should be identified and implemented where feasible.

-- Recycle or reuse of waste byproducts, either liquid, solid or gas. The objective is to identify ways in which recycling and reuse of internal waste streams can be employed to reduce the loadings of pollutants to the environment. This is a common practice in industry and can reduce energy, raw material and waste disposal costs. The proponent of the proposed activity should investigate the process involved to determine whether or not opportunities exist to implement such changes where they would alleviate the need for a significant lowering of water quality.

-- Manufacturing Process Operational Changes. The focus of this part of the investigation should be to identify different means of achieving the desired end that will produce either smaller quantities of toxic waste products or waste products that are less toxic. All of the processes that will contribute to the significant lowering of water quality should be examined and alternatives that would reduce or eliminate the need to lower water quality significantly should be identified.

The pollution prevention possibilities discussed above are not intended to be all inclusive. Dischargers seeking approval for an action that will result in a significant lowering of water quality should evaluate all aspects of the proposed activity for opportunities to reduce pollutant loadings. The categories of pollution prevention discussed above should be viewed as guidance to those performing an antidegradation demonstration and those evaluating it.

Pollution prevention is applicable to municipal as well as industrial dischargers. Where a significant lowering of water quality will result from increased industrial use of a municipal treatment plant, the municipality should ensure that the loadings from the industrial users are minimized through pollution prevention to the extent possible. Tools available to municipalities to encourage pollution prevention include local limits and fees levied on industrial users. Municipalities should also consider public education and bans on certain substances to reduce loadings from nonindustrial sources.

The determination that an alternative or combination of alternatives is cost-effective is the decision of the Director, and not the entity that is seeking to significantly lower water quality. States and Tribes are encouraged to develop their own guidelines to follow when evaluating pollution prevention alternatives identified by the entity to select those that are cost-effective.

ii. <u>Alternative or Enhanced Treatment to Eliminate the Significant Lowering of Water Quality</u>

The second part of determining whether or not a significant lowering of water quality is necessary is the alternative or enhanced treatment analysis.

This analysis should be undertaken after the pollution prevention analysis is completed and should focus on removing the remaining incremental increase in pollutant loadings after cost-effective pollution prevention measures are taken. If application of pollution prevention techniques alone are sufficient to eliminate the significant lowering of water quality, the alternative or enhanced treatment analysis need not be performed.

The objective of the alternative or enhanced treatment analysis is to ensure that the actual degradation of the high quality water is reduced to the greatest extent practicable. The analysis proceeds by identifying the least costly options for additional treatment under which the proposed activity could occur without resulting in a significant lowering of water quality. The costs of the different treatment options are determined and compared to the costs of the treatment needed to achieve all applicable standards, including Federal effluent guidelines, water quality-based effluent limits and all other applicable Federal and State or Tribal requirements. Where treatment options are identified that are comparable in cost to baseline treatment costs and allow the proposed activity to occur without leading to a significant lowering of water quality, those treatment options should be implemented in lieu of lowering water quality.

In the proposed Guidance, EPA considered using a ten percent increase in treatment costs as a benchmark for determining whether or not alternative or enhanced treatment options identified through this analysis were affordable. Where treatment options with costs up to ten percent more than the cost of meeting all applicable discharge requirements were identified, the discharger would have been required to implement the treatment option identified and the request to lower water quality would be denied. In the final Guidance, the ten percent cost benchmark is provided as guidance only. Tribes and States may use the ten percent value to assist them in evaluating antidegradation demonstrations. Tribes and States may also use other appropriate means of identifying practicable treatment options such as the cost-effectiveness approach described in the preamble to the proposed Guidance (see 58 FR 20910). The final Guidance does not provide specific direction to Tribes and States on how to determine the affordability of a treatment option under consideration because to do so would limit their ability to respond to the unique circumstances of each antidegradation demonstration. Tribes and States retain the ability to require treatment beyond the benchmarks discussed in the preamble to the proposal, this document (SID), proposed or final Guidance, or to require treatment that will only reduce the magnitude of the significant lowering of water quality. Tribes and States should also see EPA's draft, Economic Guidance for Water Quality Standards Workbook, (November 1993) for additional guidance on how to evaluate the affordability of treatment options.

iii. Important Social and Economic Development

In the final part of the antidegradation demonstration, the proponent of the activity that will result in a significant lowering of water quality must show that the significant lowering of water quality proposed will support social and economic development. This part of the demonstration should occur only if no pollution prevention or alternative treatment options are identified that will eliminate the need for a significant lowering of water quality. In determining whether or not a proposed activity will support important social and economic development, Tribes and States should consider the geographic area in which the significant lowering of water quality will occur, the current or baseline economic condition of that area, the net positive impacts that will result from the proposed activity and the possibility of other development occurring in the area that will result in similar economic and social benefits but will not cause a significant lowering of water quality.

-- Identification of the Affected Area

The area in which the economic benefits occur should correspond with the area in which water quality is lowered. Determining the area is a case-by-case decision, made taking into account the pollutants involved as well as the location of the discharge.

-- Baseline Economic Condition

Once the affected area is identified, the baseline economic condition of the area should be assessed. Factors that may be useful include unemployment rates, percentage of the population living below poverty levels, percentage of the population that are elderly and average household income relative to State and National averages.

-- Net Positive Impact

In determining net positive impact the Tribe or State should attempt to assess the benefits of the proposed activity corrected for any negative economic impacts of the activity. The types of benefits from the activity to be considered include an increase in the number of jobs, an increase in personal income and/or wages, reduction in unemployment rates or social service expenses, increased tax revenues and provision of necessary social services. Other measures may be relevant on a case-by-case basis.

Adverse economic impacts may also result from an activity that supports social and economic development. For example, a new industrial facility may provide additional jobs in a community; however it may also make the receiving water less attractive for recreation and cause a loss in tourism dollars. Such impacts should be considered in determining whether or not a project or activity that will result in a significant lowering of water quality will also support important social and economic development.

-- Other Developments

Tribes and States should also consider whether a proposed activity will preclude another activity that may not affect water quality yet yield comparable social and economic benefits. In the example above, the siting of an industrial plant may preclude water front development or building of a marina that would provide comparable social and economic development at less cost to the environment.

4. Antidegradation Decision

a. Background

The final section of the proposed Guidance established the process to be used by the Director for arriving at a final decision regarding whether or not to allow a significant lowering of water quality. The proposed Guidance specified how the information obtained through each of the antidegradation demonstration components was to be evaluated and presented two alternatives for factoring public comment into the final decision. Under the proposed Guidance, public comment could be sought following a tentative analysis of the available data, or the data analysis could be deferred and public comment sought on a tentative decision to deny the request to lower water quality.

b. Discussion of Significant Comments

Comment: Many commenters stated that Tribes and States should be allowed greater flexibility in how data are used and public comment is sought in arriving at a final decision regarding an antidegradation demonstration.

Response: EPA agrees with the views expressed by the commenters. The final Guidance no longer specifies how States and Tribes should consider the data and public input they obtain in making a final decision. Also, States and Tribes are required to adopt a procedure consistent with the final Guidance for BCCs only; States and Tribes may develop their own decision-making procedures for non-BCCs consistent with the requirements 40 CFR 131.12.

c. The Final Guidance

The final Guidance is less prescriptive than the proposed Guidance in that the process for arriving at a decision is left to individual Tribes and States. States and Tribes are only required to adopt procedures consistent with the Guidance for BCCs. However, the essential requirements remain the same and the options presented in the proposed Guidance may be used by Tribes and States. The Director must examine each of the demonstrations submitted by the proponent of the activity that will lower water quality. Also, an opportunity for public comment must be provided and public comment must be factored into the final decision, consistent with the antidegradation standard. EPA expects that the process of making a decision will parallel the antidegradation demonstration process. The Director should first evaluate the analysis of cost-effective pollution prevention alternatives and determine the extent to which pollution prevention can reduce or eliminate the significant lowering of water quality. The Director should then review the information generated through the alternative and enhanced treatment analysis. If the analysis identifies affordable treatment options that, combined with the pollution prevention alternatives, will eliminate the need to lower water quality significantly, the Director should deny the request to lower water quality. If, however, the pollution prevention and alternative treatment analyses are unable to eliminate the need to lower water quality, the Director should weigh the social and economic development that will result from the significant lowering of water quality in the affected area. If the proposed activity is found to support important social and economic development, the Director may decide to grant all or part of the requested significant lowering of water quality, provided water quality sufficient to protect existing and designated uses is maintained and provided the decision is subject to public comment.

Opportunity for public comment is an essential element of the antidegradation decision making process and is required under Federal regulations at 40 CFR 131.12. If the tentative decision relates to an activity subject to a NPDES permit, the public participation requirements may be fulfilled by the public notice of the draft permit and fact sheet. In any event, the public notice of the tentative decision must either set forth the extent to which water quality will be significantly lowered and the basis for the tentative decision to allow the lowering, or, if analysis of the demonstration has been deferred, a tentative decision to deny the request to lower water quality pending public comment and analysis of the information obtained through the antidegradation demonstration.

VIII. IMPLEMENTATION PROCEDURES

A. Site-Specific Modifications to Criteria and Values

1. General

As discussed in the proposed Guidance, there currently exists National guidance to modify aquatic life criteria on a site-specific basis, but there is no such guidance for modifying human health or wildlife criteria on a site-specific basis (see 58 FR 20918). The proposed Guidance continued to allow more stringent site-specific modifications to the wildlife and human health criteria or values and to bioaccumulation factors (BAFs). Sections 1 through 4 below discuss the changes to the site-specific modifications for aquatic life, wildlife, BAFs, and human health.

2. Aquatic Life

a. Proposal: The proposed Guidance, consistent with the current national Guidance, provided that Great Lakes States and Tribes may adopt site-specific modifications allowing more stringent or less stringent aquatic life criteria or values when local water quality characteristics such as pH, hardness, temperature, color, etc., alter the biological availability or toxicity of a pollutant; or criteria when the sensitivity of the local aquatic organisms (i.e., those that would live in the water absent human-induced pollution) differs significantly from the species actually tested in developing the criteria. The proposal suggested use of the existing national guidance provided in the U.S. EPA Water Quality Standards Handbook (1983) (1983 Handbook) when modifying the criteria. (Since the proposal, the 1983 Handbook has been reformatted and republished as the U.S. EPA Water Quality Standards Handbook, Second Edition - Revised, 1994) (Revised Handbook) The Revised Handbook is available in the docket for this rulemaking.

The proposed Guidance went beyond existing national guidance by also allowing the Great Lakes States and Tribes to develop site-specific modifications to chronic aquatic life criteria for the Great Lakes System to reflect local physical and hydrologic conditions. Such conditions might include natural features of a water body, such as lack of proper substrate, cover, flow, depth, pools, and riffles, unrelated to ambient water quality. Specifically, such conditions would include any local physical or hydrological condition which precluded aquatic life from remaining at the site for 96 hours or more. The proposal stated that sites where conditions precluded all but a few forms of aquatic life from living may be protected by less stringent chronic criteria. EPA expected that this provision would typically be used for waters where a full aquatic life use is unattainable. The proposal did not include such a provision for acute aquatic life criteria.

b. Comments: Many commenters supported the proposal for allowing more or less stringent site-specific modifications to aquatic life criteria/values when local water quality parameters alter the biological availability or toxicity of a pollutant; or criteria when the sensitivity of the local aquatic organisms differs significantly from the species actually tested in developing the criteria. A few commenters requested that EPA not allow any less stringent site-specific modifications to aquatic life criteria. These commenters were concerned that less stringent criteria in localized areas in the Great Lakes System would cause declines in downstream water quality.

Several commenters suggested that EPA also allow less stringent site-specific modifications for acute aquatic life criteria to reflect local physical and hydrologic conditions. They reasoned that when physical or hydrological conditions preclude aquatic life from remaining at a site for a period of time in which acute effects may occur, less stringent site-specific aquatic life criteria should be allowed. Further, commenters pointed out that EPA offered no support for why this exception was allowed for chronic criteria, but not acute criteria.

EPA agrees with the commenters suggesting that there may be instances where aquatic life might not inhabit a site due to the site's physical or hydrological characteristics (e.g., natural features of a water body, such as lack of proper substrate, cover, flow, depth, pools, and riffles, unrelated to ambient water quality). To make such modifications, EPA will expect the State or Tribe to demonstrate that aquatic organisms do not inhabit a site or do not spend sufficient time at the site to experience acute effects. The final Guidance provides that the acute criteria may be modified to be less stringent to reflect local physical and hydrological conditions. Such modification may be made to the criterion using the recalculation procedure provided in Chapter 3 of the Revised Handbook.

Like the National program, State and Tribal programs must ensure that less stringent site-specific modifications do not impair the water quality of downstream waters. In addition, allowance for less-stringent site-specific criteria must still ensure protection of species which do "occur at the site" (as defined in appendix F.A.1.a.ii of this rulemaking); in other words, the absence of acute and chronic criteria is unacceptable.

c. Final Guidance: The final Guidance maintains the requirements in the proposal with the following changes: States or Tribes are allowed to develop site-specific modifications to both acute and chronic criteria to reflect local physical and hydrological conditions. This is a change from the proposal which only allowed modifications for physical or hydrological conditions to chronic criteria. The final Guidance still allows modifications to both acute and chronic criteria/values to reflect water chemistry and to criteria to reflect species sensitivity differences. The final Guidance provides the State or Tribe with some options for achieving the requirement to protect endangered or threatened species, such as: (i) if the Species Mean Acute Value (SMAV) for a listed species, or for a surrogate of a listed species, is lower than the calculated Final Acute Value (FAV), such lower SMAV is used instead of the calculated FAV in developing site-specific modified criteria; or (ii) the site-specific criteria may be calculated using the recalculation procedure described in Chapter 3 of the Revised Handbook. In option (ii), acceptable toxicity data (as defined in appendix A to part 132 for the aquatic life Tier I criteria methodology) for the listed species or a surrogate for the listed species must be included in the data set in which the criterion is recalculated.

In defining a site the State or Tribe should consider the known range of the threatened or endangered species. Either option will ensure protection for species listed under the Federal Endangered Species Act when adequate data are available. If there is a critical food source which is also an aquatic animal, option (ii) might provide a greater level of protection for that listed species if that food organism were more sensitive than the listed species itself. By including data for the organism which is a critical food for the listed species, option (ii) will ensure protection of that food source from water quality effects. Option (i) only considers the sensitivity of the listed species itself. EPA wishes to clarify that the recalculation procedure contains a provision that the recalculated FAV, Criterion Maximum Concentration (CMC), and/or Criterion Continuous Concentration (CCC) should be lowered if necessary to ensure that the criterion is not likely to jeopardize the continued existence of any endangered or threatened species listed under section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat.

For metals criteria, a State or Tribe may wish to use total recoverable metals criteria rather than dissolved criteria to provide a greater level of protection for such species. EPA recommends use of total recoverable metals criteria when it is known that an endangered or threatened species is chronically sensitive to metals and lives in or on sediments and whose diet is substantially comprised of benthic aquatic organisms.

If the SMAV for a listed species, or for a surrogate of a listed species, is not lower than the calculated FAV or if the recalculated criteria (with data for the listed species included) is less stringent than the established Tier I criteria or Tier II value, then the existing Tier I criteria or Tier II value provides adequate protection for the listed species.

3. Wildlife

Many comments were received on the proposed use of site-specific modifications to wildlife criteria. The significant comments, including EPA responses and changes to the proposal, are set out below. Responses to all comments are contained in the Response to Comments Document, which is part of the docket for this action.

a. Site-specific Modifications

i. Proposal: The proposed procedure 1 allowed wildlife criteria and values to be modified on a site-specific basis to provide an additional level of protection. This additional protection could be provided through the use of an intraspecies uncertainty factor (UF), which was applied in addition to the other UFs in the wildlife methodology (58 FR 20880). The proposal did not allow for less-stringent modification to wildlife criteria or values.

ii. Comments: Many commenters agreed with the need for site-specific modifications for wildlife, citing such factors as waterbody-specific characteristics driving the bioavailability of the chemical in question, the geographical representation of the representative species, and the dietary habits of the representative species. Many of the commenters criticized the proposal for allowing only those modifications which would be more stringent than the Great Lakes System-wide criteria, stating that it is not technically defensible because certain taxa may be missing from specific locations, the assumptions of the environmental fate of the chemical of concern may not be valid for all sites in the system, and wildlife mobility may affect exposure assumptions.

EPA recognizes that there may exist situations in which a site-specific modification, resulting in a less stringent criterion or value, may be appropriate; therefore, the final Guidance allows for the development of site-specific modifications to wildlife criteria that may be more or less stringent than the Great Lakes System-wide criteria. The following discussion provides additional guidance for the development and application of site-specific modifications that are more or less stringent than system-wide wildlife water quality criteria.

(A). Less Stringent Site-specific Modifications

Modifications to wildlife criteria that result in less stringent site-specific criteria may be allowed when a site-specific BAF is derived, which is lower than the System-wide BAF derived under appendix B to part 132. At the same time, it is important that a site-specific relaxation of system-wide criteria not produce off-site impairments of designated uses due to wildlife and prey mobility, pollutant transport, and interbreeding of populations of varying sensitivities. To safeguard against that, the final Guidance requires that a showing be made before approval of any site-specific modification is granted that: any increased uptake of the toxicant by prey species utilizing the site will not cause adverse effects in wildlife populations in the Great Lakes System; wildlife populations utilizing the site, or boundary or interconnecting waters will continue to be fully protected; and, the mobility of all prey organisms and wildlife populations have been adequately described in justifying the site.

EPA considered allowing less stringent modifications to the wildlife criteria based on site-specific distributions of wildlife species, and their associated dietary habits. EPA believes that in most cases a less stringent site-specific modification based on these factors will be difficult because the representative species listed in the final Guidance were not selected to be the sole species targeted for protection; rather, they were selected to exemplify the highly exposed wildlife species resident in the Great Lakes basin. Hence, even if a representative species is not found at a specific geographic site, or has a diet different than that listed in appendix D to part 132. other highly exposed wildlife species would still need the protection granted by the criteria derived under appendix D to part 132, or those criteria listed in Table 4 to part 132. In addition, because in many cases it is difficult to determine the relative sensitivities of the species within a specific area, the use of the highly exposed species to represent all species ensures that the majority of species will be protected if they are more sensitive. Although, EPA believes it would be difficult to demonstrate that there are no species within an area that are not as exposed or not as sensitive as the representative species, EPA believes it should not preclude calculating wildlife criteria using a different set of species than those used in deriving the four wildlife criteria.

An important component of a site-specific modification is the definition of the site to which the modification is applicable. A site may range from being a portion of a watershed to the entire part of the Great Lakes System under the jurisdiction of the State or Tribe proposing the modification.

(B). More Stringent Site-specific Modifications

States retain the authority through section 510 of the Clean Water Act (CWA) to develop site-specific modifications that are more stringent than system-wide criteria. Use of the wildlife methodology described in appendix D to part 132 is recommended, with the appropriate changes to the toxicological or exposure parameters that are contained in that methodology. The allometric equations provided in appendix D to part 132, section III.E may be used if feeding or drinking rates for the species are not available. Because the site-specific modifications subject to this subsection will be more stringent than the corresponding system-wide value or criterion, the concerns behind the demonstration described above for less stringent modifications are not applicable.

iii. Final Guidance: A Tier I wildlife criterion may be modified to be either more or less stringent than the corresponding system-wide criterion or value. Where a site-specific modification is proposed that is less stringent than the system-wide criterion, a demonstration is needed that the site-specific modification will not only protect on-site wildlife species but also protect off-site wildlife species and their prey. The demonstration must consider the mobility of both the wildlife species and the wildlife prey which utilize the site.

b. Protection of Endangered or Threatened Species

i. Proposal: The proposed Guidance did not contain any specific provisions regarding protection of endangered or threatened wildlife species.

ii. Comments: Some commenters stated that protection of the individual, rather than the population, is warranted in cases of endangered or threatened species, but were concerned that the proposed Guidance was too broad in allowing the application of site-specific modifications for protecting individuals beyond those listed under the ESA.

Procedure 1.A of the final Guidance provides that States or Tribes must develop site-specific modifications to protect endangered or threatened species listed under section 4 of the ESA; it also describes a recommended methodology to accomplish such a modification (procedure 1.A.2.c). The final Guidance recommends the use of the methodology contained in appendix D to part 132, modified as described below, to provide a greater degree of protection for endangered or threatened species. Where available, toxicological or exposure data for the species in question shall be used. Where ingestion rates are not available, the allometric equations contained in appendix D to part 132 may be used. Also, EPA strongly encourages the use of the methodology for determining BAFs (Appendix B to part 132) to derive appropriate BAFs for the site-specific modification.

The equation from appendix D to part 132 is modified by the inclusion of an intraspecies UF to provide additional protection for the benefit of individual members of populations. The recommended range of this UF is 1 to 10 and additional discussion is provided in the final Great Lakes Technical Support Document for Wildlife Criteria. In addition, the selection of endpoints for protection of listed species may be broader than those described in appendix D to part 132; however, the selection of an endpoint must be defended by establishing its relevancy to the viability of an individual or its ability to reproduce.

In developing the site-specific modification, it is important to delineate the geographic area to which the modification shall apply. In designating the appropriate site, it is important to consider fully not only the current and potential ranges of the wildlife species in question, but also the range and mobility of the prey organisms. Therefore, a site could, by necessity, be defined as the entire Great Lakes System within the jurisdiction of the State or Tribe.

iii. Final Guidance: Because the equation contained in appendix D to part 132 has been revised in accordance with comments received (see section VI of this document), the following equation is recommended in place of the equation presented in the proposal. In addition, where available and appropriate, toxicological, epidemiological, or exposure information for the species in question is recommended to be used in the methodology.

$$WV = \frac{\dfrac{TD}{UF_A \times UF_L \times UF_S \times UF_I} \times Wt}{W + \sum (F_{TLi} \times BAF_{TLi})}$$

Where the terms are defined in section II, appendix D to part 132, and also include:

UF_I = Intraspecies Uncertainty Factor for extrapolating to the most sensitive individuals within a population (unitless).

The lowest of the wildlife values calculated from the above methodology contained in appendix F.1.2 to part 132, and the two class-specific wildlife values derived for the system-wide wildlife water quality criterion should be selected as the site-specific modification.

4. Bioaccumulation Factors

a. Proposal: The proposed Guidance allowed only more stringent site-specific modification for BAFs pursuant to authority reserved to the States and Tribes under CWA section 510. BAFs could be modified on a site-specific basis where reliable data showed that local bioaccumulation was greater than the system-wide value.

b. Comments: Many commenters stated that it was not scientifically justifiable to allow only more stringent criteria (a higher BAF) and that EPA should also allow less stringent criteria (a lower BAF).

Many commenters stated that less stringent modifications to the BAFs should be allowed based on both chemical- and site-specific characteristics, such as particulate organic matter and dissolved organic matter which may modify the bioavailability of an organic chemical at a specific location; and the partitioning of the chemical between the water column and sediment since this may be a significant factor affecting the bioavailability of the contaminant.

Several commenters stated that they wanted the flexibility to adjust the percent lipid value to reflect that of fish consumed from a particular location. Other commenters were concerned that the fish species used in deriving the BAF may not be present at a particular site, which may lead to a more stringent value than needed at that site.

Many commenters stated that the current BAF methodology precludes using site-specific information. The commenters wanted EPA to instead allow for calculation of a BAF using field data from the site of discharge or other modifications to reflect the characteristics of the site. In particular, commenters suggested modifications to the food-chain model based on chemical-, site- and species-specific data. Some commenters wanted EPA to develop both the methodology and the data for deriving site-specific BAF values.

EPA agrees that both more and less stringent modifications of the BAFs should be allowed on a site-specific basis if there is scientific justification.

EPA agrees with commenters that modifications to the BAFs should include consideration of the bioavailability of the chemical. EPA does not agree that the partitioning of the chemical between the water column and sediment, and other fate processes affect the BAF. However, modifications based on chemical-specific characteristics are not specific to a particular site, and therefore not appropriate for procedure 1 of appendix F to part 132. Chemical-specific considerations are addressed in the derivation of the system-wide BAF for the chemical. Because the final criteria are based on the total concentration of the chemical in the water, the final BAF used in the calculation of the criteria may be modified for site-specific particulate and dissolved organic carbon concentrations.

EPA also agrees that site-specific modifications should be allowed if it can be demonstrated that the percent lipid of aquatic organisms is different than the percent lipid values used in the derivation of BAFs. The percent lipid of 1.82 for trophic level three and 3.10 for trophic level four in edible tissue for use in determining human health BAFs and the percent lipid of 6.46 for trophic level three and 10.31 for trophic level four in whole fish for use in determining wildlife BAFs for an organic chemical are protective of most sites in the Great Lakes. In cases where it can be documented that the percent lipid for the fish species consumed at a site differs from these values, modifications can be made to the BAF.

In the final Guidance, derivation of Food Chain Multipliers (FCMs) based upon the model of Gobas (1993) is used because the input parameters are easily defined and measured, the calculated BAFs are in better agreement with measured BAFs for chemicals with very high K_{ow}s than the Thomann model (1989) used in the proposal, and the model uses equilibrium partitioning theory to predict chemical residues in benthic organisms. The model of Gobas (1993) can also be adjusted for site-specific considerations. The FCMs in Table 1 of appendix B to part 132 were calculated using Great Lakes-specific data. If it can be demonstrated that the values for input parameters used by EPA are not appropriate for a given site, use of other values is permitted. In particular, States and Tribes can use site-specific data for the food web and accompanying lipid content of the aquatic species, and concentrations of the dissolved organic carbon and particulate organic carbon. If one input parameter is modified, site-specific values must be used for all input parameters. Selective modification of the FCM is not allowed because it will not accurately represent the characteristics of a specific site.

For the final Guidance, a distinct single BAF for each trophic level of concern for derivation of human health criteria and a separate distinct single BAF for each trophic level of concern for derivation of wildlife criteria were calculated using the concentrations of POC and DOC in Lake Superior as reasonable worst-case conditions. As noted in the above responses and in the methodology set forth in procedure 1 of appendix F to part 132, and subsequently in appendix B to part 132, EPA is allowing for modifications to the BAF based on site-specific characteristics.

c. Final Guidance: EPA is allowing site-specific modifications to the BAF based on the procedure set forth in procedure 1 of appendix F to part 132.

5. Human Health

a. Proposal: The proposed Guidance stated that there is no specific EPA guidance regarding site-specific modifications to human health water quality criteria. (The 1983 Handbook does not offer any guidance in the area of human health site-specific criteria development.) Consistent with the Steering Committee proposal, the proposed Guidance restricted site-specific modification to human health criteria/values to only those which would increase the level of protection for humans. The proposed Guidance also stated that human health criteria or values shall be modified on a site-specific basis to provide additional protection appropriate for highly exposed subpopulations.

EPA invited comments on whether the proposed approach for humans and wildlife was reasonable or whether less stringent site-specific modifications could be allowed under certain circumstances.

b. Comments: EPA received numerous comments that States should be allowed to make a demonstration for less stringent human health criteria based on site-specific conditions, if scientifically supported. The majority of commenters suggested that two exposure components, fish consumption and fish lipid content should be evaluated on a site-specific basis. These same commenters believed that there could be parts of the Great Lakes System (especially tributaries) where one could demonstrate that the fish consumption rate and/or fish lipid concentration are significantly different (presumably lower) from those in the proposed Guidance. Other commenters argued that the body weight of sensitive subpopulations (women of childbearing age and children) should be accounted for in developing human health criteria on a site-specific basis. Commenters also believed that site-specific criteria should be generated only if the resulting criterion were protective of potential uses at the site and all downstream uses. Commenters stated that EPA did not provide scientific justification for allowing only more stringent site-specific human health criteria.

A few commenters were opposed to the idea of less stringent site-specific human health criteria. Commenters stated that less stringent criteria should not be allowed for the open waters of the Great Lakes, since this would result in inconsistency throughout the basin, but was in favor of allowing less stringent modifications for tributaries (waters other than the open waters of the Great lakes). Other commenters believed that EPA should not allow site-specific modifications for fish consumption of subsistence and recreational angler; but should select a fish consumption rate protective of sport anglers and other highly exposed subgroups. Still other commenters pointed to the impractical nature of conducting meaningful site-specific studies because the Great Lakes Basin is large with free movements of fisheries and distribution of pollutant loadings, believing the practice would only result in States imposing different health advisories and ultimately non-attainment of water uses.

EPA agrees with many of the comments, and has changed the final Guidance to allow for demonstrations for less stringent site-specific human health criteria as related to fish consumption rate and BAFs. Other exposure parameters such as drinking water consumption rate, body weight and incidental ingestion rate can fluctuate on a population basis, but are not considered parameters likely to change on a site-specific basis. For example, the mean body weight of a State may be greater or less than the 70 kilograms assumed in the criteria methodology, but making a determination that a specific site has a higher or lower mean body weight may be implausible and impractical. To make a showing for a less stringent criterion, a State or Tribe would have to demonstrate that there was a site-related population of people weighing more than 70 kilograms. In addition, EPA has provided guidance on choosing protective body weights for those parts of the population considered more vulnerable to the toxicological effects of environmental contaminants. With regard to toxicological assessments, EPA does not believe there are likely conditions under which a site-specific toxicological assessment can be made. For example, to make a site-specific toxicological assessment, it would have to be shown that a particular human population at a specific site was more or less sensitive to an environmental contaminant due to genetic predisposition or site-related conditions which mitigate or enhance the toxicological effects of a specific chemical contaminant. Again, EPA believes making such a showing is highly unlikely and probably implausible.

i. <u>Fish Consumption Rate:</u> EPA believes, on the other hand, that it is conceivable that there might be isolated tributaries and populations of people who do not consume as much fish as the rate presented in the proposal. Such a demonstration would likely be difficult to make, due to the transience of people in the Great Lake area, but if a State or Tribe can demonstrate based on data that a group of people who are the exclusive users of a waterbody has a significantly lower fish consumption rate than the rest of the Great Lakes population, they may apply that lower rate in developing their human health criteria for that waterbody. The States and Tribes must ensure that fish migration from the waterbody in question will not lead to increased exposure to other human populations. The State or Tribe must also demonstrate that the specified waterbody is not associated with a known or anticipated group of individuals who may consume more fish, such as a sport or subsistence angler population. To ascertain such information, the State or Tribe must conduct a site-specific fish consumption survey. When determining a site-specific fish consumption rate, a site-specific fish lipid percentage must also be determined.

In response to commenters who stated EPA should not allow for site-specific criteria adjustments due to the difficulty in conducting meaningful site-specific surveys, EPA does not believe it is fair to disallow such a demonstration if a State or locality believes there is a basis for such a showing. While it is true that a well conducted fish consumption survey is costly and sometimes open to various interpretations, the data from such a survey may be more useful in determining subpopulation consumption trends than a default value or a generalized assumption for an entire population of people.

ii. <u>Percent Fish Lipid:</u> EPA has concluded that the percentage of fish lipid can be adjusted on a site-specific basis. This can be done in conjunction with a fish consumption survey or localized monitoring data on fish species of the area. From a site-specific fish consumption survey, the predominant fish species consumed, the percentage of each species consumed, and the lipid concentration of those species can be determined. If the recalculated weighted mean percent lipid is significantly different than that in the final Guidance, it may be used in calculating site-specific human health criteria.

iii. <u>BAF:</u> EPA has concluded that the BAF can be adjusted on a site-specific basis. (See section A.4 of this document on BAFs to determine how a site-specific BAF can be derived.)

In response to the commenters who stated site-specific criteria should be limited to tributaries only, EPA concludes that a showing can be made for any part of the Great Lakes System as long as it is scientifically justified. Site-specific conditions must be the basis for the criteria adjustment regardless of geographical location in the Great Lakes System.

With regard to the Guidance which states that human health criteria or values shall be modified on a site-specific basis to provide additional protection appropriate for highly exposed subpopulations, EPA believes the best way to determine whether a highly exposed subpopulation exists is through the use of fish consumption surveys targeted toward waterbodies and sites which are known (qualitatively, if not quantitatively) for high levels of sport and subsistence angler usage. Once a site/waterbody is established as a high-use site, a fish consumption survey should be conducted to determine average and high level (90th or 95th percentile consumption rates) consumption rates for the sport and subsistence angler subpopulations. Once it is established that a highly exposed subpopulation does exist at a distinct site, the criteria or values must be modified using the fish consumption rate, the percent lipid, and the resulting BAFs associated with the higher consumption rates attributed to the subpopulation in question. For information on how to conduct a fish consumption survey and how to analyze the results of such a survey, refer to the following EPA document: Consumption Surveys for Fish and Shellfish. A Review and Analysis of Survey Methods. Feb. 1992. EPA 822/R-92-001.

An alternative to conducting site-specific fish consumption surveys is to use default assumptions for fish consumption by recreational and subsistence anglers. Several commenters recommended default assumptions for recreational and subsistence fish consumption. For recreational fish consumption, the commenters recommended using a range of 45-150 grams/day in developing water quality criteria protective of sport anglers. For subsistence fishing, the commenters recommended using a range of 90-165 grams/day in developing water quality criteria protective of subsistence anglers. EPA believes the use of default assumptions are acceptable. The actual default values used, however, will depend on the circumstances in that State or Tribal area. For more details on the commenters' recommendations refer to the Environmental Defense Fund/ Penobscot Indian Nation/NAACP Legal Department document entitled: The Protection of Sport and Subsistence Fishing Populations in the United States: Recommendations to the Administrator, EPA, For Implementation of the President's Executive Order on Environmental Justice and the Subsistence Consumption of Fish and Wildlife, June 1994 which is available in the docket for this rulemaking.

c. <u>Final Guidance:</u> The final Guidance allows human health criteria or values to be modified on a site-specific basis based on differences in fish consumption, or BAF where the resulting criteria may be less stringent than the final criteria listed in Tables 3, for the reasons stated above.

B. Variances from Water Quality Standards for Point Sources

The final Great Lakes Water Quality Guidance allows Great Lakes States and Tribes to include water quality standards variance provisions in their water quality standards, and grant variances based on those provisions, as long as they are consistent with procedure 2 of appendix F. These water quality standards variance procedures provide a mechanism for States and Tribes to maintain the basic standards (uses and criteria) as goals and assure compliance with sections 301(b)(1)(C) and 402(a)(1) of the CWA that require NPDES permits meet applicable water quality standards, while granting temporary relief to point source dischargers under appropriate circumstances. This Guidance does not require the States or Tribes to include a variance provision as part of their standards program.

The intent of the variance provision is to: provide a mechanism by which permits can be written to meet a modified standard where compliance with the underlying water quality standard is demonstrated to be infeasible; encourage maintenance of original standards as goals rather than removing uses that may be ultimately attainable; identify conditions under which variances may be granted; identify the requirements for variance applications; and ensure the highest level of water quality achievable while the variance is in effect.

The final variance procedures included in procedure 2 of appendix F differ little from the proposal and provide for consistent application of water quality standards variances for Great Lakes States and Tribes. Variances can be requested for any of the same reasons which justify removing designated uses as described at 40 CFR 131.10(g).

In the final Guidance, States and Tribes retain the discretion to define what specific information they will require in a permittee's variance demonstration and application. States and Tribes also have the discretion to define the decision criteria to use when approving or disapproving a variance, as long as they are at least as stringent as the requirements in procedure 2 of appendix F and subject to EPA review and approval.

A State or Tribe choosing to adopt variance procedures as part of its part 132 submission will provide information on the requirements for the variance demonstration and application as well as the evaluation criteria that the State or Tribe will use to approve or disapprove specific variances. A variance procedure should assure that: the public has sufficient information to comment on the appropriateness of a State's or Tribe's WQS variance process; EPA has sufficient details to determine if the State or Tribe procedures comply with the CWA and are approvable; and both EPA and the public have adequate information on which to judge State or Tribal compliance with its own procedures when making individual variance decisions. The final guidance does not require States or Tribes to grant variances in any specific circumstance.

In addition to reviewing individual variances granted by a State or Tribe, EPA will review the State or Tribal variance procedure itself as part of its review of the State or Tribe's GLI submission.

1. Applicability

a. Proposal: The proposed Guidance limited the availability of a variance to the permittee requesting the variance and only for the pollutant(s) specified. The water quality standards for the affected water body would not otherwise be changed by a variance. The proposal also did not allow variances for new or recommencing dischargers as those terms are defined at 40 CFR 122.2.

In procedure 2.C of the proposal, EPA also did not allow a variance to be granted if standards would be attained by implementing effluent limitations required under sections 301(b) and 306 of the CWA and by the permittee implementing cost-effective and reasonable best management practices. (In the final Guidance, this requirement has been moved to the Applicability section for clarity.)

b. Discussion of Significant Comments

Comment: Several commenters suggested that EPA also allow basin-wide or waterbody variances often citing the need for relief from "ubiquitous" pollutants. Other commenters objected to allowing waterbody variances.

Response: EPA considered these comments and has decided not to incorporate waterbody variances into the final guidance for the following reasons: (i) EPA has not developed methodologies for applying waterbody variances and has not allowed this practice nationally, (ii) EPA is concerned that waterbody variances could provide inappropriate relief to nonpoint sources and cause an additional regulatory burden to point source dischargers, and (iii) EPA believes that the appropriate long term solution to the problem of "ubiquitous" pollutants is the total maximum daily load (TMDL) process which can account for all sources of pollutant loading both point and nonpoint, and that the appropriate short term relief consists of discharger specific variances and determinations made pursuant to the Reasonable Potential portion of the final guidance. See sections VIII.C. and VIII.E. of this document for a discussion of TMDLs, Reasonable Potential and "ubiquitous" pollutants. In order to provide the most efficient short term relief to "ubiquitous" pollutants, EPA encourages States to consider multiple discharger specific variance requests on a watershed basis where appropriate. Multiple discharger variances are similar to, but not the same as a waterbody variance. Where all point source discharges on a waterbody request a variance, both approaches will have the same effect on the point sources. The difference is that a waterbody variance applies to all nonpoint sources of the pollutant as well, whereas a multiple discharger variance does not.

Comment: Some commenters stated that variances should be available to dischargers who applied for NPDES permits on or before the effective date of the rule.

Response: EPA agrees. The new definition of "new discharger" at §132.2 developed for purposes of compliance schedules and mixing zones will accomplish this.

Comment: Several commenters objected to excluding new or recommencing dischargers for consideration for WQS variances, citing the presence of "ubiquitous" pollutants in the Great Lakes System. Other commenters agreed with the proposal to exclude new and recommencing discharges from variances.

Response: As was stated in the preamble to the proposed Guidance, and reiterated above, WQS variances are used to allow existing dischargers to comply with a modified standard when compliance with the underlying standard is infeasible. Variances are not intended to allow water quality that is already below standards to be further degraded, which would be the case if new or recommencing dischargers add increased loads of a pollutant to a waterbody. This concept is reinforced in the proposed and final Guidance at procedure 2.F.1 which requires that the NPDES permit limitation be no less stringent than that achieved under the previous permit. Since new or recommencing dischargers have no previous load, they could not add any load under the variance procedure's terms. If new, recommencing or existing dischargers desires relief from requirements to control "ubiquitous" pollutants and will not add increased loads of the pollutant to the waterbody, the appropriate mechanisms are found in the TMDL procedure 3 and the Reasonable Potential procedure 5 in appendix F.

Comment: Some commenters requested that EPA more clearly define "recommencing discharger," and specify "...that facilities that cease discharging temporarily, but retain their NPDES permits, are not recommencing dischargers."

Response: EPA disagrees that further definition of "recommencing discharger" is needed. 40 CFR 122.2 defines the term as "...a source that recommences discharge after terminating operations." EPA interprets terminating operations to mean eligible for NPDES permit revocation. Hence, sources that retain their NPDES permits would not be considered "recommencing dischargers."

Comment: Several commenters suggested that EPA should eliminate the requirement of Best Management Practices as a condition for obtaining a variance. Other commenters stated that the BMP requirement should be clarified, or that BMPs should be limited to those that may be implemented by a particular discharger on a reasonable and cost-effective basis.

Response: EPA disagrees that the BMP requirement should be eliminated. EPA agrees, however, that the BMPs that must be implemented before a variance may be granted should be limited to those that may be implemented by a particular discharger. WQS variances are not intended to allow water quality that is already below standards to be further degraded. In addition, as stated in procedure 2.F.1, the purpose of variances are to improve water quality as much as possible by requiring effluent limitations that represent the level of water quality achievable by the permittee. If the permittee can implement cost effective and reasonable BMPs for nonpoint sources, over which it has control, that will attain water quality standards, the permittee should implement those BMPs rather than requesting a variance for its point source discharge. If implementing such BMPs will improve water quality but not meet the standards, implèmentation by the permittee will result in a reduced variance request and an overall improvement in water quality.

c. Final Guidance: For the reasons stated above, EPA has retained paragraph A, the Applicability section of procedure F.2, in the final variance procedures except: (i) the term "new discharger" has been changed to "new Great Lakes discharger" and defined at §132.2, (ii) a new paragraph 2.A.2 has been added to assure compliance with section 7 of the Endangered Species Act, and (iii) the final sentence from procedure 2.C of the proposal has been moved and re-numbered as procedure 2.A.3.

2. Maximum Timeframe for Variances

a. Proposal: Procedure 2.B of the proposal, specified a variance term not to exceed three years. EPA proposed the three-year term to reinforce the triennial review required of all water quality standards in accordance with section 303(c) of the Clean Water Act.

b. Discussion of Significant Comments

Comment: This section received a large number of comments. Some commenters favored retaining the three-year requirement but the majority favored extending the life of a variance to five years or the term of the NPDES permit for which it is granted. Several commenters stated that a three year variance term would present a substantial administrative burden on both the discharger and the permitting authority, especially for situations where a variance renewal is appropriate.

Response: EPA's 1979 Guidance (see the preamble to the proposed Guidance (58 FR 20921) for discussion of EPA's 1979 Guidance) clearly indicated that variances are granted for a specific time period and must be reviewed every three years, but does not suggest that variances must expire at the same three-year interval.

c. Final Guidance: Based on the comments and the rationale above, EPA has extended the allowable term for a water quality standards variance to five years or the term of the NPDES permit, whichever is less. This reduces the administrative burden of a facility in preparing a variance request since the facility can prepare the request at the same time it prepares the NPDES permit application. To ensure that variances are indeed reviewed triennially with the rest of the State or Tribal standards, and modified as appropriate, EPA has added that requirement to procedure 2.B. In addition, a new requirement has been added at procedure 2.F.4 to provide for reopening and modifying the NPDES permit as appropriate based on changes made during the water quality standards review, *e.g.* if the variance is terminated or modified.

3. Conditions to Grant a Variance

a. Proposal: Variances under the proposed Great Lakes Guidance were applicable if any of five specified types of waterbody conditions exist and/or the affected community would encounter substantial and widespread economic and social impacts as a result of the point source having to install controls, beyond technology-based requirements, necessary to meet the WQS.

The permittee was required to make two other demonstrations. The first demonstration was that the requested variance is consistent with State or Tribal antidegradation procedures. In the second demonstration, the applicant was required to characterize the extent of any increased risk to human health and the environment associated with granting the variance compared to the original water quality standards, and the State or Tribe was required to find that any such increased risk is consistent with the protection of the public health, safety and welfare before granting the variance. Because variances are from water quality standards that meet the goals and requirements of the Clean Water Act, this language was intended to ensure that the general requirement of section 303(c)(2)(A) of the CWA be met even though specific protective criteria may be temporarily exceeded.

Consistent with other approaches for regulatory relief, the permittee was responsible for providing sufficient relevant information, pursuant to State or Tribal requirements, to make a variance demonstration for the pollutant(s) in question. Failure of the permittee to make an adequate demonstration or to provide sufficient information was sufficient for a State or tribal denial of the variance.

b. Discussion of Significant Comments

Comment: Some commenters suggested adding additional reasons for granting a variance to those proposed at procedure 2.C including technological infeasibility and background pollutants.

Response: Based on current EPA guidance (discussed in the preamble to the proposed rule at 58 FR 20921), the justifications for a WQS variance are the six reasons for removing a designated use found at 40 CFR 131.10(g). Because the final Guidance is to be no less restrictive than national guidance (CWA §118(c)(2)(A)), EPA has decided that it would be inappropriate to provide additional justifications for variances at this time. However, it is EPA's intent to provide the Great Lakes States and Tribes reasonable discretion in defining, characterizing and developing decision criteria for the conditions for granting a variance, subject to EPA review and approval. It is EPA's position that by maintaining this discretion, States and Tribes will be able to address specific concerns in the State/Tribal procedures developed pursuant to procedure 2. Flexibility for addressing background pollutants is provided for in the Reasonable Potential section of the Guidance.

Comment: Some commenters were confused about the last two requirements in proposed procedure 2.C regarding: (i) the demonstration that antidegradation requirements had been met, and (ii) the demonstration of the extent of increased risk to human health and the environment.

Response: EPA agrees that the proposal was confusing and has clarified this in the final Guidance. The term "demonstrates" as used in the proposal was not intended to be synonymous with the "antidegradation demonstration" required in appendix E. The "demonstration" in procedure 2 was intended to be a showing that either water quality would not be lowered in the waterbody (the requirement at procedure 2.F.1 requiring dischargers to maintain the level of treatment achieved under the previous permit would almost always prevent a discharger from being granted a variances that would result in an actual lowering of water quality) or, if water quality would be lowered, that the antidegradation requirements of appendix E were met. For these reasons, EPA anticipates that an "antidegradation demonstration" pursuant to appendix E would rarely be required when granting a variance. To avoid further confusion in this section, the term "demonstrates" has been changed to "shows" in the final guidance.

In addition, the two requirements have been re-formatted at procedure 2.C.2 to indicate that they are indeed separate requirements, as was the intent of the proposal, and are not associated with the social/economic justification at procedure 2.C.1.f.

Comment: Some commenters thought it important to integrate the variance procedures with the antidegradation procedures while others objected to this requirement. Many of those objecting were concerned with the amount of effort required to conduct an antidegradation demonstration for every variance request. Commenters also stated that this language was necessary to ensure that granting a variance does not have a downstream impact on high quality waters.

Response: EPA believes that many of the objections to the antidegradation requirement stem from the confusing terminology discussed in the previous comment/response. The terminology change in the final guidance, as discussed above, addresses these objections.

This antidegradation requirement in the variance procedures was intended to prevent a variance that would result in a lowering of actual water quality for any pollutant where water quality for that pollutant does not support either the designated or existing uses or in any water constituting an outstanding national resource (ONRW) at part 132, appendix E, section I.C as well as to prevent dischargers from avoiding the proposed requirements of part 132, appendix E, section I.B in high quality waters by requesting a variance rather than conducting an antidegradation demonstration. The requirement at procedure 2.F.1 requiring dischargers to maintain the level of treatment achieved under the previous permit is expected to prevent a discharger from being granted a variance that would result in a significant lowering of water quality, and an appendix E antidegradation demonstration would not normally be necessary. An appendix E antidegradation demonstration would only be necessary if required by the language in appendix E. The antidegradation showing here would most often demonstrate to the State and public that a concurrent antidegradation question is not at issue or that, if one is, the regulatory provisions for antidegradation are being met.

Comment: Comments were also received on several of the specific conditions for granting a variance at procedure 2.C. Some of these comments requested more specific guidance on some of the conditions.

Response: It is EPA's intent to provide the Great Lakes States and Tribes reasonable discretion in defining, characterizing and developing decision criteria for the conditions for granting a variance, subject to EPA review and approval. It is EPA's position that by maintaining this discretion, States and Tribes will be able to address specific concerns in the State or Tribal procedures developed pursuant to procedure 2.

c. Final Guidance: EPA has maintained procedure 2.C, including the requirements on antidegradation and on demonstrating that there will be no increased risk to human health and the environment from granting the variance, essentially unchanged in the final Guidance. EPA has made a terminology change, discussed above, to clarify the intent that an antidegradation demonstration pursuant to appendix E will apply only if the variance results in significant lowering of water quality in a high quality waterbody, a circumstance which is not expected to occur under procedure 2. In addition, the two "showing" requirements have been re-formatted at procedure 2.C.2 to indicate that they are separate requirements, and not associated with the social/economic justification at procedure 2.C.1.f.

4. Submittal of Variance Application

a. Proposal: The proposed Guidance required permittees to submit a variance application to the State or Tribe no later than 60 days after the regulatory authority reissued or modified the permit. The application was required to provide information necessary to evaluate whether the conditions for granting a variance, as set forth in procedure 2.C of the proposal, were met.

b. Discussion of Significant Comments

Comment: Some commenters stated that the 60 day time frame was too short and/or that the variance application should be allowed at other times (e.g., during the permit application process or any time during the permit cycle). Several commenters pointed out that this language would require all permits for which a variance is granted to be reopened and modified and suggested that processing a variance request during the permit application process would substantially reduce the administrative burden on the discharger as well as the permitting authority. Many similar comments were received regarding the timeframe for application for a variance renewal at procedure 2.H.

Response: EPA agrees and has modified procedure 2.D to allow States and Tribes to determine the most appropriate variance application schedule to suit their administrative procedures for both first-time variances at procedure 2.D and for variance renewal at procedure 2.H.

c. Final Guidance: In the final guidance EPA has removed both the 60 day limit and the requirement that a variance be applied for after a final NPDES permit is issued. EPA expects States and Tribes to specify in their variance procedures the timing that best suits their own regulations and permitting procedures.

5. Public Notice

a. Proposal: The proposed Guidance provided for public notice and opportunity to comment on a variance request (procedure 2.E) and on the draft modified NPDES permit (procedure 2.G.). In addition, the requirement at procedure 2.J that variances be appended to State water quality standards rules ensured that the public is made aware of which variances have been granted.

b. Discussion of Significant Comments

Comment: Commenter stated the proposed public notice requirements for variance procedures were not adequate to allow full public involvement.

Response: EPA does not agree. Procedure 2 does not modify the normal public participation requirements for adopting WQS, but rather adds a requirement that the notice also present the State or Tribe's preliminary decision.

The following is a summary of the elements that EPA expects to be made available to the public in order to meet the public notification requirements of the water quality standards regulation (40 CFR 131.20(b)). If these items are not included in detail in the public notice, they must be in the public record and the public must be made aware of their existence and of how and where they may be obtained.

(i) A statement that the action complies with the State's or Tribe's variance procedures and description of those procedures;

(ii) The permittee's demonstration, including the rationale for the requested variance and the extent of any increased risk to human health and the environment associated with granting the variance; and

(iii) The public notice for any draft NPDES permit, the public comments and public hearing records pursuant to procedure 2.E, and the State approval. This public notice can be combined with the public notice for a draft NPDES permit, as long as the variance is identified and all the necessary information pertaining to the variance is included.

Comment: Some commenters stated that a timeframe should be required for the public notice and/or comment period.

Response: EPA does not agree that timeframes for these activities need to be specified in the Guidance because the various State and Tribal administrative procedures are different. EPA does, however, expect the States and Tribes to include appropriate timeframes in their variance procedures, pursuant to their administrative procedures, to provide meaningful opportunity for public comment as well as orderly and timely State or Tribal action.

c. Final Guidance: For the reasons stated above, EPA has retained the language contained in the proposal, with the clarification that the public notice can be combined with the public notice for a draft NPDES permit, as long as the variance is identified and all the necessary information pertaining to the variance is included.

6. Final Decision on Variance Request

a. Proposal: The proposed Guidance required the State or Tribe to issue a final decision on a variance request within 90 days of the expiration of the public comment period. The proposed Guidance also required that this decision specify all NPDES permit conditions needed to implement the variance. These conditions were to assure that: the permittee minimizes the water quality standards exceedance by implementing the level of treatment currently achievable (i.e., conditions requiring effluent limitations at least as stringent as those achieved under the previous permit); the permittee makes reasonable progress toward attaining the water quality standards; and effluent limits sufficient to protect water quality standards are in effect upon expiration of the variance. States/Tribes were to deny a requested variance if the permittee failed to make the demonstrations required under section C of the proposed procedure.

b. Discussion of Significant Comments

Comment: Some commenters objected to the permit condition requiring "reasonable progress" be made toward attaining water quality standards, stating for example, that in most cases, the permittee receiving a variance will not contribute to the conditions that prevent the receiving waters from attaining water quality standards and therefore will be powerless to make "reasonable progress" toward attaining water quality standards for the waterbody.

Response: EPA does not agree that a discharger is always "powerless" to affect pollution sources outside its immediate contribution. Dischargers can, for example, participate in total maximum daily load (TMDL) development and/or engage in pollution trading schemes to reduce load from outside its facility.

Comment: Some commenters were unclear about what EPA intends by "reasonable progress."

EPA agrees that "reasonable progress" is imprecise, but believes this is necessary to provide flexibility to the State or Tribe to require activities appropriate to the State or Tribal programmatic objectives and the individual situation subject to EPA review and approval. In addition to progress reducing loads outside its immediate contribution discussed above, reasonable progress can be made in improving the quality of the discharge through conditions such as: (i) the establishment of a capital improvements fund; and (ii) continued investigations of treatment technologies, process changes, pollution prevention, wastewater reuse and/or other techniques that will reduce the level of the pollutant or result in compliance by the permittee with the WQS and submission of reports on the investigations at such time specified by the State. It would be difficult for EPA to define what "reasonable progress" is without considering site-specific information on the facility, pollutant and receiving water for a given situation. In instances where a discharger is indeed "powerless" to affect any change in conditions, the State or Tribe may interpret existing practices as "reasonable."

Comment: Procedure 2.F.3 proposed requiring, upon expiration of a variance, compliance with the effluent limitation in effect prior to the granting of the variance. Commenters thought this requirement confusing.

Response: Because the final Guidance no longer requires that a final NPDES permit be issued prior to a variance application, there may well be no pre-existing effluent limitation implementing the underlying WQS with which to comply. EPA has, therefore, modified this requirement to provide that effluent limitations be in compliance with applicable water quality standards upon expiration of the variance.

c. Final Guidance: For the reasons stated above, EPA has retained procedure 2.F essentially unchanged. Because of the changes to procedure 2.B which extend the allowable term for a variance beyond the 3 years in the proposal (see discussion at B.2.c, above) new language has been added at procedure 2.F.4 requiring a permit condition that allows the permitting authority to reopen and modify a permit which is based on a WQS variance if that variance has been rescinded or modified pursuant to a State or Tribal triennial standards revision.

7. Incorporating Variances into NPDES Permits

a. Proposal: Once a variance is granted, the proposed Guidance required the State or Tribe to modify the NPDES permit to incorporate all NPDES permit conditions determined to be necessary to implement the variance.

b. Discussion of Significant Comments

Comment: Some commenters stated that the Guidance should not routinely require that a permit be modified in order to implement a variance.

Response: EPA agrees. EPA has removed the requirement in procedure 2.D that a variance may be applied for only after a final NPDES permit is issued. By allowing variance applications any time during the permit renewal process, EPA anticipates that most permits that receive variances will have the provisions of the variance incorporated into the permit when it is reissued.

c. Final Guidance: EPA has removed the requirement in procedure 2.D that a variance may be applied for only after a final NPDES permit is issued. The final Guidance allows the permitting authority to incorporate the provisions of the variance into the permit at a time, and in a manner which is appropriate, given the circumstances of the variance.

8. Renewal of Variances

a. Proposal: The proposed Guidance required a permittee to re-apply for a variance no later than the submission of a permit application or 60 days prior to the expiration of the variance. The permittee was required to make a new showing of justification; variances would not be automatically renewed. As part of the renewal application, the permittee would be required to demonstrate that it has met the NPDES permit conditions implementing the existing variance. The same public notice requirements for the initial issuance of a variance applied to the renewal. Permittees not demonstrating compliance with these conditions would not be eligible for a variance renewal.

b. Discussion of Significant Comments

Comment: Several commenters stated that an application for variance renewal should not be required until the permit renewal becomes final. Others stated that the variance reapplication process should occur in conjunction with the permit renewal process.

Response: EPA agrees that such flexibility is reasonable and has modified procedure 2.H to allow States and Tribes to determine the most appropriate variance re-application schedule to suit their administrative procedures.

Comment: Some commenters stated that discharges that violate conditions of a variance should not necessarily be ineligible for a renewed variance pointing out that EPA and the states already have ample authority to impose enforcement sanctions on dischargers violating their permit conditions, including variance conditions, and that EPA need not require states to impose a second penalty on those dischargers. Other commenters also stated that EPA proposes to treat all violations of variance conditions the same, and therefore, even de minimis violations would result in the inability to renew a variance.

Response: The permit conditions are intended to implement the basic principles of water quality standards variances that (i) the non-attainment of standards be minimized, (ii) progress toward attaining standards be achieved where possible, and (iii) the discharger must meet the standard upon expiration of the variance (see discussion of current EPA policy in the preamble to the proposed guidance at 58 FR 20921.) Dischargers that fail to meet permit conditions designed to achieve these basic principles should not be allowed to continue the practice through a variance renewal. EPA intends, however, that States and Tribes should have discretion in determining whether a particular non-compliance with variance conditions in NPDES permit would warrant denial of a variance renewal request, subject to EPA review and approval.

c. Final Guidance: Based on the rationale above, EPA has retained procedure 2.H but has modified it to allow States and Tribes to determine the most appropriate variance re-application schedule to suit their administrative procedures. EPA has also modified the final Guidance consistent with 40 CFR 122.64 to allow the permitting authority to deny a variance renewal where the permittee has not fully complied with the permit conditions applicable to the variance.

9. EPA Approval

a. Proposal: The proposed guidance listed the information to be submitted to EPA for review and approval, including the permit application, public comments, State or Tribal approval, and NPDES permit; and gave timeframes for those submittals.

b. Discussion of Significant Comments

Comment: Some commenters stated that a time requirement for EPA review of WQS variances was needed.

Response: EPA does not agree that it is necessary for this Guidance to specify an EPA deadline for review of variances. Variances are modifications of State or Tribal water quality standards and are, therefore, subject to EPA review and approval. Like other water quality standards changes, variances are effective when adopted (under the terms of the adoption), whether or not EPA review is complete. In addition, there are already statutory and regulatory timeframes, at §303(c)(2)(B) of the CWA and 40 CFR 131.21(a) respectively, that govern EPA approval/disapproval decisions on all State or Tribal water quality standards revisions including variances.

c. Final Guidance: Based on the rationale above, EPA has retained procedure 2.I as proposed. Editorial changes have been made for clarity.

10. State or Tribal Water Quality Standards Revisions

a. Proposal: The proposed Guidance required the State or Tribe to append the State- or Tribal-adopted variances to the State or Tribe's water quality standards.

b. Discussion of Significant Comments

Comment: EPA requested comment on whether a timeframe was necessary for the State or Tribe to append variances to their standards. Commenters stated that a timeframe is not necessary.

Response: EPA agrees and expects States and Tribes to append variances to their standards in as timely a fashion as possible, consistent with their administrative procedures, so that the public is fully informed on the variance that have been adopted. The appended information should include at a minimum: the discharger receiving the variance, the term (beginning and ending dates) of the variance, the waterbody or waterbodies affected, the pollutant(s) affected by the variance, and the modified allowable ambient concentration value(s) for those pollutants.

c. Final Guidance EPA has retained procedure 2.J as proposed.

C. Total Maximum Daily Loads

1. Background

Section 303(d) of the Clean Water Act requires the establishment of total maximum daily loads (TMDLs), in accordance with priority rankings, for waters that are failing to meet or not expected to meet applicable water quality standards despite implementation of technology-based and other existing controls. See 40 CFR 130.7 and existing EPA guidance including "Guidance for Water Quality-based Decisions: The TMDL Process," EPA 440/1-91-001, April 1991.

TMDLs quantify the maximum allowable loading of a pollutant to a water body, and allocate this loading capacity to contributing point and nonpoint sources (including natural background, in-place contaminants, direct wet and dry deposition, groundwater inflow, and overland runoff) such that water quality standards will be attained. A TMDL must incorporate a margin of safety (MOS) that accounts for uncertainty about the relationship between pollutant loads and water quality. TMDLs may involve a single pollutant source or multiple sources (e.g., both point sources and nonpoint sources). Current regulations specify that TMDLs need to take into account critical conditions for stream flow, loading, and water quality parameters (see 40 CFR 130.7(c)(1)). Site-specific factors are thus to be reflected in the TMDL even though the TMDL process may be used to ensure that water quality goals are achieved for a waterbody segment, whole waterbody or watershed.

Under the CWA, States and Tribes are primarily responsible for developing TMDLs. EPA is required to review and approve or disapprove TMDLs developed and submitted by States and Tribes. If EPA disapproves a State or Tribal TMDL, EPA must establish such TMDL {CWA section 303(d)(2)and 40 CFR 130.7(d)}.

When applicable water quality standards cannot be attained through the implementation of controls on point sources, within the time period specified in the applicable standards or implementing regulations, States and Tribes may choose to develop TMDLs using a phased approach. The phased approach to TMDL development is intended to achieve load reductions capable of ensuring the attainment and maintenance of water quality standards. EPA expects the allocations within phased TMDLs to be based on a reasonable expectation that water quality standards will be met in a reasonable period of time.

The phased approach to TMDL development is an iterative process that provides for pollution reduction while the regulatory agency collects and uses new monitoring data and the demonstrated performance of existing controls to evaluate the TMDL and revise it as necessary. TMDLs established using the phased approach are based on best available information, sound professional judgment, and a margin of safety to account for uncertainty in available data and the anticipated relationship between controls, loading reductions and predicted changes in water quality. Such TMDLs require a monitoring plan, a schedule for installation of controls, collection of monitoring data to verify point and nonpoint source load reductions, assessment of water quality standards attainment and additional modelling, where appropriate. If standards are not attained after implementation of controls recommended by the TMDL, the data obtained through the monitoring program should be used to revise the TMDL.

The phased approach to TMDL development recognizes that water quality standards cannot be attained immediately, but TMDLs developed on this basis nevertheless must reflect reasonable assurances that water quality standards will be attained in a reasonable period of time. When developing a TMDL using the phased approach, all known sources of pollution are considered, although specific controls on those sources may be implemented in stages. The time period associated with these stages of implementation ultimately determines when water quality standards will be met for a particular waterbody. The phased approach may provide a scheduled time frame in which to implement controls recommended by the TMDL and achieve water quality standards and may be particularly appropriate when addressing difficult water quality problems in cases when data, models and predictive tools are generally less well-developed than for water quality problems associated primarily with the discharge of a few point source pollutants into small watersheds. Determining the reasonable period of time in which water quality standards will be met is a case-specific determination. This determination depends upon a number of factors, including, but not limited to, receiving water characteristics, persistence, behavior and ubiquity of pollutants of concern, type of remediation activities necessary, available regulatory and non-regulatory controls and individual State requirements for the implementation of water quality standards.

TMDLs established using the phased approach are the preferred approach for developing schedules of how and when water quality standards will be met in cases when data, models, and predictive tools are not yet adequate to address complex water quality situations characterized by persistent, ubiquitous pollutants and water quality impacts resulting from nonpoint sources of pollution. EPA believes that it is reasonable and appropriate in these circumstances to establish TMDLs which schedule implementation activities over a period of time. This would result in some sources achieving load allocations prior to other sources, provided that progress is being made in achieving water quality standards in accordance with the schedule established by the TMDL. Thus, for example, EPA believes it is reasonable to consider expected nonpoint source load reductions if they will result from the implementation of specific voluntary or non-voluntary controls, are specific to the pollutant of concern and the waterbody for which the TMDL is being developed. In some cases, for example, water quality standards may reasonably be expected to be met within one NPDES five-year permit cycle. In other cases the reasonable expectation of meeting water quality standards could be twenty years, following the implementation of controls on nonpoint sources such as sediment. In still other cases, the reasonable expectation of meeting water quality standards could be keyed to the implementation of other controls, (e.g. air quality standards.)

The final Guidance is not intended to comprehensively address all aspects of TMDL development and implementation of CWA section 303(d). Rather, for specific matters not addressed by the final Guidance, national regulations and guidance for the TMDL program will continue to apply to States and Tribes in the Great Lakes System (see 40 CFR 130.7 and existing EPA guidance documents such as the Technical Support Document for Water Quality-based Toxic Control, (TSD) EPA 505/2-90-001, March 1991, and Guidance for Water Quality-based Decisions: The TMDL Process, EPA 440/1-91-001, April 1991, both available in the docket).

The final Guidance does not include specific provisions for deriving nonpoint source load allocations and implementing nonpoint source controls. While general guidance on how TMDLs should consider nonpoint source loadings is provided, EPA regulations and technical guidance should be consulted for more specific information. (See, e.g., Guidance Specifying Management Measures for Sources of Nonpoint Pollution in Coastal Waters, EPA 840-B-92-002, January 1992, for a discussion of best management practices for nonpoint sources; and Technical Guidance for Estimating Total Maximum Daily Loads (TMDLs): Integrating Steady-State and Episodic Point and Nonpoint Sources, draft June, 1994, both available in the docket).

Procedure 3 specifies procedures for establishing total maximum daily loads, wasteload allocations, and load allocations. Portions of this procedure also apply to wasteload allocations calculated in the absence of a TMDLs, and to preliminary wasteload allocations for the purpose of determining the need for Water Quality Based Effluent Limits (WQBELs) under procedure 5 of appendix F. See procedure 5.A.2 and 5.F.2 of appendix F and corresponding discussion at section VIII.E.2.A and VIII.E.2.H of this document for further information.

2. Overview of Proposed Procedures 3A and 3B

a. Proposal: The proposed guidance included two distinct approaches for developing TMDLs: procedure 3A (Option A) and procedure 3B (Option B). Both options contained the same eleven general conditions applicable to TMDL development and special conditions regarding control of bioaccumulative chemicals of concern (BCCs). Options A and B were also essentially the same with respect to the development of TMDLs for open waters and connecting channels of the Great Lakes System as defined at section 132.2 of the proposed Guidance.

The main differences between the two options existed in the development of TMDLs for discharges to tributaries. These differences reflected the process by which such TMDLs were developed and the degree of specificity contained in the particular procedure. A TMDL developed for discharges to tributaries under Option A was to be based on evaluation of the basin as a whole, followed by site-by-site adjustments. In contrast, Option B focused initially on evaluating limits needed for individual point sources, with supplemental emphasis on basin-wide considerations as necessary. Specific components of Options A and B are discussed in greater detail below, and in the preamble to the proposed guidance. Readers are encouraged to review the preamble to the proposed guidance for more detailed information on the proposed Options A and B (58 FR 20928).

EPA sought comments on all aspects of both options, including the overall technical and programmatic approaches set out in each option, the consistency of each option with regard to existing national policy and program approaches, and the degree to which each option allows for integrated development of effective point and nonpoint source controls. EPA requested comments on how the options should be incorporated into the final implementation procedure and specifically asked whether all States and Tribes in the Great Lakes System should be required to adopt either Option A or B, or whether States and Tribes should be allowed to choose an approach that is consistent with one of the proposed options depending on the situation at hand. EPA also solicited comments on the option of not providing specific TMDL provisions in the final Guidance and instead relying on existing TMDL regulations and guidance.

b. Comments: Several commenters claimed that the proposed TMDL procedures were confusing, fragmented and provided insufficient guidance on how water quality-based permit limits would be calculated. For example, many commenters found the formulas specified in Option B confusing and some suggested that certain components of the formulas were inaccurate or inappropriate.

Most commenters expressed no clear preference for either option. Many commenters advocated that the final Guidance allow States to choose either procedure 3A or 3B. Some expressed preferences for particular elements of an option. For example, one commenter suggested that the State or Tribe should be given discretion to deviate from Option A's basin-wide approach and use an area-specific approach if appropriate in a particular circumstance.

A number of commenters suggested that, although both options had merit, and/or limitations, only one should be adopted to ensure consistency throughout the Great Lakes System. Many commenters, including a number of States, preferred Option B and maintained that if a single procedure is adopted in the final Guidance, it should be Option B. These commenters believed that Option B would provide greater consistency among the States than Option A. Several commenters preferred Option B but suggested that stronger elements from Option A should be incorporated into a revised Option B. A number of commenters suggested that Option A was too burdensome.

Several commenters supported the watershed-based approach reflected in Option A. Other commenters preferred Option A but recommended specific modifications. Among the recommended changes to Option A were establishing specific requirements for mixing zones for non-BCCs. Some commenters suggested including specific formulas for calculating nonpoint source loadings.

c. Final Guidance: In response to these comments, EPA simplified the TMDL procedure in the final Guidance and clarified a number of provisions. EPA includes only one TMDL procedure in the final Guidance in response to concerns that the TMDL procedure promote consistency throughout the Great Lakes System. The final procedure 3 combines aspects of both Options A and B, and, in response to comments, includes some of the more specific provisions of both options A and B. For example, in order to promote consistency among the Great Lakes States and Tribes, EPA is retaining, with some modifications, certain mixing zone provisions for non-BCCs from option B. EPA eliminated some of the more burdensome and confusing aspects of both the proposed options. For example, in the final Guidance, the formulas in Option B are no longer included.

The final Guidance provides a greater degree of flexibility than afforded by either proposed procedure 3A or 3B by allowing States and Tribes to choose different implementation approaches while at the same time ensuring a level of consistency by requiring implementation of specific components of the procedure. For example, the final Guidance does not specify whether a State must adopt a basin-wide approach such as that in proposed Option A, or an approach like proposed Option B, which would focus initially on evaluating limits needed for individual point sources.

The final Guidance also retains the flexibility provided in the proposal. For example, although the final Guidance specifies that States and Tribes consider nonpoint source loadings, EPA has not adopted the commenters' suggestion to specify a formula to calculate nonpoint source contributions. Rather, States and Tribes are provided flexibility to evaluate such contributions and to address nonpoint source contributions through existing programs.

The final Guidance retains the eleven general conditions and the separate provisions for open waters of the Great Lakes System and tributaries, with certain modifications. Like both the proposed options 3A and 3B, the final Guidance requires the elimination of mixing zones for BCCs; however, the final Guidance adds a procedure to grant an exception for existing discharges of BCCs in limited circumstances. The general conditions of application and specific provisions of the final procedure 3 are discussed in detail below.

In addition, procedure 3 has been revised to include new language (section A), which authorizes the use of certain assessment and remediation plans in lieu of TMDLs whenever, in the final Guidance, a TMDL would be used as the basis for a wasteload allocation. Specifically, these assessment and remediation plans could be used in lieu of TMDLs when deriving wasteload allocations under procedures other than the "baseline" procedures in procedure 5.F.2 of appendix F, when establishing mixing zones for existing discharges of BCCs in waters not attaining water quality standards under procedure 3.C.6 of appendix F, or as an alternative to TMDLs and the intake pollutant procedures in procedures 5.D-E of appendix F when adjusting point source controls to account for intake pollutants as provided in procedure 5.D.1.c of appendix F. Thus, for example, when developing a WLA for a particular pollutant and point source, a State or Tribe would rely upon the applicable WLA established in an approved TMDL or assessment and remediation plan. If no such TMDL or assessment and remediation plan exists, the WLA would be derived using procedure 5.E.2.a or 5.F.2 of appendix F as appropriate.

Under procedure 3.A of appendix F, assessment and remediation plans may be used in lieu of TMDLs if they meet all the requirements of procedure 3, satisfy the public participation requirements applicable to TMDLs, and are approved by EPA under 40 C.F.R. § 130.6 as meeting these requirements. Once approved by EPA, the assessment and remediation plans will function as updates to State or Tribal continuing planning processes, which may include, among other things, TMDLs and areawide waste management plans under section 208. When seeking EPA approval of these assessment and remediation plans, States and Tribes must certify that the requirements of procedure 3 are met. Procedure 3.A also authorizes the use of qualifying assessment and remediation plans, such as Remedial Action Plans (RAPs) and Lakewide Management Plans (LaMPs), under section 118(c)(3) & (4) of the CWA.

The TMDL process is an important planning tool that helps identify water quality problems and recommends solutions that link the development and implementation of control actions to the attainment of water quality standards. The objective of a TMDL is to allocate allowable loads of a particular pollutant among difference sources of that pollutant so that the appropriate control actions can be taken and water quality standards achieved. As discussed in section VIII.C.1 above, when water quality standards cannot be attained immediately, TMDLs may be developed under a phased approach if appropriate. While TMDLs are the preferred mechanism for addressing water quality impairments, particularly where nonpoint source contributions are significant, EPA recognizes that other mechanisms can employ the same type of analysis and obtain the same results as formal TMDLs. EPA also acknowledges the comments, particularly of States, that identify comparable planning tools. In particular, as described in section I.D.4 of this document, the States and EPA Regional offices in the Great Lakes basin have undertaken significant assessment and remediation planning efforts through the development of RAPs and LaMPs. Some States may undertake similar efforts through water quality management plans under sections 208 of the CWA. Accordingly, the final Guidance specifically recognizes that assessment and remediation plans other than TMDLs can be used with comparable water quality effect, provided that they contain certain basic elements. In other words, EPA expects that assessment and remediation plans developed and approved under procedure 3.A of appendix F can function in lieu of a TMDL for water quality decisionmaking in the Great Lakes System because such plans, at a minimum, will assess the sources causing or contributing to a particular water quality impairment, identify remediation activities that are reasonably expected to result in nonpoint source load reductions as necessary, in combination with point source controls, to achieve water quality standards within a reasonable period of time, incorporate a margin of safety, and establish wasteload allocations for point sources that are consistent with these water quality objectives. Procedure 3.A also provides that any part of an assessment and remediation plan that also satisfies one or more requirements under CWA section 303(d) or implementing regulations may be incorporated by reference into a TMDL as appropriate. If a State or Tribe submits for EPA approval an assessment and remediation plan under procedure 3.A that fully satisfies the requirements for a TMDL, EPA may also approve that plan under section 303(d).

3. General Conditions of Application

As proposed, Options A and B both contained the same eleven general conditions of application for every TMDL established under the GLWQI to assure that TMDLs employed consistent methodologies, analytical approaches and assumptions. Commenters overwhelmingly supported the proposal to include a set of general conditions applicable to all aspects of TMDL development.

Language is added in the final Guidance to clarify that the general conditions also apply, where indicated, to wasteload allocations (WLAs) calculated in the absence of TMDLs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of the final Guidance.

a. General Condition 1 - TMDLs Required

i. Proposal: General condition 1 described the circumstances under which a TMDL would be required upon State or Tribal adoption or EPA promulgation of the Guidance. In the proposal, general condition 1 specified that, at a minimum, TMDLs were to be established for each pollutant for which it was determined that there is reasonable potential that a discharge will cause or contribute to an exceedance of water quality standards as determined pursuant to proposed procedure 5. As proposed, such TMDLs would need to be established in advance of the issuance of any new or revised permit for the discharge of the pollutant, unless it was determined pursuant to the proposed procedures that a TMDL is not needed.

Proposed procedure 5 specified that the State or Tribe was to include a water quality-based effluent limit in an NPDES permit whenever a pollutant is or may be discharged into the Great Lakes System at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value. Under procedure 5, as proposed, States or Tribes would have been required to develop preliminary effluent limitations to determine if all Tier I criteria and Tier II values would be met after discharge, where there was data to develop such criteria or values. Preliminary effluent limitations were to be derived from preliminary wasteload allocations, which in turn were to be based upon and consistent with the wasteload allocation procedures defined in the proposed procedure 3. As proposed, the procedure 3 requirement that a TMDL be developed whenever reasonable potential to cause or contribute to an exceedance of water quality standards was found, and the requirement that preliminary effluent limits based on preliminary WLAs developed under procedure 3 be used to determine if there is reasonable potential, were confusing and implied a circular logic. The proposal provided, in effect, that TMDLs be developed when reasonable potential was demonstrated, and that reasonable potential be demonstrated on the basis of preliminary effluent limits, normally derived from TMDLs.

ii. Comments: EPA received numerous comments on general condition 1. A number of commenters were concerned with the perceived burden associated with developing TMDLs under the proposal and, in particular, many were concerned with the burden associated with requiring a TMDL for a waterbody in advance of issuing any new or revised permits. These commenters asserted that general condition 1 would essentially prohibit any point source discharges of a particular pollutant in the absence of a TMDL for that pollutant. The commenters contended that the effect of the prohibition would be to require TMDLs on the basis of a single discharger's "reasonable potential" to exceed standards even in waters where TMDLs would have minimal environmental benefit, and thus would be inefficient. Several commenters claimed that the existing national TMDL program requirements for identifying waters not meeting standards, and for setting priorities to develop TMDLs, are sufficient to ensure that TMDLs are developed for those waterbodies most in need.

Numerous commenters pointed out the ambiguity between proposed procedure 3 and proposed procedure 5 relating to determination of reasonable potential. Under proposed procedure 3, a TMDL was required when there was a finding of reasonable potential. However, under proposed procedure 5, a finding of reasonable potential would be based on a "preliminary wasteload allocation" prepared using the procedures set forth in the TMDL procedure. The proposal did not define "preliminary WLA."

A number of commenters suggested other circumstances that should trigger the requirement to establish a TMDL. Several commenters suggested that TMDLs be required for pollutants that have caused fish consumption advisories on the premise that waters subject to fish consumption advisories are exceeding narrative water quality criteria, if not numeric criteria.

iii. Final Guidance: General condition 1 in the final Guidance no longer specifies that a TMDL would need to be developed for each pollutant for which reasonable potential is found. Instead, TMDLs shall be established in accordance with the waterbody listing and prioritization process outlined in CWA section 303(d), 40 CFR 130.7 and existing EPA guidance. Under existing law, if existing required controls are not sufficient to attain and maintain applicable water quality standards, the waterbody must be included on the 303(d) list, which, under the regulations, is to be submitted to EPA for review and approval or disapproval. The list must include a priority ranking of listed waters and must identify those waters targeted for TMDL development as required by CWA section 303(d)(1)(A) and 40 CFR 130.7(b)(4). EPA makes this change in response to commenters' concerns about the proposal. First, the final Guidance refers back to the national TMDL program rather than creating a new trigger for TMDL development based on a finding of reasonable potential under procedure 5. This should minimize the confusion created by the proposal. The final Guidance, by referring to existing TMDL regulations, should also minimize concerns about the additional burden that might have occurred under the proposal (e.g., permitting subject to TMDL development). Changes to the proposal were also made to address concerns about the use of limited resources to develop TMDLs in waters presently attaining water quality standards but where the discharge of a particular pollutant has the reasonable potential to cause or contribute to an excursion above those water quality standards. While TMDLs for waters currently attaining water quality standards are important tools to ensure that such standards are maintained, EPA recognizes that many States and Tribes may choose to place a higher priority on restoring impaired or threatened waters and will choose to use their limited resources for that purpose. This change is intended to preserve State and Tribal discretion in establishing priorities for TMDL development and implementation.

In response to comments advocating that fish consumption advisories should trigger TMDL development EPA is developing guidance to clarify the relationship between fish advisories and section 303(d) lists. (Draft memo dated July, 1994, available in the docket). EPA believes that, absent information to the contrary, it should be presumed that fish consumption advisories demonstrate use impairments for waters designated for the uses specified in section 101(a) of the Clean Water Act, when defined by a State or Tribe to include fishing. The listing of such waterbodies on section 303(d) lists is consistent with the purpose and intent of the Clean Water Act.

General condition 1 also provides that, when water quality standards cannot be attained immediately, the TMDL must reflect reasonable assurances that they will be achieved in a reasonable period of time. For a more thorough discussion of this concept, see section VIII.C.1 above.

b. <u>General Condition 2 - Attainment of Water Quality Standards</u>

i. <u>Proposal</u>: In the proposal, general condition 2 discussed the load reductions that should be achieved through TMDLs. The first sentence of general condition 2 supplemented the provisions of proposed general condition 1 by specifying that TMDLs would also need to be developed whenever the sum of existing point source and nonpoint source (including natural background) loadings of a particular pollutant exceeds the loading capacity of the water for that particular pollutant, minus any margin of safety and minus any capacity reserved for future growth. As proposed, general condition 2 also established that a TMDL for a given pollutant must implement all criteria for that pollutant that are applicable to the waterbody in question.

ii. <u>Final Guidance</u>: EPA did not receive significant comments on general condition 2 as proposed. However, EPA has reorganized proposed general conditions 2 (Load Reductions), 3 (WLA Values) and 9 (TMDL Allocations) in order to present the same material in a sequence that more closely tracks the requirements of CWA section 303(d). General condition 2 is now entitled "Attainment of Water Quality Standards" and consists of a single sentence on that subject drawn from proposed general condition two. The final guidance specifies that a TMDL must ensure attainment of water quality standards, including all numeric and narrative criteria, Tier I criteria, and Tier II values where applicable for each pollutant or pollutants for which a TMDL is established. By including a specific reference to water quality standards in addition to criteria, the final Guidance clarifies that, under section 303(d), TMDLs must provide for the attainment of water quality standards in their entirety, and not just their criteria components.

The third sentence of proposed general condition 2 has been incorporated into general condition 3 (now entitled "TMDL Allocations") of the final Guidance. The final Guidance does not include the proposed language specifying that TMDLs be prepared if the sum of existing point source and nonpoint source loadings exceeds the loading capacity minus any specified margin of safety for a substance. This sentence was intended merely to restate existing requirements under section 303(d) of the Clean Water Act and TMDL regulations at 40 CFR 130.7, and therefore is unnecessary. In EPA's view, these provisions and other applicable requirements of the Guidance are sufficient to ensure that TMDLs developed under this final Guidance will provide for attainment of water quality standards.

c. General Condition 3 - TMDL Allocations

i. Proposal: This general condition was numbered as general condition 9 in the proposal. As proposed, this condition provided that nonpoint source load allocations must be based on existing loading rates or on anticipated increased loading rates unless a lower loading rate is expected to occur within a reasonable period of time as a result of implementation of best management practices or other control measures. It also provided that the portion of the loading capacity not assigned to nonpoint sources, or to an MOS, or reserved for future growth is allocated to point sources. Finally, it stated that, upon reissuance, NPDES permits for these point sources must include limitations consistent with the WLAs in EPA-approved or EPA-established TMDLs.

ii. Comments: Some commenters advocated that the final Guidance only allow the incorporation of nonpoint source reductions where such reductions are required by legally enforceable mechanisms to ensure that reductions from nonpoint sources are "reasonably expected to occur" within relevant time frames. Furthermore, the commenters suggested that a reasonable period for such reductions would be eight years. Another commenter supported the phased approach for load allocations because it allowed an iterative process for implementing nonpoint and point source controls.

iii. Final Guidance: As part of its reorganization of the general conditions in the final Guidance, EPA has renumbered proposed general condition 9 to become general condition 3 in the final Guidance. As part of that reorganization, EPA has also incorporated into new general condition 3 the language proposed under the heading "Load Reductions" that defines the elements of a TMDL. EPA has also established subparagraphs within general condition 3 of the final Guidance to correspond to the discussion in general condition 3 of the elements of a TMDL, nonpoint source load allocations, point source wasteload allocations, and monitoring.

Specifically, EPA has added as subparagraph (a) the statement from proposed general condition 2 that TMDLs shall include wasteload allocations and load allocations for nonpoint sources, including natural background, such that the sum of these allocations is not greater than the loading capacity of the water for the pollutant addressed by the TMDL, minus the sum of a specified margin of safety and any capacity reserved for future growth. EPA has made only minor changes to the proposed language to clarify that the nonpoint source load allocations include natural background conditions and to link loading capacity to the pollutant for which the TMDL is being developed.

Subparagraph (b) comprises the portions of proposed general condition 9 pertaining to nonpoint sources. These provisions were modified in general condition 3 only to make consistent use of the term loadings and to clarify that expectations regarding decreased loadings from nonpoint sources must be based on a reasonableness standard. The only significant comments EPA received on proposed general condition 9 addressed nonpoint source issues. EPA disagrees with the commenter's suggestion that nonpoint source reductions be considered only when such controls are required by legally enforceable mechanisms. EPA suggests that means other than legally enforceable mechanisms are available to ensure that nonpoint source reductions that are "reasonably expected to occur" within a specified time frame actually do occur. For example, funding nonpoint source controls and using the monitoring component of the phased approach to TMDL development, as described earlier in this document, are means to assure that anticipated load reductions are actually occurring. Although EPA supports the use of a phased approach to TMDL development where appropriate, EPA stresses that smaller load allocations to nonpoint sources can be used to justify larger WLAs to point sources only when the anticipated reductions in nonpoint source loadings are reasonably expected to occur.

EPA agrees with the comment that a TMDL can consider anticipated nonpoint source loading reductions. TMDLs developed using the phased approach are based on the reasonable expectation that water quality standards will be met in a reasonable period of time and that specific controls may be implemented in stages. What constitutes a reasonable period of time will vary depending upon the situation. Therefore, EPA will not specify any particular period, such as eight years. The time period associated with these stages of implementation will ultimately determine when water quality standards will be met for a particular waterbody. To the extent consistent with other applicable law concerning schedules of compliance, permits issued after the completion of a TMDL should be consistent with implementation schedules established by the TMDL.

Placed within new subparagraph (c) are the provisions in proposed general condition 9 pertaining to point source wasteload allocations and their effect on NPDES permits. Apart from including a reference to natural background in connection with nonpoint sources, these provisions are unchanged from the proposal.

In the final Guidance, EPA added subparagraph (d) to address the monitoring issues encompassed within the proposal's discussion of anticipated decreases in pollutant loadings from nonpoint sources. Subparagraph (d) provides that, for load allocations established on the basis of (a)(iii) of general condition 3, monitoring data shall be collected and analyzed in order to validate the TMDL's assumptions, to verify the anticipated load reductions, to evaluate the effectiveness of controls being used to implement the TMDL, and to revise the WLAs and load allocations as necessary to ensure that water quality standards will be achieved within the time period established in the TMDL. This monitoring can be performed as part of the water monitoring program established by the State (or at its election by the Tribe) under 40 CFR 130.4, which specifies development and review of TMDLs, wasteload allocations and load allocations as among the uses for such monitoring data.

d. <u>General Condition 4 - WLA Values</u>

i. <u>Proposal:</u> This general condition was numbered as general condition 3 in the proposal. As proposed, this condition specified that point sources be regulated to ensure attainment of all downstream water quality standards. Proposed general condition 3 also recognized that TMDLs developed for a particular waterbody may include WLAs for sources already covered by a TMDL of a different geographic scope. For example, a source-specific TMDL may already be in place when a basin-wide TMDL is developed. General condition 3, as proposed, provided that water quality-based effluent limits (WQBELs) in NPDES permits for a particular pollutant be consistent with the most stringent of the WLAs for that pollutant and point source included in any EPA-approved or EPA-established TMDLs. This provision was intended to assure that water quality standards will be met throughout a drainage basin, including in downstream waters.

ii. Final Guidance: EPA did not receive significant comments on proposed general condition 3. Thus, the final Guidance retains the substance of the general condition with slight modifications, but EPA has renumbered it as general condition 4 in the final Guidance to reflect EPA's decision to move proposed general condition 9 (TMDL Allocations) up to become new general condition 3 in the final Guidance.

This provision in the final Guidance, like the proposal, directs permit writers to apply the most stringent of the WLAs included in any EPA-approved or EPA-established TMDL. The final Guidance clarifies that this provision applies only when more than one approved TMDL establishes a different WLA for the same pollutant discharged by the same point source. In addition to renumbering this as general condition 4, EPA made one other change. The proposed language stating that "point sources must be regulated so as to ensure attainment of all downstream water quality standards" has been deleted in the final Guidance because it merely restated current law. Specifically, under existing CWA section 402 and 301(b)(1)(C), WQBELs in NPDES permits must ensure attainment of all applicable water quality standards, including downstream water quality standards. Under 40 CFR 122.44(d)(1)(vii), such WQBELs must be consistent with any available WLAs developed and approved pursuant to 40 CFR 130.7.

e. General Condition 5 - Margin of Safety

i. Proposal: This general condition was numbered as general condition 4 in the proposal. As proposed, this condition reiterated the requirement in CWA section 303(d) that each TMDL include a margin of safety (MOS) and described the manner in which the MOS is provided. It also reiterated EPA guidance that the MOS may be established either by setting aside a portion of the loading capacity or by using conservative modelling assumptions in deriving the TMDL.

ii. Comments: Several commenters were concerned that it would be inappropriate to leave determination of an MOS to the discretion of the permit writer. One commenter recommended that in order to facilitate basin-wide consistency and maximum environmental protection, the Guidance should implement an explicit MOS factor equal to the Criterion Maximum Concentration (CMC) value (which equals one-half of the Final Acute Value (FAV)). Other commenters advocated specifying a specific confidence level to use in modeling a MOS.

Several commenters believe that the MOS requirement is redundant given the number of conservative assumptions built into the criteria development process and into the assumptions on fate and transport.

Several commenters were concerned that including uncertainties regarding controlling pollutants from nonpoint sources into the margin of safety merely shifted the control burden to point sources without requiring EPA, States or Tribes to regulate other sources of pollution. They were concerned that a larger MOS would result in a smaller WLA, thus requiring a facility to discharge less and treat more while nonpoint sources would not be controlled.

iii. Final Guidance: Apart from minor changes to improve clarity and renumbering to reflect the overall reorganization of procedure 3.B of appendix F, the final Guidance is unchanged from the proposal. General condition 5 maintains flexibility for the State or Tribe to consider a number of factors, including case-specific conditions (e.g., availability and quality of data) in establishing a margin of safety. As indicated in 40 CFR 130.7(c)(1), the margin of safety is intended to account for uncertainty in the available data or in the actual effect controls will have on loading reductions and receiving water quality. EPA has determined that because of the need to reflect local conditions and case-specific technical considerations, it is inappropriate to specify a universal MOS factor. Although EPA recognizes the flexibility of the State or Tribe to assess available information, EPA retains the authority to disapprove a TMDL if EPA finds that a MOS is inadequate.

In response to comments that the MOS has the effect of shifting the burden of load reductions to point sources, EPA notes that the MOS requirement does not compensate for failure to consider some sources (e.g., nonpoint sources as suggested by commenters) but rather is intended to account for any technical uncertainty regarding both point and nonpoint source loading data and the effectiveness of controls. EPA acknowledges that the technical uncertainty related to nonpoint sources may in fact be greater than uncertainty regarding the effects of point sources. EPA believes that the phased approach to TMDL development provides, over time, an effective mechanism for reducing technical uncertainty related to nonpoint sources. This reduction in uncertainty will, over time, quantify and consider relative contributions and water quality impacts and lead to appropriate levels of control for both point and nonpoint sources.

EPA disagrees with the commenters' suggestion that the MOS is redundant given the conservative assumptions built into the criteria development and into assumptions on fate and transport. The MOS, as required by CWA section 303(d), is intended to account for technical uncertainties regarding the relationship between pollutant loads and water quality. These factors are not considered in the development of criteria and thus are not duplicative of assumptions used in developing criteria. Conservative assumptions in criteria development are designed to address specific uncertainties and concerns regarding extrapolations of toxicity data to individual or population endpoints. EPA also suggests that there should not be an issue of redundancy regarding the fate and transport assumptions and the MOS. The assumption of no pollutant degradation for purposes of TMDL development is rebuttable when scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur.

f. <u>General Condition 6 - More Stringent Requirements</u>

This general condition was numbered as general condition 4 in the proposal. As proposed, this condition provided that States may employ section 510 of the CWA to establish TMDLs more stringent than those developed pursuant to procedure 3. The condition reiterated the reserved right of States to require more stringent controls than those required under the CWA.

EPA received no significant comments on this provision. The proposed language is modified slightly in the final Guidance to clarify that both States and Tribes may employ section 510 and to correct a typographical error. It has also been renumbered as general condition 6 to reflect the overall reorganization of procedure 3.B of appendix F.

g. <u>General Condition 7 - Accumulation in Sediments</u>

i. <u>Proposal</u>: This general condition was numbered as general condition 6 in the proposal. As proposed, this condition specified that TMDLs must be stringent enough to prevent accumulation of the pollutant of concern in sediments to levels injurious to designated or existing uses, human health, wildlife and aquatic life. It also specified that TMDLs consider contributions to the water column from sediments inside and outside applicable mixing zones. Although TMDLs are calculated on the basis of pollutants in the water column, the preamble to the proposal indicated that all sources of pollution, including sediment re-release of pollutants to the water column, would need to be considered in establishing TMDLs.

ii. <u>Comments</u>: EPA received numerous comments on this condition. A number of commenters disagreed with the proposal. Several suggested that proposed general condition 6 be deleted until EPA finalizes and implements a national sediment strategy. One commenter suggested that proposed general condition 6 be optional depending on the availability of information or, if not, that general condition 6 should be removed entirely.

Several commenters stressed the importance of considering the release of toxics from contaminated sediments, which in many instances may result in a failure to meet water quality standards. Several commenters, while agreeing with the need to consider all sources of pollutants, including sediment release or resuspension of pollutants, believe that methodologies do not currently exist to accurately reflect the sediment re-release process. One commenter suggested that sediments should only be accounted for by concentrations measured in the water column and that any additional factors would be duplicative. Commenters recommended that EPA continue to work on National guidance for such methods and suggested that any process for developing sediment criteria should be subject to a peer review process.

iii. Final Guidance: The final Guidance retains the requirement that TMDLs reflect processes such as re-release of pollutants from sediments, because, as noted by many commenters, contaminated sediments are often a source of pollutant loading to the water column and thus may cause or contribute to an exceedance of water quality standards. However, EPA has modified this provision to clarify that such contributions should be considered only where appropriate and where sufficient data are available. EPA has renumbered this provision as general condition 7 to reflect the overall reorganization of procedure 3.B of appendix F.

EPA agrees with commenters that existing methodologies may not fully reflect all aspects of the sediment re-release process. However, EPA recently proposed its Contaminated Sediment Management Strategy (EPA 823-R-94-001) for public comment, 59 FR 44880, (August 30, 1994, available in the docket), and is continuing to develop methodologies to evaluate the sediment re-release process. The strategy proposes establishing standardized test methods to assess whether sediments are contaminated and proposes to continue supporting research on the re-release of pollutants from contaminated sediment. Under the strategy, EPA would develop new biological methods to assess the ecological and human health effects of sediment contaminants, sediment wasteload allocation models, and technologies for remediation of contaminated sediment. EPA is also working to develop chemical-specific sediment quality criteria. This process will involve review from outside parties. See 59 FR 2652, January 18, 1994 for further information.

EPA is moving forward with many of the activities described in the draft Contaminated Sediment Management Strategy and expects many of these activities to be completed in time to support State and Tribal procedures under part 132. The final Contaminated Sediment Management Strategy and associated outreach efforts will support States and Tribes in implementing general condition 6. Therefore, EPA disagrees with the comment that this condition needs to be deleted until EPA finalizes the Strategy.

Several commenters suggested that situations may exist where information is not available to determine the nature and extent of contaminated sediments' contributions of pollutants to the water column. EPA has modified the final Guidance to specify that contributions to the water column from contaminated sediments be included where appropriate. It may be considered appropriate to reflect contributions of pollutants from contaminated sediment only where data exist regarding sediment re-release of the pollutant(s) of concern. Where such information does exist, however, the TMDL must account for contributions from contaminated sediments.

In the final Guidance, EPA has reversed the order of the two sentences appearing in proposed general condition 6 in order to emphasize that contaminated sediments can be sources of pollutants to the water column and that TMDLs need to account for contributions from that source. As in the proposal, in addition to specifying that sediment re-release of pollutants shall be considered where appropriate, the final Guidance provides that TMDLs must be sufficiently stringent so as to prevent injurious accumulation of the pollutant of concern in sediments, because such injurious accumulations would represent exceedances of water quality standards (at a minimum by impairing a designated aquatic life use).

h. General Condition 8 - Wet Weather Events

i. Proposal: This general condition was numbered as general condition 7 in the proposal. As proposed, this condition recognized that some of the TMDL development procedures may be appropriate for wet weather events (e.g., nonpoint sources, storm water discharges, and combined sewer overflows). However, the proposed TMDL implementation procedures did not include explicit procedures detailing how to develop TMDLs to reflect wet weather events; rather it left maximum flexibility to the States and Tribes on how best to accomplish this. The preamble discussion of proposed general condition 7 interpreted that condition as providing that loadings from wet weather events be included in establishing TMDLs, but the proposal itself was silent on this point.

ii. Comments: Several commenters suggested that proposed general condition 7 needed to clarify that all TMDLs must include consideration of necessary waste load allocation and load allocations for wet-weather pollutant contributions. Another commenter pointed out that certain POTWs face compliance difficulties as a result of wet weather flows. The commenter suggested that these factors, which are beyond the control of the POTW, be considered in developing permit limits. Several commenters asserted that wet weather contributions cannot be accurately estimated and therefore suggested this general condition be removed all together.

iii. Final Guidance: The final Guidance retains the proposed language on wet weather flows with minor modifications and an additional sentence for clarification purposes. This provision has been renumbered in the final Guidance as general condition 8 to reflect the overall reorganization of procedure 3.B of appendix F. EPA agrees with the commenter's suggestion that this general condition should be clarified to state specifically that TMDLs must consider pollutant loadings resulting from wet weather events, where appropriate and where sufficient data are available. EPA believes TMDLs reflecting wet weather events would be appropriate where such events contribute the pollutant(s) during the flow conditions for which the TMDL is being developed. For example, the TMDL for a pollutant that has an annual averaging period (e.g., dioxin) would need to consider loadings from wet weather events because such events can occur during the yearly averaging period. However, a TMDL based on a 7-day critical low flow (e.g., lead) for a pollutant that has a 4-day averaging period would not directly consider loadings from wet weather events because such events are unlikely to occur during critical 7-day low flows. Contributions from previous wet weather events would be considered through load allocations to the sediment. In addition, a TMDL based on dynamic or stochastic water quality model would include all dry and wet weather loadings from all sources. In any case, where the TMDL for the receiving water accounts for loadings that occur from wet weather events, the resulting WLAs, including those for POTWs, must be consistent with the TMDL and WLAs. The only exception to this is where the POTW discharge meets the definition of wet weather point source under 132.2. The final Guidance does not regulate wet weather point sources.

Many nonpoint sources and wet weather point sources as defined at section 132.2 of this Guidance typically have their greatest impacts following storm events and the influx of pollutants from these events needs to be factored in when establishing a TMDL to ensure attainment of water quality standards. Accordingly, EPA has inserted language to clarify this point in the final Guidance and has amended 132.4(e)(1) to provide specifically that procedure 3 applies to wet weather events, as appropriate. Like the proposal, the final Guidance does not require a specific procedure to address wet weather flows, but rather leaves it to the discretion of the State or Tribe to choose the most appropriate procedure, considering all relevant facility specific, pollutant specific, and receiving water specific factors.

In EPA's view, this clarification will not subject POTWs to any additional burden. Any adjustments to a POTW's permit conditions to account for wet-weather flows should be addressed through the NPDES permitting and enforcement policies and procedures. Finally, EPA disagrees with the comments asserting that wet weather contributions cannot be accurately estimated. A number of models currently exist to generate loadings estimates from a range of wet weather events. EPA is working on additional guidance on assessing pollutant loadings associated with CSOs and nonpoint sources (see "Technical Guidance for Estimating Total Maximum Daily Loads (TMDLs): Integrating Steady-State Episodic Point and Nonpoint Sources, draft, June 1994, available in the docket).

i. General Condition 9 - Background Concentrations of Pollutants

This general condition was numbered as general condition 8 in the proposal. As proposed, this condition established procedures for determining representative background concentrations of pollutants to assure that background concentrations are consistently considered in TMDL development among the Great Lakes States. The proposal included provisions for calculating background. The proposal defined background, described the choice of data set, the use of the geometric mean, and the treatment of data sets with data points above and below detection. EPA received no significant comments on the definition of background and the proposed language is retained in the final Guidance with only minor changes to account for the use of the term in procedure 5. The proposal, comments and the final Guidance for each provision are discussed below. EPA renumbered this provision as general condition 9 in the final Guidance to reflect the overall reorganization of procedure 3.B of appendix F.

i. Choice of Data Set

(A) Proposal: The proposal provided that the representative background concentration for a pollutant shall be established as the geometric mean of one of three possible data sets: available ambient water column data (e.g., ambient monitoring data), representative caged fish tissue data, or representative pollutant loading data. When more than one data set exists, best professional judgment (BPJ) would be used to determine which data set most accurately estimated background concentrations. The preamble to the proposal stated that, in general, ambient monitoring data are preferred over other sources of data. The preamble also recognized that there may be instances where other data sets may be more appropriate, such as where ambient data are not available, or where ambient data are not as informative or reliable as either caged fish tissue data or pollutant loading data because of limits in analytical detection methods.

(B) Comments: Several commenters supported EPA's proposal to allow States and Tribes to choose among data sources. Others suggested that, by allowing a choice of data sets, there was too much discretion allowed to the State or Tribe in establishing background levels and suggested that EPA provide more specific guidance on the choice of data sets.

One commenter suggested that States and Tribes should be required, where possible, to eliminate unrepresentative data from the data set using factual information and statistical methods. Commenters suggested that more recent data should take precedence over older data even when the more recent data set is smaller. Furthermore, they believe that data more than five years old should not be considered. One commenter suggested that fish tissue and pollutant loading calculations should be rejected as acceptable data sets when those calculations predict background concentrations above the criteria for ambient monitoring data and such concentrations were not detected by ambient monitoring.

Several commenters advocated that only ambient data be used to estimate background concentrations. Other commenters wanted the Guidance to require regulators to use ambient monitoring data to calculate background concentrations of pollutants when such data is available.

A number of commenters disagreed with the requirement to consider caged fish tissue data in calculating background concentration because procedures for the use of caged fish analysis have not been thoroughly evaluated, validated, or standardized. Several commenters believe that the quality data necessary to provide accurate background data using the caged fish approach is not available. Commenters suggested that using resident fish tissue as a basis for deriving background would be more accurate. A commenter further suggested that EPA attempt to calibrate the fish tissue and pollutant loading models with real data. Commenters also requested more specific procedural and technical information relating to use of caged fish data.

(C) Final Guidance: In response to comments and concerns, EPA has added resident fish tissue data as a fourth specified data set available for calculating background. Apart from that, EPA retains the proposed language with only minor modifications to ensure clarity and avoid redundancy.

In the final Guidance, EPA has consolidated into a single section the list of available data sets and the basis for determining what available data is acceptable for use in calculating background. These provisions are now included in the subparagraph specifying calculation requirements. The final Guidance retains flexibility for States and Tribes to choose from among a number of data sets, including fish tissue data, in calculating background concentrations. EPA concludes that because of wide variability in the suitability of available data for a particular situation and because of site-specific considerations, use of BPJ is appropriate to make case-by-case determinations. EPA recognizes that more recent data, with improved detection or quantification levels may be more appropriate, while some older data with poorer detection or quantification levels may be less acceptable. However, EPA recognizes that, in some instances, the older data may be the only data available may be the only representative data of sufficient quality from which to make decisions and thus is not establishing a prohibition on the use of older data. In the final Guidance, the State or Tribe retains the flexibility to use BPJ to eliminate unrepresentative data or to give greater weight to the most recent data as suggested by commenters. States and Tribes may also use statistical techniques to identify and eliminate unrepresentative data.

The final Guidance thus does not include more specific direction to limit the use of any particular data set. Although EPA agrees with the commenters' suggestion that ambient monitoring data are generally preferred over other data sources, there may be situations where ambient data are not available, or are not as informative or reliable as either fish tissue or pollutant loading data because of limits in analytical detection methods. Because of limits in existing technologies, ambient data may still yield non-detects above criteria levels. Fish tissue data and pollutant loading data may be particularly useful alternatives for these situations.

EPA recognizes that caged fish tissue studies may have limitations in that such studies may not fully account for duration of exposure and food chain magnification. However, EPA has determined that such studies should be considered with other data sources in choosing among data sets to calculate background concentration. Aquatic organisms can serve as valuable indicators of whether water quality standards are being attained. The final Guidance also authorizes the use of resident fish tissue data, as suggested by commenters, because of concerns regarding food chain effects and in response to concerns about the lack of caged fish tissue data. Use of resident as well as caged fish tissue data is intended to provide more latitude in selecting the appropriate data set.

Like the proposal, the final Guidance does not provide a methodology to use in translating fish tissue concentrations to a water column concentration, or for evaluating their validity. EPA agrees that care should be exercised in determining what fish tissue data are representative of background pollutant concentrations and encourages permitting authorities to consult EPA guidance on this topic. For example, EPA recommends that when fish tissue data are available from resident fish the geometric mean is divided by the bioaccumulation factor pursuant to the methodology in appendix B of this final Guidance, to yield estimated ambient concentrations. See Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish: A Guidance Manual (USEPA, September, 1989, EPA-503/8-89-002, available in the docket).

EPA believes that best professional judgment should be used to determine if caged fish tissue data is appropriate for calculating background concentration in a given situation. Furthermore, the use of caged fish tissue data is not required unless no other data exist to calculate background pollutant concentrations. Even in a situation where only caged fish tissue data exists, a facility always has the option to collect alternative data that more accurately reflects background concentrations (e.g., ambient monitoring data). In addition, the final Guidance does not require that new fish tissue "studies" be conducted in the absence of existing fish tissue data.

ii. Geometric Mean

(A). Proposal: The proposal specified that the representative background concentration for a pollutant shall be established as the geometric mean of one of the selected data sets described in that paragraph and the preamble offered guidance for performing the calculations. EPA is retaining the proposed language in the final Guidance. The Agency received no significant comments on this provision.

As the preamble to the proposal explained, a geometric mean is calculated for the set of data chosen to represent background conditions. The geometric mean calculated is based on both measured concentrations and an appropriate methodology for treating measurements below quantification levels. For pollutant loading data, the geometric mean should be taken of pollutant loading data from individual sources. The individual means of each of the individual sources should then be added to estimate total loading to the receiving water. Background concentration is calculated by dividing total loadings by the volume of water available at the appropriate design flow. Design flow will vary depending on the criterion being implemented at the point immediately upstream of the watershed, water body or water body segment for which the TMDL, WLA in the absence of a TMDL, or preliminary WLA for the purpose of determining reasonable potential under procedure 5 of this Guidance is being established. For further discussion, see the preamble to the proposal at 58 FR 20929.

(B). Final Guidance: EPA received no significant comments on this provision. EPA believes that the use of the geometric mean is the best approach for calculating a median concentration from data chosen to represent background conditions. An arithmetic mean would be one appropriate method for calculating median values when a sample concentration is as likely to be above the true average concentration as it is to be below the true average concentration. However, concentration measurements in fish tissue and water are more likely to be below the true average concentration. Under these conditions, the geometric mean is an appropriate estimator for the median while the arithmetic average will generally produce a value that is higher than the median. More explicitly, fish tissue and water concentration measurements generally follow positively skewed probability distributions where the median is appropriately estimated by the geometric mean.

iii. Data Points Above and Below Detection

(A) Proposal: The proposal allowed the use of best professional judgment to determine which data points are acceptable. However, within a given data set, some data points may indicate that the pollutant was not present at levels capable of being detected by the analytical method used. For these data points, the true concentration of the pollutant can be zero or is somewhere between zero and the detection level of the analytical method. Other data points may indicate that the pollutant was detected, but at levels below which the analytical method is capable of reliable quantification. For these data points, the true concentration will be between the detection level and the quantification level of the analytical method. Finally, there may be data points showing reliably quantified levels of the pollutant. The proposed Guidance specified that the following assumptions be used in calculating background when, within a data set, some data points are determined to be above and others are below the detection level. The proposal included the following assumptions: data points reported at levels below detection shall be set equal to one half of the detection level; and data points reported at levels greater than the detection level but less than the quantification level, shall be set equal to the midpoint between the detection level and the quantification level. If all acceptable available data points in a data set are reported as below the detection level for a specific pollutant, then all the data for that data set are assumed to be zero.

Section 132.2 of the proposed Guidance included a definition of detection level that is identical in substance to the definition at 40 CFR 136.2(f). There is no similar long-established definition of the term quantification level. However, the proposal defined the quantification level as the concentration at which a particular substance can be quantitatively measured using a specified laboratory procedure. EPA solicited comment on the definition and on the issue of whether a particular degree of confidence should be specified.

(B) Comments: EPA received a number of comments on the proposal to assign values equal to one-half of the detection level to data points reported below the detection level when other data points in the data set were reported above the detection level.

Several commenters supported the use of one-half of the detection level as a default. Another commenter suggested that if 25% or more of the data points are quantifiable, the remaining values reported as less than the detection limit should be zero. One commenter advocated that the requirement to use one-half of the detection level as a background concentration be deleted and the evaluation left to best professional judgment. Another commenter recommended that if a large proportion of the data is reported as non-detect, assumptions regarding what value to assign should be left up to the permitting agency and that such determinations need to be made on a case-by-case basis rather than through the application of a general rule. Several commenters wanted EPA to allow the use of appropriate statistical methods for data sets that include a large number of values below the detection limit and further advocated that the final Guidance cite examples of such statistical methods. One commenter suggested that a statistically valid sliding scale be used to assign concentration values to any non-detect measurements. Another commenter expressed concern that the proposed approach will result in unrealistically high background concentrations for data sets with a large share of measurements below the detection level and suggested that the final Guidance include methods presented in "NCASI Technical Bulletin No. 621." Several commenters supported the use of one-half the detection level when calculating means or averages from data sets that include non-detect values.

EPA also received comments addressing situations where some of the data is between the detection level and the quantification level. One commenter suggested that the final Guidance require the quantification level be used as the default value in determining the mean for pollutants that have caused or contributed to fish advisories downstream. Another commenter suggested that when data points are below the detection level or quantification level, zero or a default percentage of the criteria value, when the criteria value is also below the level of detection, should be assumed.

In situations where all the data points in a particular data set are below detection, several commenters agreed with the proposal that these data points should be assumed to be zero. One commenter suggested that for a data set of more than ten data points, the proposal should apply, but that if there are fewer than ten data points and all the data points are below detection, background shall be assumed to be one-half the detection level. Several commenters supported EPA's definition of quantification level. A few commenters did not support including the quantification level definition. Another commenter suggested that the definition of quantification level should be the same as that used in setting the Compliance Evaluation Level (CEL) for determining permit compliance in proposed procedure 8. The CEL was defined in the proposal, as the level at which compliance with an effluent limit is assessed. Some commenters advocated that the term "detection level" be changed to "method detection level" since the proposal defined detection level the same as method detection level is defined in 40 CFR 136.

(C) Final Guidance: The final Guidance recognizes the need for flexibility when calculating background using a data set containing data points both above and below the detection level or quantification level. EPA has concluded that, for these data sets, although default values of one-half of the reported detection level for data points reported as below detection, and the mid-point between the detection level and quantification level for data points reported below the quantification level and above the detection level, are a reasonable and appropriate estimate for purposes of calculating background concentration, they are not the only reasonable and appropriate approach. As many of the commenters pointed out, there are a number of commonly accepted statistical approaches to evaluating mixed data sets (also known as censored data sets). Therefore, in the final Guidance, States and Tribes are required to use commonly accepted statistical techniques to evaluate data sets containing values both above and below the detection level. Commonly accepted statistical techniques can include a variety of approaches, including the use of default values as proposed. Some commonly accepted statistical techniques are outlined in Chapter 14 of *Statistical Methods for Environmental Pollution Monitoring* (Richard O. Gilbert; published by Van Nostrand Reinhold) and *Truncated and Censored Samples* (A.Clifford Cohen; published by Marcel Dekker).

Because there is no universal method to reliably quantify pollutant concentrations below the detection level, EPA believes that using a default value of one-half of the reported detection level is a reasonable balance of a State and Tribes' obligation to provide dischargers with an appropriately stringent WLA and the statutory requirement that TMDLs ensure the attainment of water quality standards. The same reasoning applies when calculating WLAs in the absence of a TMDL. Likewise, EPA has concluded that the reasoning above also supports using the mid-point between the detection level and quantification level as an acceptable, reasonable approach for dealing with data points above the detection level but below the quantification level. In this situation, EPA does not endorse using the detection level as a default value. Using the detection level as a default to calculate background could result in WLAs that would not provide the necessary assurances, as required by the CWA, that water quality standards will be attained. Again, EPA believes this is of particular concern for pollutants with criteria values below the level of detection.

EPA retains the approach in the proposal that assigns zero values to data points when all the data in the data set are below the level of detection for the particular pollutant. When all analytical tests for a chemical result in determinations that fall below the detection level, one would have, in effect, a finding that the target analyte cannot be known with confidence to be present in any of the samples. Where this is the case, and no other analytical results are available to indicate that the chemical may be present in any sample, EPA believes the appropriate finding is that the chemical is not present. In contrast, as described above, where analytical tests show the chemical to be present in some samples, EPA believes that an appropriate and reasonable approach is to assume that the chemical may be present even in those samples in which the chemical is not detected, and therefore assign a value to the non-detect measurement of one-half the value of the detection level. Although EPA recognizes that this could potentially result in an underestimate of background concentration for a given pollutant, it could also result in an overestimate of background concentration for a given pollutant. EPA believes that this approach is reasonable because it strikes a balance between the desire to accommodate dischargers with a reasonable WLA and the CWA requirement that TMDLs ensure the attainment of water quality standards. In addition, as discussed in the preamble to the proposal, there is no universal method to reliably quantify pollutant concentrations below the detection level. States and Tribes may want to consider a more stringent approach, whether as a general matter or in establishing individual TMDLs, as authorized by section 510 of the Clean Water Act and general condition 6 of this procedure.

EPA is retaining the proposed definition of "quantification level" for purposes of this procedure. EPA has concluded that a standard definition of quantification will improve consistency among States and Tribes in the Great Lakes System when calculating the background concentration of pollutants. Consistency among Great Lakes States and Tribes is one of the major objectives of the final Guidance, although the definition is broad enough to allow consideration of other factors as appropriate. For example, a State or Tribe may consider the nature of the pollutant, the method being used, and the past performance of the testing facility or laboratory. In addition, EPA agrees with commenters that asserted the proposed definition of "detection level" is confusing since it is substantively identical to the existing 40 CFR 136 definition of "method detection level." EPA has therefore, renamed "detection level" to "method detection level" to avoid confusion and maintain consistency. Substantively, the text of the definition was not changed.

A State or Tribe's use of procedures for estimating representative background concentrations of pollutants will also be reviewed by EPA on a case-by-case basis when it approves or disapproves State or Tribal TMDLs submitted under section 303(d). A State or Tribes's approach will be reviewed as part of the program submission and adoption process set forth at section 132.5 of this Guidance. EPA also retains the authority to object to an NPDES permit containing a WQBEL derived from a WLA in the absence of a TMDL if EPA determines that the estimates of representative background concentrations were unreasonable and that the permit would therefore not implement water quality standards as required by section 301(b)(1)(C) of the CWA.

The only substantive change to the proposal is the addition of language authorizing the use of commonly accepted statistical techniques in evaluating data sets consisting of values both above and below the method detection level. EPA added this additional flexibility in response to a number of comments supporting the use of such approaches. EPA encourages the use of commonly accepted techniques. Such statistical approaches can be a useful tool when dealing with sparse data sets. In all other respects, general condition 9 is substantively the same as the proposal, except that it states explicitly that it applies to data sets having values both above and below the method detection level. The final Guidance has also been modified to ensure that the term "reported" is used consistently throughout this condition.

j. <u>General Condition 10 - Effluent Flow</u>

General condition 10 in the proposal provided that, if WLAs are expressed as a concentration of a pollutant in a discharge, the TMDL must also specify the point source effluent flow assumed in deriving the WLA. Since

TMDLs are based on mass loadings to a system, the assumed flows used to derive the mass loadings need to be specified. This provision also facilitates the establishment of mass loading limitations in NPDES permits as required by procedure 7 of appendix F. Substantive comments on establishing an effluent flow are addressed in the loading limits section of this document (section VIII.G). The final Guidance retains the proposed language with minor changes to improve clarity. This should assure that common assumptions are used in establishing TMDLs and corresponding NPDES permit limits.

k. General Condition 11 - Reserved Allocations

i. Proposal: General condition 11, as proposed, provided that once a TMDL for a particular pollutant is in place for a waterbody, a new source or new discharger can discharge that pollutant to the waterbody only if its loadings are consistent with the existing TMDL. The existing TMDL must include a reserved allocation for future growth or the TMDL must be revised to include an allocation for the new discharge.

ii. Comments: Many commenters suggested that the provision related to the use of "reserved allocations" for future growth should be strengthened to require that a specific share be set aside. One commenter suggested that EPA should describe the procedure to determine a reasonable reserve capacity for future growth while allowing the State the discretion to make this determination.

iii. Final Guidance: The final Guidance makes only minor modifications to change the title from "New Source or Discharger" to "Reserved Allocations" and to clarify that the general condition applies only to new discharges of the particular pollutant for which the TMDL was developed. The purpose of general condition 11 is to assure that the impacts of new pollutant sources will be considered. Without such a condition, a TMDL might fail to take into account new discharges of the pollutant of concern with the result that the TMDL would need to be revised in order to allow the new discharge. While EPA appreciates the comments urging that this provision be strengthened by establishing a specific procedure for reserving capacity for future growth, EPA believes that States and Tribes are in the best position to determine a reasonable allocation for future growth and thus the final Guidance provides them the flexibility to make the determination. States and Tribes will need to make the determination by balancing local and economic development with water quality requirements.

4. Special Provisions for BCCs

a. Proposal: The proposed Guidance recommended restrictions on the introduction of bioaccumulative chemicals of concern (BCCs) in the Great Lakes System by specifying, in general, that mixing zones for existing dischargers of BCCs be eliminated within 10 years of the effective date of this final Guidance, and for new dischargers or new sources, that no mixing zone for BCCs be provided. The proposal also specified that mixing zones calculated during the ten year phase-out period prior to elimination of mixing zones for BCCs would be established using the mixing zone provisions for non-BCCs, set forth in sections C and D of proposed options A and B. The proposal allowed a limited exception to the elimination of mixing zones for BCCs when water conservation measures result in an increased concentration but lead to an overall reduction in load.

b. Comments: EPA received numerous comments both supporting and opposing the provision to eliminate mixing zones for BCCs. Many commenters supported the phase-out of mixing zones for all discharges of BCCs within the Great Lakes System. Several of these comments pointed out that the proposed elimination of mixing zones is consistent with the Great Lakes Water Quality Agreement's emphasis on limiting any future introduction of persistent toxics into the Great Lakes System.

A number of commenters urged that the elimination of mixing zones be broadened to include all persistent toxic chemicals, not just BCCs. Several commenters specifically mentioned the need to address lead and cadmium. One commenter suggested that in order to ban the discharge of toxic substances into the Great Lakes Ecosystem, EPA needs to ensure that all sources of pollution, including air, contaminated sediments and runoff, are controlled and that EPA should require comprehensive pollution prevention programs throughout the basin. One commenter suggested that while mixing zones for BCCs should, in general, be eliminated, mixing zones should be allowed under strict conditions, such as when pollution prevention measures are implemented and have resulted in reduced loadings.

Many commenters opposed the elimination of mixing zones for existing dischargers of BCCs and believe that the mixing zone prohibition is unattainable and inefficient. Many commenters mentioned that there would be high costs associated with elimination of mixing zones in return for limited environmental benefits. Commenters claimed that the elimination of mixing zones requiring dischargers to meet criteria end of pipe would, in effect, result in a zero discharge requirement.

Several municipalities mentioned that they would be unable to impose additional requirements on their industrial dischargers that would allow them to meet water quality goals without mixing zones. They also felt the phase-out of mixing zones for BCCs would provide a disincentive for them to take on new industrial dischargers.

Many commenters suggested that if mixing zones are phased out, reductions must be limited to levels that are economically and technically feasible. Several commenters advocated that additional pollution prevention measures also be required to help minimize the release of BCCs into the Great Lakes.

Commenters also suggested that eliminating mixing zones for BCCs may not be the most cost-effective means of reducing certain BCC loadings (e.g., mercury) and that reductions need to come from other sources, such as atmospheric deposition. Commenters suggested that greater load reductions would occur if nonpoint sources were targeted for controls. Commenters asserted that extraordinary controls on point sources of BCCs will have little impact on water quality because point sources only contribute a small percentage of the total load of BCCs to the basin and that the major loading of BCCs is from nonpoint sources. Several commenters claimed that the increased stringency in permits would not lead to an overall improvement in ambient water quality and that limits without mixing zones would be unduly restrictive.

Numerous commenters stated that the elimination of mixing zones has no scientific merit and is merely a policy decision. Many commenters pointed out that existing EPA technical guidance, such as the Technical Support Document for Water Quality-based Toxics Control (TSD), does not disallow mixing zones. Commenters suggested that existing EPA and State policy should determine when mixing zones are appropriate. One commenter advocated that methods recommended in the TSD be used to predict the fate and transport of pollutants such as BCCs and that these approaches be used to develop TMDLs for the BCCs rather than disallowing mixing zones.

A number of commenters indicated that the proposed time frame for the phase-out is reasonable. One commenter suggested that the final Guidance should make it clear that the mixing zone phase-out for existing discharges will be effective ten years after the Guidance is incorporated into state rules rather than ten years after publication of the final Guidance. Numerous environmental groups suggested that the implementation period is too long and recommended an accelerated phase-out of mixing zones for BCCs. Many supported a 5-year phase-out rather than 10 years. Commenters specifically suggested partial reductions of mixing zones, in terms of the available dilution ratio, be used at the time of the first NPDES permit reissued after the final Guidance is published.

One commenter advocated that EPA establish a mass loading-based limit on the proposed water conservation exemption by placing a cap on the increased concentration allowed in exchange for water conservation measures. Commenters supported the proposed restriction that the mixing zone granted under this provision be consistent with the mixing zone provisions of sections C (deriving TMDLs for discharges to Lakes) and D (deriving TMDLs for discharges to Tributaries) of proposed procedure 3.

c. Final Guidance: The final Guidance retains the ten-year phase-out of mixing zones for BCCS and the immediate elimination of mixing zones for new discharges, which are defined for the purpose of procedure 3.C as (i) discharges from new Great Lakes dischargers; or (ii) a new or expanded discharge from an existing Great Lakes discharger. All other discharges of BCCs are defined as existing discharges. The final Guidance is consistent with the Steering Committee's policy that every reasonable effort be made to reduce all loadings of BCCs to the Great Lakes System. The Steering Committee recommended that mixing zones be eliminated for BCCs as a way to reduce mass loadings to the Great Lakes. However, in response to numerous comments that the proposed phase-out may be technically or economically infeasible, the Guidance does provide a limited exception to the elimination of mixing zones for existing discharges of BCCs to the Great Lakes System. This exception is provided only in limited circumstances when the State or Tribe finds that the discharger seeking the exception is implementing controls to reduce the BCCs for which a mixing zone is sought to the maximum extent possible yet still cannot meet a WQBEL based on no mixing zone. EPA has concluded, after considering all the comments, that elimination of mixing zones for BCCs may not be reasonable in all circumstances, and thus has provided for a limited exception (described below) in the final Guidance.

The final Guidance uses the terms "new Great Lakes discharger" and "existing" Great Lakes discharger as discussed in section II.B of this document. In the final Guidance, the time deadline has been clarified to provide that mixing zones for existing Great Lakes dischargers will be phased-out within twelve years from the date of publication of the final Guidance. The proposal set the phase-out at ten years, but this has been modified in the final Guidance to reflect explicitly the two years allowed for State and Tribal adoption of implementation procedures for the final Guidance. The phase-out deadline for new Great Lakes dischargers is stated in the final Guidance as two years after publication of the final Guidance.

The phase-out of the elimination of mixing is consistent with existing EPA regulations and guidance, and the Great Lakes Water Quality Agreement. EPA regulations provide that States and Tribes may, at their discretion, provide for mixing zones as part of their State and Tribal water quality standards (40 CFR 131.13). However, the Technical Support Document for Water Quality-based Toxics Control recommends that States and Tribes provide a definitive statement in their water quality standards as to whether or not mixing zones are allowed and suggests that: "As our understanding of pollutant impacts on ecological systems evolves, there may be cases identified where no mixing zone is appropriate." For example, EPA's Water Quality Standards Handbook (EPA-823-B-93-002) states that "Careful consideration must be given to the appropriateness of a mixing zone where a substance discharged is bioaccumulative, persistent, carcinogenic, mutagenic, or teratogenic." The Handbook recommends that "denial (of mixing zones) should be considered when bioaccumulative pollutants are in the discharge."

A general principle of the Great Lakes Water Quality Agreement (see Annex 2 Paragraph 2.(d)) supports the elimination of point source impact zones (i.e., mixing zones) for toxic substances as consistent with the overall policy of the virtual elimination of persistent toxic substances. According to the Agreement, pending the achievement of the virtual elimination of persistent toxic substances, the size of such zones shall be reduced to the maximum extent possible by the best available technology so as to limit the effects of toxic substances in the vicinity of these discharges.

Although levels of certain bioaccumulative chemicals of concern (BCCs) have significantly declined in the Great Lakes System in recent years, EPA estimates that under current loadings it will take years, perhaps decades, for fish tissue concentrations of certain BCCs to decline to levels that would allow unrestricted consumption of fish in the Great Lakes. Due to the unique characteristics of the Great Lakes, special limitations are necessary to reduce loadings of BCCs to assure that similar problems do not occur in the future for other BCCs. For a more thorough discussion of ambient concentrations of BCCs, see sections I and II.C.8 of this document.

A number of commenters mentioned that there would be significant costs associated with complying with the mixing zone ban for existing discharges and that EPA should not mandate reductions that are technically and economically infeasible. Mixing zones allow facilities to exceed applicable water quality criteria in a portion of the stream segment or lake close to the discharge point. EPA recognizes that, in certain limited situations, the elimination of mixing zones for BCCs for existing discharges may be technically or economically infeasible, and in limited circumstances, may not be a reasonable approach despite the ten-year phase-out period. Therefore, the final Guidance provides a process whereby a State or Tribe may grant a mixing zone for existing discharges of BCCs in limited circumstances. EPA emphasizes that no such exception to the mixing zone prohibition is authorized for new Great Lakes dischargers or new or expanded discharges from an existing Great Lakes discharger because EPA has determined that facilities contemplating such discharges have more flexibility in designing and constructing their processes and treatment technologies to meet applicable water quality criteria at the point of discharge. In addition, EPA notes that States and Tribes are not required to grant mixing zones in any instance.

The final Guidance authorizes the granting of a mixing zone for BCCs for existing discharges, after the phase-out period, only upon finding that: (1) the facility is in compliance with and will continue to implement all applicable treatment and pretreatment requirements of Clean Water Act sections 301, 302, 304, 306, 307, 401, and 402, including existing NPDES water-quality based effluent limitations; and (2) the discharger has reduced its discharge of the BCC for which a mixing zone is requested, and will continue to implement controls to further reduce such discharge, to the maximum extent possible. Because of concerns about the impacts of BCCs to the Great Lakes System and the significant public support for the elimination of mixing zones for BCCs, EPA intends that this exception only be granted in limited situations.

In making a finding that a discharger has reduced the discharge of BCCs for which the mixing zone is sought to the maximum extent possible, the State or Tribe should consider the availability and feasibility of additional controls for that discharger to reduce and ultimately eliminate BCCs, including those controls and strategies used by similar dischargers. For purposes of this subparagraph, "similar dischargers" is to be interpreted broadly to include, at a minimum, facilities with similar industrial or treatment processes, similar pollutants, and similar products or similar by-products.

For purposes of determining whether to grant a mixing zone for an existing discharges of BCCs after the phase-out period, the State or Tribe should also consider whether the discharger, or affected community or communities, will suffer severe economic hardship if the mixing zone is eliminated. In evaluating economic impacts, State or Tribe should consider costs of all pollution reduction options including available treatment technologies and control strategies beyond those already being implemented. Costs should reflect design and current operating flow. States or Tribes should also evaluate the influent water quality, type of BCC, volume of effluent and concentration of the BCCs for which the mixing zone is being sought present in the effluent, and ambient receiving water quality. Finally, the State or Tribe should evaluate information on the facility's current financial health including, where appropriate, existing municipal and pretreatment user charges and existing profitability. Where appropriate, the State or Tribe may also want to consider information on the current profitability and overall financial health of the facility's parent corporation, where such information is available. EPA expects that factors to be considered in assessing economic impacts will vary on a facility-by-facility basis. (See Economic Guidance for Water Quality Standards - Workbook, Draft, November 1993, available in the docket for this rulemaking.) The State or Tribe should also evaluate potential effects on employment rates, tax revenues, and where appropriate, on user fees from increased costs associated with meeting water quality criteria in the absence of a mixing zone.

Under the final guidance, a mixing zone for a BCC may be granted only if the permitting authority determines, inter alia, that the discharger has reduced its loadings of that BCC to maximum extent possible. Therefore, an exception to the mixing zone elimination provision may not be granted if pollution prevention and/or control and treatment strategies exist that make it technically possible for the discharger to achieve the applicable water quality criteria at the point of discharge, and if the discharger, or affected community or communities, will not suffer severe economic hardship in implementing such strategies. For example, in assessing whether the discharger has reduced its discharge of the BCC for which a mixing zone is requested to the maximum extent possible, the State or Tribe should consider the availability and feasibility of alternate treatment technologies and control strategies including pollution prevention measures that reduce and eliminate BCCs, and whether or not these technologies and strategies are currently being implemented by the facility. Relevant strategies include those that would apply both to the facility and upstream sources (e.g., a municipalities's industrial users). After evaluating alternate technologies and strategies, the permitting authority should consider the technical reasons that implementation of some or all of them cannot reasonably be expected to eliminate the discharger's need for a mixing zone. EPA emphasizes that this exception to the elimination of mixing zones for existing discharges of BCCs is intended to be very limited and only granted in exceptional circumstances. In addition, if a mixing zone for existing discharges of BCCs is proven necessary, the State or Tribe should only grant the amount of mixing needed to address the remaining technical and economic limitations. In no circumstance should the amount of mixing allowed exceed the maximum mixing zones specified for non-BCCs in sections D (deriving TMDLS for discharges to Lakes) and E (deriving TMDLS for discharges to tributaries) in procedure 3 of appendix F.

The State or Tribe should also consider whether or not the discharger agrees to develop and implement an ambient monitoring plan. Monitoring data compiled by dischargers could be used to supplement State or Tribal monitoring data and provide additional information on receiving water assimilative capacity and on the extent of impacts, if any, associated with the mixing zones. Ambient monitoring data would be used, in attained waters, to ensure compliance with water quality criteria at the edge of any mixing zone, and in non-attained waters to ensure that the projected improvement in water quality under the TMDL or comparable assessment and remediation plan is occurring. Ambient monitoring data can also be used to provide the basis for future decisions on the granting of mixing zones for BCCs. The State or Tribe is encouraged to seek additional information, as necessary, to determine whether a mixing zone for BCCs is warranted for an existing discharge.

The final Guidance incorporates a number of limitations on any mixing zones for existing discharges of BCCs granted after March 23, 2007. Specifically, under the final Guidance, no mixing zone for existing discharges of BCCs shall result in any less stringent limitations than those existing prior to March 23, 1997. Furthermore, the mixing zone shall be limited to one permit term. Mixing zones may not be granted thereafter unless the State or Tribe makes the necessary findings discussed above for each successive permit application in which a mixing zone for BCCs is sought. The size of the mixing zone shall also be evaluated and shall reflect all new information obtained by the State or Tribe in considering mixing zones for BCCs after the phase-out. In addition, any mixing zone for BCCs granted under this exception for attained waters must protect all designated and existing uses of the receiving water and must ensure the attainment of applicable aquatic life, wildlife, and human health criteria. In non-attained waters any mixing zone granted for BCCs under the exception must be consistent with the TMDL or comparable assessment and remediation plan under procedure 3.A of appendix F.

EPA recognizes that pollution prevention approaches are an effective means of reducing loadings to the environment and are usually less costly than treatment. Thus, the final Guidance provides that, in granting any exception to the mixing zone elimination provision for existing discharges of BCCs, the State or Tribes needs to ensure that the discharger has developed and conducted a pollutant minimization program for that pollutant consistent with procedure 8 of the Guidance, where applicable. Procedure 8 of the final Guidance provides that when a water quality-based effluent limitation for a pollutant is determined to be less than the quantification level, the permitting authority shall include a condition in the permit requiring the permittee to develop and conduct a pollutant minimization program. The goal of the pollutant minimization program is to reduce all potential sources of the pollutant and thus to maintain the effluent at or below the WQBEL. Based on current detection levels for the twenty-eight BCCs that are included in Table 6 of the final Guidance as pollutants of Initial Focus in the Great Lakes Water Quality Initiative, it is estimated that 22 of the BCCs will have criteria established at levels below what the most sensitive analytical techniques can currently quantify, and will also likely result in WQBELs less than their quantification levels. Therefore, EPA believes that in most instances, a facility will already be required to develop pollutant minimization programs for most BCCs. It is possible that in some situations, addition of a mixing zone may result in an increased limit that will then cause the WQBEL to be greater than the quantification level; procedure 8 would no longer apply and a pollutant minimization program would no longer be required. In those instances, States and Tribes should consider requiring the permittee to develop and conduct a pollutant minimization program as a condition of receiving the mixing zone for BCCs.

Finally, the final Guidance provides that no mixing zone for a BCC shall be granted unless alternative means for reducing BCCs elsewhere in the watershed are evaluated. This limitation reflects concerns raised by many commenters that nonpoint source contributions of BCCs might be more significant than point source contributions and therefore nonpoint sources should be taken into account when determining the availability of mixing zones for existing point source discharges of BCCs. This evaluation can be conducted either by the State or Tribe or by the discharger seeking the mixing zone for BCCs. EPA expects that this evaluation may identify opportunities to reduce BCC loadings within the watershed from other sources and may facilitate a more effective and less costly strategy for point sources to achieve overall reductions in BCCs. EPA expects controls necessary to obtain additional reductions in BCCs will be implemented under existing State, Tribal, federal and local authorities and believes that this provision will provide additional incentives for dischargers to assist States and Tribes in identifying other sources of BCCs. As suggested by some commenters, reductions of some of these nonpoint source loadings may prove to be more cost-effective and may result in greater environmental benefits than would be achieved by increasing controls on point sources.

The final Guidance provides that exceptions to the mixing zone elimination provision will be granted solely at the discretion of the State or Tribe on a case-by-case basis. States or Tribes may also choose not to authorize such exceptions as part of their part 132 adoption, and thus could simply require the elimination of mixing zones for existing discharges of BCCs no later than March 23, 2007.

Because of the importance of controlling BCCs in the Great Lakes System, it is critical that the public have an opportunity to comment on permit-specific exceptions to the general policy of eliminating mixing zones for existing dischargers of BCCs. The final Guidance provides that each draft permit that includes a mixing zone for one or more BCCs after the phase-out period must specify, either in the fact sheet or in the statement of basis for the draft permit, the mixing provisions used in calculating the permit limits, and must identify each BCC for which a mixing zone is proposed. The draft permit, including the fact sheet or statement of basis, is required to be publicly noticed and made available for public comment under 40 CFR 124.6(e). The final Guidance also specifies that any mixing zone for existing BCC dischargers authorized under procedure 3.C.6 of appendix F must also be consistent with procedure 3.D and 3.E of appendix F.

Under the final Guidance, the elimination of mixing zones will continue to be limited to BCCs. BCCs are the pollutants of primary concern in the Great Lakes System. Documented widespread impacts warrant the special emphasis on controlling BCCs (see section I of this document, and the preamble to the proposal at 58 FR 20806). In addition, States already have the discretion under current EPA regulations to eliminate mixing zones for other persistent chemicals such as lead and cadmium.

The final Guidance retains the ten year phase-out period for existing discharges but clarifies that this begins after States and Tribes adopt the part 132 implementation procedures. As authorized by section 132.5, States may be granted up to two years in which to adopt and submit for EPA approval criteria, methodologies and policies and procedures consistent with the final Guidance. The ten year time period corresponds to two five-year NPDES permit terms. EPA has determined that it represents a reasonable period for implementing the mixing zone phase-out and that this period is consistent with the Great Lakes Water Quality Agreement goal of virtual elimination of persistent toxic substances.

EPA has concluded that a shorter time period for existing Great Lakes discharges, such as a phase-out within five years as suggested by some commenters, may not afford facilities with existing discharges sufficient time to retrofit existing treatment technologies or to adopt new pollution prevention or alternative control strategies as necessary to achieve the applicable water quality criteria at the point of discharge. Therefore, EPA is retaining the proposed ten year phase-out period. EPA notes, however, that States and Tribes may choose to establish a shorter phase-out time when they adopt the final Guidance.

The proposal also included a provision that WLAs be set at a more stringent level than the most stringent water quality criteria or values if necessary due to background concentrations to meet criteria and values at the point of discharge. This clause has been omitted from the final Guidance. The final Guidance provides simply that the WLA for new and existing discharges of BCCs shall be set equal to the most stringent applicable water quality criteria or values for the BCC in question. This would also be the case for a BCC for which the water body is in non-attainment. See section VIII.E.2.h of this document for a discussion of the rationale. Section 301(b)(1)(C) and 402 of the Clean Water Act and implementing regulations address discharges to non-attained waters and ensure that limitations more stringent than criteria will be imposed where appropriate; thus EPA determined that the omitted clause was unnecessary.

EPA has made other modifications to the mixing zone section. The order of this section has been rearranged to correspond to the chronological sequence of events. Also, the final Guidance clarifies that specific provisions in this section apply to WLAs calculated in the absence of TMDLs and preliminary WLAs developed for purposes of determining reasonable potential under procedure 5 of appendix F, as well as to the development of TMDLs. This change reflects the modification to General Condition 1, discussed above, which no longer specifies that TMDLs must be developed prior to the issuance of a new or revised NPDES permit upon a finding of reasonable potential. WLAs and corresponding WQBELs may be calculated in the absence of a TMDL. The new reference in this section is intended to clarify that these mixing zone provisions apply even in those situations when no TMDL has been established.

The final Guidance retains the exception to the mixing zone elimination for BCCs for existing discharges from a facility implementing water conservation measures. EPA recognizes that, as a result of water conservation measures, concentrations of a BCC in an effluent may increase, while the mass of the BCC being discharged does not. EPA concludes that because water conservation is desirable, an exception may be appropriate in certain circumstances. The primary concern for BCCs is the mass of the pollutant entering the Great Lakes System. EPA agrees with commenter's concerns regarding allowable increases above criteria and has retained the provision that restricts mixing zones under the water conservation provision to those allowed for non-BCCs (i.e., a 10:1 dilution ratio for lakes and 25 percent of design flow for tributaries).

5. <u>TMDLs for Open Waters of the Great Lakes (OWGLs)</u>

Both options A and B described the process for developing TMDLs for open waters of the Great Lakes (OWGLs), inland lakes and other waters of the Great Lakes System that exhibit lentic conditions {see proposed sections 3A.C (58 FR 21036) and 3B.C (58 FR 21039)}. Both options provided general guidance for development of TMDLs on a lake-wide basis, including specifications for mixing zones for non-BCCs, calculation of load allocations, protection from acute effects, procedures when high background concentrations are present, and a provision for a margin of safety for chronic and acute effects.

In the final Guidance, language has been added to state explicitly that TMDLs developed under this section must comply with General Conditions 1 through 11 and requirements of section 303(d) of the CWA and 40 CFR 130.7. (see citations under general condition 1 in procedure 3 of appendix F). The final Guidance also identifies the provisions of this section that apply for purposes of calculating WLAs in the absence of TMDLs and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of appendix F. Aspects of both procedures 3A and 3B have been retained in the final Guidance and modifications to specific components of the proposal are described in more detail in the following sections. It should be noted that nothing in this section should be construed as authorizing mixing zones for BCCs that are prohibited under procedure 3.C of appendix F. These procedures are to be used, however, when establishing a mixing zone allowed under procedure 3.C of appendix F.

a. <u>Mixing Zones for non-BCCs</u>

i. <u>Proposal</u>: Both options provided that, absent a mixing zone study, individual wasteload allocations for point sources shall not be based on a mixing zone larger than is provided by mixing one part effluent with ten parts lake water, including background concentrations of pollutants. Option A described the 10:1 mixing zone in a narrative format, while Option B embodied the concept in a formula. Option B included language providing that in no case shall the permitting authority grant a mixing zone that exceeds the area where discharge-induced mixing, i.e., the area in which the momentum from the discharge pipe ceases to have a major impact, occurs.

Under proposed Option B, for non-BCCs, when a facility believes the actual area of discharge-induced mixing is greater than 10:1, a larger mixing zone could be allowed if a mixing zone demonstration is successfully completed in accordance with proposed section 3B.E. Under Option A, the mixing zone available is not necessarily constrained by the area of discharge-induced mixing if a facility demonstrates that an alternative mixing zone is appropriate for protection of designated and existing uses and implementation of all criteria and values.

ii. Comments: Several commenters disagreed with the provision limiting allowable mixing zones to the area of discharge-induced mixing. Several commenters advocated that credit be given for the use of diffusers and other forms of enhanced mixing to increase discharge-induced dilution.

Several commenters suggested that there is not sufficient justification for a maximum dilution factor and therefore disagreed with the 10:1 specified in the proposal. One commenter stated that the studies cited in the proposal support setting the 10:1 factor as a default value but do not provide a scientific basis to establish the 10:1 as a maximum. Several commenters mentioned that the proposal is inconsistent with existing State mixing zone policies and recommended that the final Guidance be modified to allow each State to use its existing mixing zone provisions, which have already been approved by EPA.

One commenter advocated that mixing zones be prohibited for new source discharges of non-BCCs to lakes unless a mixing zone demonstration was conducted by a discharger. One commenter suggested that, for new sources, a dilution factor of up to 75% should be allowed without a mixing zone demonstration.

iii. Final Guidance: The final Guidance consolidates aspects of both options A and B into one provision. Like both options, the final Guidance specifies that WLAs calculated in the absence of a TMDL and preliminary WLAs for purpose of determining the need for WQBELs under procedure 5 of appendix F shall assume no greater dilution rate than one part effluent to 10 parts receiving water. The final Guidance clarifies that this dilution factor applies to both new and existing dischargers. Language appearing in both proposed options was modified to clarify that the provision applies to WLAs developed both for numeric and narrative criteria. The final Guidance retains the provision in Option B that limits the area of the mixing zone to the area of discharge-induced mixing. Consistent with both proposed options, a larger mixing zone is allowed if a facility successfully completes a mixing zone demonstration pursuant to procedure 3.F of appendix F. As discussed below, the final Guidance adopts the mixing zone demonstration provisions proposed as part of Option B.

As described in the preamble to the proposal (58 FR 20932), the 10:1 mixing factor was derived from mixing zone studies conducted for the Milwaukee Metropolitan South Shore wastewater treatment plant and for the Green Bay Metropolitan wastewater treatment plant. For these cases, it was shown that the 10:1 mixing factor represented an area of mixing where the velocity and momentum associated with an effluent being discharged from the end of a pipe was dissipated and any further dilution or mixing that then occurred was associated only with the typically slower natural process of diffusion, wind, temperature or current induced dispersion. While recognizing that mixing zone allocations are largely a policy decision, EPA believes that these studies provide a scientific basis for default mixing zone assumptions for discharges to open waters of the Great Lakes. The final Guidance does allow for recognition of site-specific conditions by allowing alternative mixing zones subject to the mixing zone demonstration requirements set forth in procedure 3.F of appendix F. EPA recognizes that mixing zone demonstrations are subject to resource and timing constraints.

EPA acknowledges that different situations, such as the use of diffusers and other technologies to enhance mixing, may increase the area of discharge-induced mixing, thereby warranting a larger dilution factor; and the final

Guidance authorizes States and Tribes to afford dischargers the opportunity to demonstrate that an alternative mixing zone is appropriate. However, in the interest of ensuring consistency throughout the Great Lakes System, in the absence of site-specific data from a mixing zone demonstration, EPA has determined that a maximum default mixing factor of 10:1 will be retained in the final Guidance.

b. Calculating Load Allocations

Under both proposed Options A and B, State law formed the basis for determining appropriate dilution assumptions to be used on a case-by-case basis when establishing load allocations for nonpoint sources for OWGLs, inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volumes. This is consistent with the general approach in the Guidance which generally allows States and Tribes flexibility to use their own procedures to address nonpoint source contributions to these water bodies.

EPA received general comments regarding the need to give States and Tribes flexibility to consider site-specific factors in addressing point and nonpoint source pollutants in developing TMDLs. The final Guidance retains the proposed language allowing States and Tribes the flexibility to consider appropriate mixing zone assumptions for nonpoint sources, consistent with applicable State and Tribal requirements.

c. Protection from Acute Effects

i. Proposal: Both options included provisions to assure attainment of acute criteria and values within the allowable acute mixing zones for discharges to the OWGLs and other waters described in paragraph B. Option A did not include a specific cap, but instead relied on site-specific analyses of limits necessary to assure attainment of acute criteria and values within the applicable acute mixing zone. Option B specified that effluent limitations for point sources may not exceed a final acute value (FAV). The preamble to the proposal noted that, in some circumstances, however, an effluent limit based on an acute mixing zone may need to be more stringent than the FAV to protect against acute effects within the mixing zone. The FAV is defined as twice the Criterion Maximum Concentration (CMC) (see section 132.2) of this final Guidance. Therefore, if the effluent is at twice the maximum concentration for protection against acute effects, acute toxicity may occur near the point of discharge depending on site-specific conditions.

ii. Comments: Most commenters opposed the use of acute mixing zones. Several advocated eliminating mixing factors altogether, at least in sensitive and/or impaired areas. Several commenters suggested that acute mixing zones for non-BCCs be developed on a case-by-case basis without an automatic FAV limit (Option A). Other commenters recommended the use of best professional judgment instead of a specified cap.

A number of commenters preferred the Option A acute mixing zone provisions to Option B because they suggested that the mixing zone limit in Option B is inconsistent with existing State policies. Other commenters argued that Option B sets an arbitrary constraint on mixing zones.

Several commenters preferred Option B because it is numeric and thus provides a well-defined benchmark for more consistent application in the Great Lakes System. Commenters argued that Option B should be mandatory, not discretionary. Several commenters were concerned that mixing zones under Option A could be substantially larger than under Option B and would not promote consistency in permit limits among States and Tribes. Many commenters were concerned that Option A provides too much discretion for establishing mixing zones and dilution flows, and that Option B, which delineates a calculation method, is needed to promote uniformity across the Great Lakes System.

Several commenters expressed confusion because the proposed Guidance specifically listed Criterion Maximum Concentration (CMC) values, thereby implying that such values should be used in establishing permit limits, while the TMDL implementation procedure allowed permit limits up to the FAV (twice the CMC value).

iii. Final Guidance: The final Guidance provides that WLAs based on acute aquatic life criteria or values for discharges to the OWGLs and other waters described in paragraph B must not exceed the Final Acute Value (FAV). As proposed in Option A, the final Guidance also requires that a WLA based on such criteria and values be reviewed to assure that it prevents acute effects at the boundary of any acute mixing zone allowed under State law.

In the final Guidance, EPA combines the two proposed approaches into a single provision. EPA acknowledges the concerns raised by commenters regarding acute mixing zones and has retained language from Option B specifying a cap based on the FAV for acute mixing zones in order to promote consistency in developing permit limits within the Great Lakes System, while also minimizing areas of acute toxicity. EPA agrees with commenters that a numeric benchmark should ensure consistency better than narrative considerations. In response to comments, the final Guidance also provides that if mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to assure that criteria and values will be met in the area where any applicable acute mixing zones overlap. In addition, EPA agrees with commenters that site-specific considerations might authorize a larger mixing zone than otherwise authorized by the FAV cap. Accordingly, the final Guidance allows the use of a mixing zone demonstration to exceed the FAV if the demonstration is conducted and approved pursuant to procedure 3.F of appendix F.

EPA recognizes that some commenters, including some States, support eliminating acute mixing zones but notes that States and Tribes retain the authority to adopt provisions more stringent than those in the final Guidance consistent with CWA section 510. Accordingly, States and Tribes may eliminate mixing zones altogether or in selected locations such as sensitive and/or impaired areas. EPA is retaining the FAV cap for acute effects because it more accurately reflects discharge specific scenarios such as cases where there is rapid mixing (e.g., where high rate diffusers are used).

6. TMDLs for Discharges to Tributaries

The principal differences between options A and B in the proposal related to TMDL development for tributaries. The initial focus of Option A was on attainment of water quality standards throughout a basin, followed up with site-specific cross checks at discharge points throughout the basin. The site-specific cross checks would assure that standards are being attained around individual discharge points. Option A did not specify the size of mixing zones. Rather, it left such considerations to existing State requirements. Option B focused initially on evaluating limits needed for individual point sources, with supplemental emphasis on basin-wide considerations as necessary. Option B also included more detailed procedures including specific mixing zone requirements.

As discussed earlier in this document, EPA has decided that one procedure will apply for development of TMDLs for tributaries to the Great Lakes in order to ensure that some level of consistency applies throughout the Great Lakes System. The procedure specified in the final Guidance includes elements of both proposed Options A and B but has eliminated some of the more burdensome and confusing aspects of the proposed Guidance. The final Guidance provides a greater degree of flexibility than afforded by either proposed procedure, by allowing States and Tribes to adopt different implementation approaches while at the same time ensuring consistency by requiring States and Tribes to implement specific components of the procedure. Nothing in this section should be construed as authorizing mixing zones for BCCs that are prohibited under procedure 3.C of appendix F. These procedures are to be used, however, to determine the magnitude of any mixing zone allowed under procedure 3.C of appendix F.

Specific components of the proposal, comments on those specific components, and modifications in the final Guidance are discussed below.

a. Steady State vs. Dynamic Modeling

i. Proposal: In the proposal, both options envisioned that, in most instances, a simple, steady-state mass balance approach would be used to develop TMDLs, WLAs in the absence of a TMDL or preliminary wasteload allocation for the purpose of determining the need for WQBELs reasonable potential under procedure 5 of appendix F. A mass balance approach is a method used to approximate the mass of pollutants within a water body. It is based on the physical law of conservation of mass which dictates that mass cannot be created or destroyed but only transformed. This approach assumes that the input of mass into a system (e.g., through point and nonpoint source loadings, atmospheric deposition, groundwater seepage) equals the loss of mass from a system plus any losses due to transformation of mass within the system.

The proposal provided that the results of dynamic modeling be used only where the results can be shown to be more restrictive than the results due to the steady-state assumptions of both options A and B. EPA requested comments on whether the States should be allowed to use dynamic modeling regardless of whether the results are more or less stringent than results from using a steady-state approach.

ii. Comments: In general, commenters supported the use of dynamic modeling without the limitation that the results must be more restrictive than the results using steady-state assumptions recommended in both options A and B. Commenters pointed out that existing EPA guidance promotes the use of dynamic modeling and that the final Guidance should not contradict existing guidance by imposing new restrictions on the use of dynamic modeling.

iii. Final Guidance: EPA agrees with commenters and the final Guidance allows the use of both steady-state and dynamic models to support establishment of TMDLs. The final Guidance therefore retains provisions for using a steady-state, mass balance approach, but also allows the use of dynamic modeling regardless of whether the results are more or less restrictive than would be generated under steady-state assumptions. For an in-depth discussion of available models, see EPA's Technical Support Document for Water Quality-based Toxics Control (TSD), EPA/505/2-90-001, 1991, available in the docket. EPA recommends that a model be selected based on its adequacy for the particular application. For example, adequacy of a model may depend on the type of pollutant (e.g., BOD/DO, toxics, etc.) or the type of waterbody (e.g., river or lake). Steady-state models compute average spatial profiles of constituents within a waterbody assuming that loadings, upstream water quality, stream flow rates, and meteorological conditions remain constant over time. Dynamic models predict both temporal and spatial variations in water quality due to varied loadings, flow conditions and meteorological conditions. Dynamic models are thus particularly useful for analyzing impacts that vary over time, such as loadings resulting from storm events and long term seasonal cycles. In determining whether to use a steady state or dynamic model, the cost of application, data requirements, the availability of historical data, and the availability of the particular model and model support need to be considered.

b. Stream Design Flows

i. Proposal: In the proposal, both options A and B specified the stream design flow under which criteria and values are to be implemented. Although most point sources discharge to continuously flowing streams, the amount of water available to dilute the discharge typically varies with the season and with periodic storms and drought conditions. Thus, in deriving TMDLs, wasteload allocations in the absence of TMDLs and wasteload allocations for the purpose of determining the need for WQBELs, it is necessary to establish the stream conditions under which applicable criteria and values will be implemented. The volume of water flowing through the tributary in a given time period at the design flow condition is the volume available to dilute all pollutants present or introduced into the water body and thus is a necessary factor in developing a TMDL, wasteload allocation in the absence of a TMDL, and a preliminary wasteload allocation for the purpose of determining the need for WQBELs using a steady-state model. The proposed Guidance specified different design flows for chronic aquatic life, acute aquatic life, wildlife, and human health criteria because of differences in how the criteria were developed. A detailed discussion of these flows and the basis for choosing these flows can be found in the preamble to the proposed guidance (58 FR 20933).

ii. Comments: Several commenters suggested that the restriction on stream low flow quantity for dischargers of non-BCCs is not scientifically defensible and recommended that EPA not specify design flows. Another commenter suggested that specifying design flows simply adds a further level of conservatism in TMDL development. They believe that this conservatism, coupled with the margin of safety (MOS) may result in overly stringent WLAs and LAs.

iii. Final Guidance: The final Guidance provides that the specified stream design flows be used as a default assumption in developing TMDLs, wasteload allocation in the absence of a TMDL and preliminary wasteload allocations for the purpose of determining reasonable potential, but allows the use of alternative stream design flow under certain conditions discussed below. The final Guidance adds new language clarifying that stream design flows are appropriate for TMDLs, wasteload allocations in the absence of a TMDL and wasteload allocations for the purposes of determining the need for WQBELs established using steady-state models but are not likely to be applicable for those calculated using dynamic modeling.

EPA retains language from Option A that the loading capacity is initially calculated at the furthest downstream location in the watershed drainage basin. The maximum allowable loading consistent with the attainment of the appropriate criteria or value is determined by multiplying the criterion or value by the flow at the farthest downstream location in the tributary basin at the appropriate design flow condition. States could calculate the loading capacity at interim points in the basin. However, States and Tribes must include the total load capacity for the entire basin when establishing the TMDL. Even though the flow at the farthest downstream point on an effluent-dominated stream may be largely effluent, the loading capacity for the water in the stream is still the product of the criterion and the total flow in the stream.

The final Guidance specifies the 7-day, 10-year low flow (7Q10) or the 4-day, 3-year biologically-based design flow (4B3) for chronic aquatic life criteria or values; the 1-day, 10-year low flow (1Q10) for acute aquatic life criteria or values; the 90-day, 10-year low flow (90Q10) for wildlife criteria or values; and the harmonic mean flow for human health criteria or values. The final Guidance also stipulates that the lowest load is then selected as the loading capacity.

Although EPA received numerous comments suggesting that flows other than those specified in the proposal be adopted, none of the commenters supplied any scientific data supporting their proposed alternative flows. Many commenters supported the proposed flows. In the interest of promoting greater consistency among States and Tribes in the Great Lakes System, EPA is retaining, with the exception of the design flow specified for wildlife (see discussion below), the proposed design flows in the final Guidance. These design flows are default values that must be used in developing TMDLs, WLAs calculated in the absence of TMDLs, and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of appendix F. EPA recognizes that in some instances, these flows may be overly conservative, or, in other situations, may not be protective enough. Thus, the final Guidance allows States and Tribes to use alternative stream design flows when data exist to demonstrate that such an alternative is appropriate for stream-specific and pollutant-specific conditions, such as using seasonal flows to obtain seasonal WLAs. Allowing alternative stream design flows is especially necessary when a dynamic model is used to calculate the TMDL. Dynamic models use the entire flow record, not just one design flow, in making TMDL calculations. States and Tribes may also adopt more stringent design flows than those specified here in accordance with section 510 of the CWA.

The criteria and values derived pursuant to the final Guidance are not designed to be never-exceeded values. Rather, EPA has determined based on scientific analyses that they may be exceeded at varying frequencies and durations without irreparable injury to human health, wildlife, or aquatic life. Current EPA guidance recommends stream design flows for chronic and acute aquatic life and human health (see p. 79 of the 1991 TSD). Until today, EPA has not implemented wildlife criteria, nor has it recommended a design flow for wildlife criteria.

iv. Wildlife

(A) Proposal: For TMDLs, WLAs calculated in the absence of TMDLs, and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of appendix, based upon wildlife criteria or values, the hydrological-based, 30-day, 5-year low flow (30Q5) flow was specified in the proposed guidance. EPA also specifically asked for comments on using the 90-day, 10-year (90Q10) low flow, and the harmonic mean flow for wildlife criteria or values in the preamble to the proposal.

Both the 30Q5 low flow and the 90Q10 low flow include a factor representing the rate-limiting step between the exposure to the pollutant and the effect on the organism (30 days and 90 days, respectively). For wildlife, the rate-limiting step is chemical bioaccumulation. The 30-day and 90-day period were proposed as representing reasonable time periods for chemical bioaccumulation. The 30Q5 low flow and the 90Q10 low flow also include a value representing the rate at which the affected organisms recover (a 5 year and 10 year return frequency, respectively).

(B) Comments: Several commenters claimed that the proposed 30Q5 low flow is not scientifically defensible for wildlife criteria and asserted that the low flow should be the harmonic mean flow. Commenters suggested that it was inappropriate to use a short term low flow such as the 30Q5 and that the harmonic mean stream flow is more consistent with the long-term nature of bioaccumulation processes. Another commenter recommended the use of the 7Q10 low flow for implementing wildlife criteria.

One commenter pointed out that both the 30Q5 low flow and 90Q10 low flow are consistent with life cycles of small water mammals (otter and mink). Several commenters support the use of a 90Q10 low flow for the implementation of the wildlife criteria because it allows a reasonable time period for chemical bioaccumulation (90 days) with a reasonable return frequency (10 years).

(C) Final Guidance: The final Guidance only establishes wildlife criteria for BCCs (see section VI of this document). Therefore, the stream design flow specified in the final Guidance for wildlife criteria would apply when a mixing zone for a BCC is authorized under procedure 3.C.6 of appendix F.

The final Guidance specifies that a 90-day, 10-year low flow be used for the implementation of wildlife criteria in tributaries. This is the lowest

90-day average flow that would occur, on average, one year in every ten years based on a statistical review of historic flow data. EPA recognizes, as some commenters suggested, that a 30-day averaging period may be viewed as conservative for some pollutants, given the long time it may take for bioaccumulation. EPA agrees with commenters that a 30-day period is too short to represent bioaccumulation and is instead specifying the use of a 90-day averaging period when no data exist to suggest an alternative.

EPA disagrees with the commenter's recommendation to use the 7Q10 low flow for wildlife. As discussed in the preamble to the proposal, for wildlife, unlike for aquatic life, the impacts of chemicals with a high propensity to bioaccumulate in aquatic organisms are of greatest concern because aquatic organisms comprise a major portion of the diet of many wildlife species. Because of the relatively slow rate of uptake by aquatic organisms of bioaccumulative chemicals, residues in the food chain have a delayed response to increases in ambient concentrations of chemicals during short-term periods, such as during low flow events. The Steering Committee thus judged a longer term averaging period to be more appropriate for wildlife than the 7-day averaging period used for aquatic life.

EPA recommends the 90-day averaging period for implementing wildlife criteria as a reasonable estimate that can be used to establish limits that are protective of wildlife. EPA suggests that the 90 day period is appropriate because concentrations of BCCs in the water column are not expected to fluctuate excessively; BCCs all have very high bioaccumulation factors (BAFs), and the toxicological data used to establish wildlife criteria are not based on acute effects. A 90-day averaging period also coincides with the length of seasons. Some studies have documented seasonal variability in fish tissue concentrations.

EPA agrees with the commenter's statement that the 10-year period represents a reasonable return frequency. EPA also agrees with commenters' suggestions that a five year return frequency is too short. EPA disagrees with commenters who recommended the harmonic mean be used. EPA believes that the harmonic mean is too long and may not be protective of shorter lived wildlife species. The harmonic mean may not be an appropriate proxy for wildlife because the lifespan of wildlife is highly variable and may be very short. The harmonic mean is used for the protection of humans with an average exposure of 70 years (e.g., an average lifespan), substantially longer than any of the wildlife species. In addition, wildlife criteria focus on reproductive endpoints, a subset of toxicological endpoints, to protect against population effects, while human health criteria cover a broad range of effects on individuals.

EPA believes specifying the 90Q10 low flow as a default and allowing the use of site-specific data balances the need for consistency while allowing the best scientific approach to be used. In response to comments that food chain effects attenuate the effects of fluctuations in ambient concentrations, the final Guidance will allow the use of an alternative stream design flow where data exist to demonstrate that such an alternative flow is appropriate for stream-specific and pollutant-specific conditions to be protective of wildlife. EPA recognizes that in some situations in the Great Lakes System, internal loadings of BCCs may dominate over external, or point source, loadings. These types of internal loadings (e.g., sediment resuspension) tend to be constant over long periods of time, and depending on local mass ratios, may buffer the fluctuations from point source loadings. However, because the design flow is an important parameter in establishing TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for the purposes of reasonable potential, it is important to specify a default value that is protective of wildlife in the absence of site-specific data. EPA recognizes the 90Q10 low flow may be conservative for certain pollutants for certain streams, and encourages dischargers to work with States and Tribes in generating site-specific data.

v. Chronic Aquatic Life

(A) Proposal: The proposal specified the 7-day, 10-year low flow (7Q10) or the 4-day, 3-year biologically-based design flow (4B3) for chronic aquatic life criteria or values.

(B) Comments: Several commenters supported the design flow for aquatic life criteria and noted that these stream design flows are consistent with EPA's 1991 TSD. One commenter agreed that for protection from chronic effects, the 7Q10 low flow is appropriate. Several commenters recommended that 30Q10 be used as an alternative. One commenter asserted that the 7-day, 10 year flow is overly conservative because the chronic water quality standards are based on toxicity tests of at least 24 days, and stated that the 30-day, 10- year low flow would be more appropriate.

(C) Final Guidance: Like the proposal, the final Guidance authorizes the use of either the 4B3 biologically-based design flow or the 7Q10 hydrologically-based design flow as the stream design flow for chronic aquatic life criteria. Unlike in the proposed guidance, however, the final Guidance also provides additional flexibility by allowing the use of an alternative stream design flow where data exist to demonstrate that the alternative is appropriate for stream-specific and pollutant-specific conditions. In the absence of such data, EPA continues to specify the 4B3 or the 7Q10 stream design flow to ensure protection of aquatic life from chronic effects.

The 4B3 is that flow, determined on a case-by-case basis, that would provide for an excursion of chronic aquatic life criteria, over a 4-day averaging period, only once every three years, on the average. This flow is selected because EPA has determined that criteria developed on that basis may be exceeded over a 4-day averaging period once every three years without injury to the aquatic ecosystem. (See 1991 TSD). A 4B3 flow can be calculated using the computer program DFLOW supported on EPA's computers at the National Computer Center in Research Triangle Park, NC. Further information may be obtained from Assessment and Watershed Protection Division, U.S. Environmental Protection Agency, 401 M St, S.W., Washington, D.C. 20460.

EPA also allows, as an alternative, the hydrological-based 7Q10 low flow. The 7Q10 is the lowest 7-day average flow expected to occur on the average one year in every ten, based on the period of record. Empirical data from approximately 60 streams show that the 7Q10 low flow provides a degree of protection approximately equivalent to the 4B3 flow. The U.S. Geological Survey routinely publishes statistics that commonly include estimates of the C for most riverain systems.

vi. Acute Aquatic Life

(A) Proposal: In the preamble to the proposal, EPA solicited comments on whether the final rule should specify a design flow for the purposes of implementing acute aquatic life criteria. The preamble discussed the recommended use of the 1Q10 low flow for acute aquatic life in existing EPA guidance (See the 1991 TSD, available in the docket).

(B) Comments: One commenter suggested that use of the 1Q10 low flow for acute aquatic life criteria is too conservative and that the final rule should specify use of the 7Q10 low flow.

(C) Final Guidance: In the final Guidance, EPA specifies the 1Q10 low flow for purposes of implementing acute aquatic life criteria. This design flow would be used in determining whether the FAV cap is sufficient to protect against acute aquatic life effects. The 1Q10 low flow is consistent with the recommended design flow specified in existing EPA guidance (e.g., TSD). EPA agrees that this design flow may be overly conservative in some instances but this flow should be used unless data exist to demonstrate that an alternative stream design flow is appropriate for stream-specific and pollutant-specific conditions. This is also consistent with the TSD, which recommends allowing for site-specific or chemical-specific conditions. States and Tribes may want to use the biologically based 1B3 as an alternative flow for acute aquatic life. The 1B3 is also discussed briefly in EPA's TSD. In addition, alternative averaging periods can be developed from data on the time course of mortality in acute toxicity tests.

vii. Human Health

(A) Proposal: In the proposal, EPA specified the use of the long-term harmonic mean flow to implement human health criteria.

(B) Comments: Several commenters supported the design flow for human health criteria and pointed out that it is consistent with existing EPA guidance. However, several commenters suggested that there was no scientific justification beyond the limited references in existing EPA guidance for using the harmonic mean instead of the arithmetic mean for human health criteria. One commenter suggested that the cost of statistically generating the harmonic mean statistic for the numerous surface water discharges in the basin could be prohibitive. The commenter also suggested that the harmonic mean flow estimate may be more error-prone than other flow estimates because statistics such as the harmonic mean flow are only useful where stream flow is highly variable. One commenter recommended the use of a mean annual flow as an alternative. Another commenter suggested that the 7Q10 low flow or 30Q10 low flow should be required rather the harmonic mean flow.

(C) Final Guidance: The final Guidance retains the use of the long-term harmonic mean flow to implement human health criteria as supported by current EPA guidance. EPA has determined that such a level will ensure that criteria will not be exceeded under stream conditions that represent long-term average conditions. The harmonic mean flow is the sum of the reciprocals of individual flow measurements divided into the total number of individual flow measurements.

The harmonic mean was chosen as a design flow for human health criteria because human health criteria are designed to protect an individual over a lifetime of exposure. Human health criteria based on cancer potencies and risk levels are based on models which extrapolate animal data to a human lifetime. Similarly, a human non-cancer criterion is based on an R_fD (or ADE, as it is referred to in the final Guidance which is an acceptable daily exposure over a lifetime. Therefore, EPA has attempted to match the longest stream flow averaging period (using harmonic mean) with the criterion which is protective over a human lifetime. EPA disagrees with the suggestion that an arithmetic mean rather than a geometric mean be used. For carcinogens, it is appropriate to determine the long-term mean exposure concentration. Because flow is not normally distributed, using the arithmetic mean flow for design purposes will underestimate the mean concentration. Using the downstream harmonic mean flow will more closely estimate the mean concentration.

In rare instances where a human health criterion or value is based on a short term toxicological effect (i.e., the critical effect upon which the criterion/value is based is significantly less than lifetime and may be an acute effect), the design flow should be adjusted accordingly. This does not pertain to ADEs (R_fDs) in which a short term study has been used as the ADE basis and an uncertainty factor has been used to account for less than lifetime study results. This pertains only to those situations where the critical effect is the short term effect and no additional uncertainty factor has been used to account for less than lifetime exposure. A good example of this is EPA's R_fD for nitrate. The critical effect, upon which the R_fD is based, is toxicity to children after a short term exposure. In this case, a harmonic mean would be an inappropriate design flow for such a short term effect. In this case, a 7Q10 or a 4Q3 design flow may be more appropriate.

EPA is setting the default design flow for human health as the harmonic mean. The harmonic mean can be calculated using the computer program DFLOW supported on EPA's computers at the National Computer Center in Research Triangle Park, NC. Further information may be obtained from Assessment and Watershed Protection Division, U.S. Environmental Protection Agency, 401 M St, S.W., Washington, D.C. 20460.

Because EPA recognizes that there may be situations, like those discussed above, where a different design flow is more appropriate, the final Guidance allows the use of an alternative design flow for human health criteria where data exists to demonstrate than an alternative stream design flow is appropriate for stream-specific and pollutant-specific conditions.

c. Mixing Zones for Non-BCCs

i. Proposal: In the proposed guidance, Option A did not provide specific requirements for mixing zones for either chronic or acute criteria. Rather, under Option A, site-specific cross-checks would be conducted at each source location to ensure that water quality standards including acute and chronic aquatic life, wildlife, and human health, are attained at the edges of applicable mixing zones, or if mixing zones are not allowed under State law, throughout the basin. Option A did not specify the size of mixing zones but suggested that mixing zone requirements, if any, adopted by the various States will be used for the cross-checks.

Option B specified for both new and existing sources that WLAs based on acute aquatic life criteria shall not exceed the Final Acute Value (FAV) in order to ensure protection of aquatic life from acute effects. The provision is identical to the provision for Open Waters of the Great Lakes System. For WLAs based on chronic aquatic life, wildlife and human health criteria, Option B specified different requirements for new and existing sources. For existing sources, Option B provided a formula to derive the dilution fraction based on the relationship of the effluent flow of the point source to the flow of the receiving waters and an assumption regarding how rapidly mixing occurs. The dilution fraction is the fraction of the 7Q10 that is available for dilution in the WLA calculation. Under the formula proposed in Option B, the dilution fraction varied from 10 to 25 percent. The proposed guidance allowed an opportunity to demonstrate that a larger mixing zone is acceptable subject to a mixing zone demonstration conducted in accordance with section E of proposed procedure 3B. This provision in the proposal specified that in no case could the dilution fraction exceed 75 percent. For new sources, option B specified that WLAs based upon chronic aquatic life, wildlife and human health criteria or values shall equal the criteria or values unless a mixing zone demonstration is provided, approved and implemented in accordance with proposed procedure 3B.E. The proposal also specified that in no case should the demonstration result in a mixing zone greater than the dilution fraction established for existing sources.

ii. Comments: Several commenters suggested that a dilution fraction of 25 percent is overly conservative based on the type and level of wildlife and human health exposure which are likely to occur and suggested the use of a larger fraction of the design flow for dilution.

Several commenters suggested that option A, by not establishing a dilution fraction and, in effect, allowing 100% of the design flow for dilution, does not provide sufficient margin of safety and is inconsistent with the Steering Committee's recommendation that only 10-25 percent of the design flow be allowed for dilution.

Several commenters suggested that Option B is inconsistent with the Steering Committee proposal, insofar as that proposal did not provide the increased mixing zone option to existing discharges of BCCs to tributaries. Only the default dilution was allowed (10-25 percent of design flow).

A number of commenters disagreed with the provision requiring differential treatment for new and existing dischargers of non-BCCs. Commenters suggested that new dischargers, like existing dischargers, should be able to adjust the mixing zone based on a mixing zone demonstration to a dilution fraction higher than the 10-25% default specified for existing dischargers in the proposal.

iii. Final Guidance: The final Guidance adopts the Option B provision that TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for purposes of reasonable potential shall not exceed the FAV, unless a mixing zone demonstration is conducted and approved pursuant to procedure 3.F of appendix F. This is intended to ensure protection of aquatic life from acute effects. The rationale described in the discussion of Acute Mixing Zones for OWGLS applies here.

In the final Guidance, for TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for purposes of determining the need for WQBELs based on chronic criteria to ensure protection of aquatic life, wildlife, and human health from chronic effects, the dilution fraction should be set at no greater than 25 percent of the appropriate stream design flow (e.g., for aquatic life, human health or wildlife criteria). Unlike the proposal, the dilution fraction is established at 25 percent of the stream design flow rather than calculated using a formula. The final Guidance does retain the proposed provision allowing the opportunity to demonstrate that a larger mixing zone is acceptable subject to a mixing zone demonstration conducted in accordance with procedure 3.F of appendix F. Unlike the proposal, the final guidance allows the dilution fraction to go up to 100% if a mixing zone demonstration is completed and approved pursuant to procedure 3.F in appendix F. Procedure 3.F of appendix F requires a site-specific analysis of local conditions around the vicinity of the discharge to ensure that unacceptable impacts do not occur. If the information and analysis justifies a dilution fraction greater than 75%, as a general rule it should not be prohibited.

EPA is retaining 25 percent as the maximum dilution fraction unless a mixing zone demonstration suggests that an alternative dilution fraction is appropriate (i.e., in the absence of site-specific data). The 25 percent dilution fraction is consistent with existing EPA guidance. As described in the preamble to the proposal, the concept of the fraction of the stream design flow is based upon recommendations found in the Water Quality Criteria - Report of the National Technical Advisory Committee to the Secretary of the Interior, April 1968 (Green Book) and upon guidance from EPA's 1983 Water Quality Standards Handbook, both of which are available in the docket. The Green Book recommended that in order to prevent the initial mixing of point source wastewater from erecting a barrier to aquatic organisms, only 25 percent of the cross-sectional area of the river should be used for mixing. The Standards Handbook suggests that the value of 25 percent of total river flow is a rational estimate of the amount of river flow in 25 percent of the cross-sectional area.

This proposal is consistent with several States' current mixing zone policies. For example, Michigan uses a straight 25 percent of the stream design flow for all categories of criteria or values with an opportunity demonstrate for a larger percentage. Ohio uses a graduated scale for the dilution fraction that ranges between 10 percent and 100 percent of stream design flow. The use of a constant dilution factor as a default should support a more consistent permitting approach throughout the Great Lakes System. Flexibility is retained, however, by allowing an alternative mixing zone to be used when site-specific information and analysis support it (i.e., through a mixing zone demonstration).

EPA agrees with commenters and has removed the distinction between new and existing discharges for purposes of calculating TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for purposes of determining the need for WQBELs using chronic aquatic life, wildlife, and human health criteria and values. Under the final Guidance, for protection of aquatic life, wildlife and human health from chronic effects, TMDLs, WLA calculated in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F, shall be calculated using a dilution fraction no greater than 25 percent of the stream design flow unless a mixing zone demonstration is conducted. In no case shall a State or Tribe grant a mixing zone which exceeds the area of discharge-induced mixing. This provision applies to both new and existing discharges of non-BCCs to tributaries. EPA suggests that while differential treatment for new and existing discharges is warranted for BCCs, because a primary goal of this initiative is to reduce loadings of BCCs to the Great Lakes, for non-BCCs, treatment of new and existing discharges will be the same.

7. Procedures for High Background Concentrations

a. Proposal: Under both Options, the proposal specified that when ambient water quality concentrations exceed narrative or numeric criteria or Tier II values, any discharge that has a reasonable potential to cause or contribute to an excursion above such a criterion or value should either be prohibited, i.e., WLAs set equal to zero, or a multiple source TMDL should be established that ensures the attainment of that criterion or value. Under both options, the procedures used in developing multiple source TMDLs for discharges were to be developed on a case-by-case basis, consistent with applicable State or Tribal regulatory requirements.

b. Comments: A number of commenters disagreed with the proposed approach to set WLAs equal to zero when background exceeds criteria because it would, in effect, force all point sources to achieve zero discharge. Commenters suggested that in addition to the use of multiple source TMDLs, EPA should make more use of readily available water quality variances, site-specific criteria, and intake credits in development of WLAs when background concentrations exceed criteria. Commenters suggested that the administrative burden of these existing mechanisms is a significant deterrent to using them. Commenters advocated a range of alternatives, from setting the WLA equal to the most stringent criterion up to setting the WLA equal to the background concentration of the receiving stream. Others suggested that WLAs be set at the greater of either the criteria or the background concentration.

Many commenters supported the use of multiple source TMDLs to prevent point sources from bearing a disproportionate share of the burden in achieving water quality goals when nonpoint source contributions dominate. Some commenters were concerned that developing multiple source TMDLs would be very resource intensive, and encouraged EPA to specify reasonable limits in the interim while TMDLs are developed.

c. Final Guidance: In response to numerous comments disagreeing with the proposal to set WLAs equal to zero when background exceeds criteria, EPA has removed this provision from the final Guidance. EPA first and foremost recommends developing TMDLs to address discharges to non-attained waters. However, EPA also recognizes the multitude of factors that need to be considered in the absence of a TMDL when background water quality concentrations exceed chronic narrative or numeric criteria, or Tier II values.

When uncertainty regarding loadings and load reductions are a consideration, a phased approach to TMDL development may be appropriate. For a more extensive discussion of multi-source, multi-media TMDLs, see the introduction to section VIII.C in this document. Permitting decisions for discharges to non-attained waters are addressed more fully in the provisions and accompanying supplementary information document discussion for eliminating mixing zones for BCCs (section VIII.C.4), considering intake water pollutants (section VIII.E), and in the supplementary information document discussion on the basis for developing WQBELs at section VIII.E.2.h.

8. Pollutant Degradation

a. Proposal: Both Options A and B allowed TMDLs to account for degradation of a pollutant provided two conditions were met. The first condition was that the regulatory authority must have information regarding the rate of degradation of the pollutant in the form of field studies or other relevant information. As discussed in the preamble to the proposal, field studies, if used, must document that degradation of the pollutant will occur under the full range of critical conditions expected to be encountered, and should quantify the degradation. Critical conditions should include the design conditions that are established for the implementation of criteria in ambient waters as well as other conditions such as periods of stratification of the water body and variability of the facility effluent flow rate. The preamble to the proposal also indicated that if field study information was not available, the regulatory authority could use other relevant information such as literature references from similar sites. Regardless of the type of information used, all information would have to be reviewed by the regulatory authority and found to be scientifically valid.

The second condition was that the studies take into account factors other than pollutant degradation that may affect the concentration of the pollutant in the water column including but not limited to resuspension of sediments, speciation and transformation.

b. Comments: Several commenters supported the procedures that provided for consideration of the environmental fate of a pollutant in the development of TMDLs. One commenter suggested that fate and transport should be considered in the development of TMDLs whenever suitable data such as existing literature or field data from similar sites are available. One commenter suggested that EPA should direct States to gather site-specific information in scientifically sound studies. Another commenter suggested that the regulatory agencies be responsible for collecting the necessary data.

Several commenters suggested that the final guidance specify that losses from the water column due to physical transfer to other media (i.e., through volatilization, bioaccumulation, sorption to sediments) are not acceptable fate processes for increasing TMDL allocations, since the pollutants may ultimately be re-released to the water column. Other commenters suggested that no transport processes should be precluded from consideration in the development of TMDLs and WLAs. One commenter suggested that pollutant degradation should not be accounted for unless rigorous studies concerning sediment re-suspension, speciation and transformation are also incorporated into the calculations.

One commenter suggested deleting the section on pollutant degradation from the final Guidance because it was not discussed in enough detail by the technical work group.

One commenter fully supported consideration of degradation and transport outside the mixing zone. The commenter recommended that existing EPA guidance such as Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals (May 1992) be used.

c. Final Guidance: The final Guidance retains the provision that TMDLs, wasteload allocations in the absence of a TMDL and wasteload allocations for purposes of determining the need for WQBELs should be based on the general assumption that a pollutant does not degrade. Like the proposal, however, it also allows degradation to be taken into account on the basis of information from scientifically valid field studies or other relevant information, including the results of properly calibrated water quality modeling.

Each of the Great Lakes States has already adopted a narrative criterion specifying that waters shall be free from pollutants that settle to form objectionable deposits. EPA's existing NPDES requirements (40 CFR 122.44(d)) require establishment of permit effluent limitations to meet these narrative and other criteria. Upon adoption by States and Tribes or promulgation by EPA, general condition 6 in the final Guidance requires that TMDLs prevent the accumulation of pollutants in sediments to levels causing impairment of designated or existing uses. Inclusion of this provision in the final Guidance reflects EPA's concern about sediment quality in the Great Lakes System and a recognition that it may often need to be considered.

EPA is currently developing new methods for preventing sediment contamination. The first step is to develop numeric sediment criteria guidance. Once a State adopts sediment criteria into its State water quality standards, regulatory authorities will need to factor such criteria into the TMDL and NPDES permitting process, in addition to applicable narrative criteria pertaining to the formation of objectionable deposits.

To the extent that volatilization does not represent a permanent loss from the Great Lakes System, current atmospheric loadings of volatile pollutants will be accounted for in determining background concentrations. In fact, atmospheric transport and degradation processes will influence the amount of volatiles available for re-entrainment in the water. Accordingly, volatilization losses can be considered when setting TMDLs, wasteload allocations in the absence of TMDLs and preliminary wasteload allocations for the purposes of determining the need for WQBELs. It would be extremely difficult to establish a significant loss of ambient pollutants as a result of bioaccumulation. The confounding factors, including the potential loss of pollutants from the water column by bioaccumulation into plants, invertebrates, fish tissue biodegradation via depuration are not expected to be quantifiable enough to meet the second condition of biodegradation.

9. <u>Mixing Zone Studies</u>

a. <u>Proposal</u>: Option B allowed any interested party to prepare a mixing zone demonstration and allowed the permitting authority to modify the dilution fraction described above in accordance with such studies. Proposed procedure 3B.E described several required elements of a mixing zone study, all designed to address the area of mixing that can be allowed consistent with attainment of water quality standards.

b. <u>Comments</u>: Commenters raised questions about specific components of the mixing zone demonstration requirements. Several commenters questioned the requirement for documentation of the substrate and geomorphology of the mixing zone. Other commenters suggested that the analysis of attraction of organisms to the mixing zone is difficult to assess or predict. Another commenter questioned the requirement to determine whether the habitat supports endemic species or naturally occurring species, and asserted that it is essentially a useless exercise. The commenter suggested that by definition, the surface water into which the discharge occurs will support whatever aquatic organisms inhabit the area, and whatever species is protected by the criteria may be present and may pass through the mixing zone.

c. <u>Final Guidance</u>: The final Guidance adopts the mixing zone demonstration language as the alternative to the mixing zones specified for both OWGLs and tributaries. The language has been modified to require consideration of potential impacts to threatened and endangered species consistent with the Endangered Species Act and otherwise to enhance clarity. The mixing zone demonstration provision provides flexibility to allow a greater dilution fraction than otherwise provided in sections D and E, as well as an exceedance to the FAV cap, to better reflect site-specific considerations.

EPA believes that characterizing the substrate and geomorphology of any potential mixing zone site is necessary to characterize potential impacts on water quality. Similarly, the effects of any potential mixing zone on endemic or naturally occurring species must also be considered. EPA recognizes that dischargers may be required to collect additional data and perform additional analyses in order to qualify for a mixing zone exception; however, EPA believes it is reasonable and appropriate to require this information if dischargers wish to use values greater than the default values specified.

10. Pollution Trading Opportunities

As described in the proposal, the TMDL process provides an opportunity for pollution trading in the water quality program as long as CWA goals and requirements are met. Effluent limits and nonpoint source controls, for example, must be designed, maintained and enforced so that water quality standards and other statutory and regulatory requirements are met. For purposes of the final Guidance, trading refers to approaches which introduce market incentives into water quality control decisions by acknowledging the ability of a point source to achieve water quality-based loading reductions through creative, enforceable market mechanisms.

The Guidance encourages States to look for pollution trading opportunities as TMDLs are established. However, trading opportunities may be limited by the general condition s and specific requirements (e.g., mixing zones for BCCs) that apply to all TMDL development.

D. Additivity

1. Background

EPA has traditionally developed numerical water quality criteria on a single pollutant basis. While some potential environmental hazards involve significant exposure to only a single compound, most instances of contamination involve mixtures of two or more pollutants. The individual pollutants in such mixtures can act or interact in various ways which may affect the magnitude and nature of potential risks or effects on human health, aquatic life and wildlife. The potential actions or interactions between multiple pollutants in a mixture can be divided into the following general categories.

1. The effects to an organism from exposure to a mixture of two or more pollutants may be greater than simply adding the predicted effect from exposure to each pollutant ("synergistic effect").

2. The effects to an organism from exposure to a mixture of two or more pollutants may be less than simply adding the predicted effect from exposure to each pollutant ("antagonistic effect").

3. Pollutants in mixtures may exert an "additive effect." Two types of additive effects are possible.

a. "Response addition" refers to situations where pollutants in a mixture each independently cause adverse effects to an organism without significant interaction. "Response addition" is generally considered to be a valid assumption in the absence of contrary data when the response rate from a pollutant is low (e.g., number of organisms showing an adverse effect from a pollutant is small). In these circumstances, the expected toxicity of the mixture can be estimated by adding the predicted response (risk) from each individual pollutant.

b. "Dose addition" refers to situations where multiple pollutants may effect an organism through a similar mechanism of action. The Toxicity Equivalence Factor approach in procedure 4.A of appendix F to part 132 is an example of dose addition. In these circumstances, the expected toxicity of the mixture can be estimated by converting the individual doses of the pollutants to an "equivalent" dose of a reference chemical (e.g., 2,3,7,8-TCDD) and adding these amounts. The "equivalent" dose is based on the relative toxicity of the individual pollutants to the reference chemical.

EPA's current regulations and the final Guidance generally account for the active and interactive effects of discharged pollutants on aquatic life through direct exposure of test organisms to a point source effluent in whole effluent toxicity (WET) tests (procedure 6 of appendix F to part 132; 40 CFR § 122.44(d)). The use of such tests to determine effects of multiple pollutants on aquatic life is a well established component of both Federal and State regulatory programs, and is discussed in subsection 5 below.

EPA currently has no specific National guidance regarding consideration of additive or interactive effects of pollutants on wildlife, and has not included such provisions in the final Guidance. This issue is discussed in subsection 8 below.

The remaining discussion in this section is devoted primarily to addressing the effects on human health resulting from exposure to pollutant mixtures. As discussed further below, the final Guidance includes provisions addressing the additive effects on human health, but does not include provisions addressing any possible synergistic or antagonistic effects.

In order to address the effects on human health resulting from exposure to pollutant mixtures, EPA published principles and procedures for conducting human health risk assessments for multiple pollutants in 1986 ("Guidelines for the Health Risk Assessment of Chemical Mixtures," 51 FR 34014), ("Guidelines for Chemical Mixtures"). The Guidelines for Chemical Mixtures recommend using "dose addition" to estimate the combined effects from threshold toxicants acting by similar mechanisms or affecting common organs (generally non-carcinogens) and "response addition" for non-threshold toxicants acting independently (generally carcinogens), in the absence of contrary information on the specific mixture. An assumption of dose or response addition could result in errors in risk estimates if synergistic or antagonistic interactions occur (i.e., additivity assumptions could result in overestimates or underestimates of the actual risks). Thus, an assumption of additivity is not a "worst-case" assumption, but a reasonable assumption when specific information on pollutant interaction is not available.

2. Additivity Considerations in Other EPA Programs

Several programs within EPA address the problems of exposure to multiple chemicals. For example, the Office of Solid Waste regulations for Hazardous Waste Burned in Boilers and Industrial Furnaces require permitting authorities to add the individual cancer risk for several carcinogenic metals (the "response addition" approach) when developing permit limits for those metals, and establish a maximum aggregate cancer risk level of no greater than 10^{-5} ((40 CFR 266.106(b)(2), (c)(2), and (d)(3); 56 FR 7134, 7165-66 (Feb. 21, 1991)).

The risks from exposures to multiple pollutants are also considered in the Superfund program. The Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual (Part A) (RAGs) requires that at most Superfund sites it is necessary to assess potential health effects of more than one chemical. This is necessary because considering only one chemical at a time might significantly underestimate the risks associated with simultaneous exposures to several substances. To assess the overall potential for cancer and non-cancer effects posed by multiple chemicals, the Superfund RAGs recommends using EPA's Guidelines on Chemical Mixtures referenced above. Specifically, for carcinogens, RAGs recommends that the individual cancer risk from each carcinogen in a mixture should generally be added to estimate the total cancer risk (the "response addition" approach). For non-carcinogens, RAGs recommends using the hazard index approach which is discussed below.

3. Existing State Water Quality Standards

Four Great Lakes States (Illinois, Minnesota, Wisconsin, and Pennsylvania) have adopted provisions in their water quality standards to address additive effects to human health from exposure to multiple carcinogens. Minnesota and Wisconsin water quality standards use a "response addition" approach by incorporating an assumption in criteria development that the risk from a combination of carcinogens in a mixture is equal to the sum of the risks associated with exposure to each individual pollutant in the mixture, unless an alternative model is supported by credible scientific evidence. Pennsylvania water quality standards provide that the State may consider synergistic, antagonistic and additive toxic impacts when developing their water quality standards. In addition, three of the Great Lake States also specifically address possible additive effects of pollutants by establishing acceptable maximum cancer risk levels for mixtures. Minnesota and Wisconsin have adopted an acceptable cancer risk level of 1 in 100,000 (10^{-5}) for exposures to either individual pollutants or to mixtures of pollutants. Illinois water quality standards do not specify a particular assumption for considering additive effects, but include a maximum acceptable cancer risk level of 1 in one million (10^{-6}) for individual pollutants and 10^{-5} for mixtures of substances.

4. Proposed Guidance Overview

The preamble for the proposed Guidance discussed several possible approaches to address additive effects from multiple pollutants. Proposed regulatory language was provided for two specific options, each with separate provisions related to aquatic life, wildlife and human health. One approach was developed by the Great Lakes Initiative Committees, modified to delete the application of toxicity equivalency factors (TEFs) for PCBs to wildlife. The other approach was developed by EPA. Neither approach addressed the possible toxicologic interactions between pollutants in a mixture (e.g., synergism or antagonism) because of the limited data available on these interactive effects. The quantitative significance of toxic interactions between chemicals in mixtures at environmental levels of exposure is often difficult to assess. For example, most of the data available on toxicant interactions are derived from acute toxicity studies using experimental animals. The use of acute toxicity data to assess the potential interactions in chronic simultaneous exposures is also difficult unless the same mechanisms of interaction are known to apply. Additionally, the limited data available on toxicant interactions from both chronic and acute studies indicate that the chronic interactions can be either greater or less than the observed acute interactions. (Technical Support Document on Risk Assessment of Chemical Mixtures, 1990. EPA/600/8-90/064). Due to these data limitations, neither specific approach presented in the preamble included procedures to estimate synergistic or antagonistic effects from mixtures of pollutants. Differences between the preamble approaches for addressing additive effects are discussed below.

5. Aquatic Life

Both approaches in the proposal accounted for the additive effects on aquatic life through use of whole-effluent toxicity (WET) limitations. Commenters on the proposal generally supported the use of WET to account for the effects of additivity on aquatic life.

EPA continues to believe that the WET provisions in procedure 6 of appendix F to part 132 are a reasonable mechanism to account for additive effects to aquatic life and, therefore, are retaining those provisions in appendix F to part 132. Because the provisions for WET have been adequately incorporated in procedure 6 of appendix F to part 132, however, EPA has removed the references to WET testing from the additivity provisions in procedure 4 of appendix F to part 132.

6. Human Health

The preamble to the proposed Guidance presented options for addressing the additive effects to human health from both carcinogens and noncarcinogens. The following sections discuss the proposed options for both carcinogens and noncarcinogens, the major comments received on these provisions, EPA's response, and the provisions for additivity in the final Guidance.

a. Carcinogens.

i. Proposal: The preamble to the proposal presented two specific approaches for implementing an additivity provision for carcinogens. One approach was developed by the Initiative Committees and specified a procedure for considering the additive effects of human health carcinogens during development of water quality based effluent limits (WQBELs). Under this approach, the permitting authority would identify those carcinogens that had been detected in the effluent; had a Tier I criterion or Tier II value; and for which a WQBEL was required. The permitting authority would then establish waste load allocations for those carcinogens at levels that would ensure that the total cancer risk for those carcinogens did not exceed 10^{-5} in the effluent.

The second approach was developed by EPA and addressed additive effects of chemical mixtures through interpretation of State and Tribal narrative water quality criteria. The narrative criteria of each of the Great Lakes States currently require that all waters be free from toxic substances (e.g. substances that injure or produce adverse responses in humans, wildlife, or aquatic life). This approach, similar to the approach of the Initiative Committees described above, specified a maximum total cancer risk of one in one hundred thousand (10^{-5}) and assumed that the incremental cancer risk of each carcinogen in the mixture was additive in the absence of a contrary determination by the State or Tribe. Discharges would be controlled to ensure attainment of a 10^{-5} total cancer risk in ambient waters.

ii. Discussion of Significant Comments on the Assumption of Additivity for Carcinogens.

Comment: Many commenters supported the assumption of additivity for carcinogens arguing that it was necessary to be consistent with existing EPA guidance that recommends an assumption of additivity unless there is specific information to the contrary. In addition, commenters stated that this approach would be consistent with provisions of the Great Lakes Water Quality Agreement (GLWQA) calling for the consideration of interactive effects of toxic substances, and that it would further the GLWQA's goal of "virtual elimination" of toxic pollutants.

Numerous other commenters disagreed with applying an assumption of additivity for carcinogens. Some argued that the procedure for deriving human health criteria for carcinogens already has multiple conservative assumptions and that the assumption of additivity is just one more conservative assumption that is not based on sound science.

Many commenters who disagreed with applying an assumption of additivity in the absence of specific data for a group of chemicals, cited the 1992 Science Advisory Board (SAB) report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," which recommended that multiple carcinogens be considered on a case-by-case basis instead of incorporating additivity as a default mechanism in all circumstances. The SAB report recommended a case-by-case consideration of possible additive effects because carcinogens are known to act by a wide variety of mechanisms and to target different organs. The SAB report also stated, however, that an assumption of additivity could be appropriate for compounds that act at the same receptor (such as dioxin, furans and PCBs).

Response: Although EPA believes an assumption that carcinogens exert additive effects in the absence of contrary data is generally reasonable and recommends it's use, for the reasons discussed below, the final Guidance does not require States or Tribes to adopt an assumption of additivity for carcinogens. This decision is consistent with the SAB comments discussed above, and with comments by the Great Lake States that flexibility was necessary in order to address any potential difficulties in implementation of an additivity provision for specific chemicals in their respective water quality programs.

EPA carefully considered comments that an assumption of additivity is overly conservative. As discussed in the preamble to the proposed Guidance, an additivity assumption could result in overestimates or underestimates of the actual risks from multiple pollutants if synergistic or antagonistic interactions occur. Thus, EPA maintains that if an assumption of additivity is used, that it would not be overly conservative or a "worst-case" assumption, but a reasonable assumption when specific information on pollutant interaction is not available.

EPA also recognizes, however, that there is some scientific debate on the assumption of additivity for carcinogens and agrees with comments in the SAB report that multiple carcinogens in a mixture should be considered on a case-by-case basis to determine whether there is adequate data to characterize the potential interactions in the mixture because carcinogens can act through a wide variety of mechanisms and target different organs. The final Guidance, consistent with these comments and with the 1986 Guidelines on Chemical Mixtures, does not preclude States or Tribes from using any such data, when available, to characterize the potential carcinogenic effects from the interaction of pollutants. In the majority of cases, however, these data will not be available. In these situations, EPA believes it would be appropriate for States and Tribes to assume that the total upper bound carcinogenic risk from a mixture is equal to the sum of the upper-bound incremental risk levels for the individual components of the mixture. EPA also believes this assumption is valid as long as the carcinogens are acting independently. EPA has determined that this assumption of independence of action for carcinogens is a valid assumption at the concentration levels of concern in the Great Lakes System. At these low concentrations, the competition for receptor sites will be reduced and the likelihood of significant interactions (e.g., synergistic or antagonistic effects) between pollutants will be minimal. In other words, if the probability of developing cancer from one pollutant is independent of the probability of developing cancer from another pollutant, then the probability of developing cancer from both substances may be obtained from summing the individual probabilities. Therefore, in the absence of data on the interactions among the carcinogens, EPA believes that it would be reasonable for States and Tribes to estimate the total upper-bound incremental cancer risks to human health by adding the separate upper-bound incremental cancer risks from each pollutant in the mixture. This assumption is consistent with the 1986 Guidelines for Chemical Mixtures.

This assumption of additivity for carcinogens at low concentrations has been adopted in regulations and reports developed by other federal agencies. For example, the Food and Drug Administration procedures governing carcinogenic impurities in color or food additives assumes in the absence of specific contrary information on the interactions among the carcinogenic impurities that the risks incurred from the presence of multiple carcinogenic impurities in a color or food additive are additive, and sum the estimated upper bound risks of these pollutants (53 FR 33118, August 30, 1988).

This assumption of additivity is also supported by information in the National Research Council Report, "Complex Mixtures: Methods for In Vivo Toxicity Testing" National Research Council, 1988. The Committee Report analyzed epidemiologic studies and current models to predict toxicity of mixtures containing multiple carcinogens, and concluded that effects of exposures to pollutants with low response rates usually appear to be additive (Executive Summary, at p.3). The report also summarizes data demonstrating additive effects from multiple carcinogens at low chemical concentrations. This data was based on several additivity models, including the two models most commonly used by EPA for low-dose extrapolation: (1) multistage and (2) the Moolgavkar models (Chapter 5, and appendix E, at p. 200). The final Guidance recommends use of the linearized multistage model to determine cancer potencies. The cancer potencies are used in the derivation of human health criteria (see section V.C.2 of this document for a complete discussion of the use of the linearized multistage model).

iii. Discussion of Significant Comments on Application of Additivity Provision for Carcinogens.

Comment: Several Great Lake States commented that both of the additivity approaches for human health presented in the preamble would be very difficult to implement, particularly if applied to the ambient waters, when developing discharge permits and assessing ambient water quality. They stated that it would be difficult to apply in the ambient environment because of the variability of concentrations of chemicals in the ambient environment due to changing environmental conditions, and the varied and sometimes uncontrolled sources of contaminants. Some recommended the continued application of numerical criteria on a single pollutant basis for discharge permit development and ambient water quality assessment. Other States commented that it would be more efficient to require the use of a more stringent risk level for individual carcinogens (e.g., 10^{-6}) to address additivity than to require the use of a specific implementation provision. Three Great Lake States currently use a risk level of 10^{-6} for individual carcinogens (Illinois, New York and Pennsylvania). Some Great Lake States supported an effluent oriented approach to account for additive effects of carcinogens. Other commenters urged that the additivity provisions need to be structured to specifically account for carcinogens in both permitted discharges and ambient water quality.

Regarding the appropriate risk level, several commenters stated that when more than one carcinogen was in an effluent or a surface water, human health criteria for those pollutants should be developed based on an assumption of dose addition with a total maximum risk of 10^{-6}. Others believed that to be consistent with goals associated with human health protection, that the total cancer risk from the mixture should be 10^{-5} (e.g., the maximum risk provided for risks from individual pollutants). Other commenters, while continuing to disagree with provisions for an assumption of additivity, argued that if an aggregate risk level ceiling is established, then that ceiling should be set at a risk level no greater than 10^{-4}.

Response: Based on careful consideration of the comments, EPA has determined that it is necessary and appropriate to provide adequate flexibility to States and Tribes to adopt and implement provisions addressing the additive effects of multiple carcinogens tailored to their individual water programs. Accordingly, the final Guidance does not specify a detailed methodology for implementing additivity similar to the methodologies for developing criteria to protect human health, aquatic life, and wildlife. EPA considered specifying in detail how States and Tribes would need to implement a general additivity provision, but decided for the reasons cited below that it was appropriate to provide sufficient flexibility at this time to ensure the provisions are fully implementable. EPA has concluded that this approach will result in State and Tribal water quality standards that will best ensure that human health is protected from potential adverse additive effects from chemical mixtures.

As discussed above, the Critical Programs Act requires that EPA specify numerical limits on pollutants in ambient Great Lakes waters to protect human health and provide guidance on minimum water quality standards and implementation procedures. EPA has interpreted this language as requiring a minimum level of protection for human health throughout the entire Great Lakes System. In light of the statutory requirements that the Great Lakes System be protective of human health, and the potential for adverse effects from exposure to multiple carcinogens in mixtures, EPA believes that measures must be taken to ensure that human health is protected from the additive effects of carcinogens. However, EPA recognizes, as many commenters noted, that there are a number of difficult issues involved in attempting to implement measures to ensure that human health is protected from the potential adverse additive effects of carcinogens; and that States and Tribes are in the best position to ensure, within their existing State programs, that human health is protected from the additive effects of carcinogens. EPA was concerned that provisions that are difficult to incorporate into existing water programs would discourage or significantly impede State or Tribal development of procedures to address the potential effects from multiple chemicals. On the other hand, EPA was concerned that if too much flexibility was allowed that the provisions would become meaningless and not fulfill the statutory goal of improving consistency within the Great Lakes System. The additivity provisions in procedure 4 of appendix F to part 132 described below have attempted to balance these two competing demands to ensure that minimum additivity provisions will be developed by the Great Lakes States and Tribes that are both implementable and will provide appropriate protection of human health.

iv. Final Guidance. Procedure 4 of appendix F specifies that the Great Lakes States and Tribes shall adopt provisions to protect human health from the potential adverse additive effects from the carcinogenic components of chemical mixtures in effluents. EPA limited the procedure 4 of appendix F to part 132 to effluents because of potential uncertainties or technical difficulties in attempting to quantify how chemical mixtures act in the environment. The techniques for modeling the fate of multiple pollutants in the ambient water are not as well developed as for individual pollutants. Because the science is still developing and because of concerns raised by the Great Lakes States responsible for implementing the final Guidance, EPA has decided to limit the requirement for additivity to effluents. This is consistent with the approach advocated by the Committees of the Initiative in the proposed Guidance. In addition, since this is the first time EPA has required Great Lakes States and Tribes to adopt an additivity provision for specific chemicals into their water quality standards, EPA believes it is reasonable to initially limit the provisions to effluents to reduce the potential implementation difficulties raised by commenters. EPA believes as States, Tribes, and EPA gain more experience in considering multiple pollutants in establishing permit limits, that the provisions could be extend to the ambient waters.

EPA believes States and Tribes have several options that will provide protection to human health from the potential adverse additive effects from carcinogens in effluents in the Great Lakes System. One option States and Tribe could consider would be to require that the total cancer risk in mixtures cannot exceed an incremental cancer risk of one in 10,000 (10^{-4}) to protect human health, EPA recommends an upper bound lifetime incremental cancer risk to an individual of more than 10^{-4} for several reasons. First, EPA believes that the establishment of this minimum level will improve consistency in permit limits within the Great Lakes System. Improvement in the consistency of water quality standards and permit limits in the Great Lakes System was a primary goal of the Great Lakes Critical Program Act (CPA) amendments to section 118 of the Clean Water Act (CWA).

Second, as noted in section V (Human Health) of this document, EPA believes that ensuring protection to human health in the risk range of 10^{-4} to 10^{-6} is acceptable and consistent with the CWA's objectives. Adoption of this provision would result in a maximum incremental cancer risk of 1×10^{-4} for mixtures of carcinogens to protect all populations Specification of 1×10^{-4} as the minimum acceptable level of protection for human health from exposure to multiple carcinogens is intended to ensure that all populations are sufficiently protected once the final Guidance provisions are fully implemented in the ambient water and in individual permits, not simply those individuals consuming 15 grams/day of fish and consuming 2 liters of water.

EPA has long maintained that 1×10^{-4} is within an acceptable range of risks. For example, the Superfund program uses 10^{-6} as its point of departure when developing its preliminary remediation goals for a site, but selects remedies that reduce the threat from carcinogenic contaminants at a site such that the excess risk from any medium to an individual exposed over a lifetime generally falls within a range from 10^{-4} to 10^{-6}. The U.S. Court of Appeals for the District of Columbia Circuit held that risk levels in a range between 10^{-4} and 10^{-6} that are used as part of the National Contingency Plan (Superfund) are adequately protective of human health (State of Ohio v. EPA, 997 F.2d 1520 (D.C Cir. 1993)). In addition to the Superfund program, the Office of Drinking Water uses.a risk range of 10^{-4} to 10^{-6} in setting the maximum contaminant level goals (MCLGs) for contaminants in drinking water (56 FR 3531, Jan. 30, 1991).

As an alternative to the above approach, States and Tribes could provide considerations for the additive effects of multiple carcinogens by lowering the human health criteria for individual carcinogens to levels corresponding to an upper-bound incremental cancer risk of one in one million

(1×10^{-6}) using the methodologies adopted pursuant to 132.4. There are currently three Great Lakes States that use 1×10^{-6} in determining criteria for individual carcinogens (New York, Illinois, and Pennsylvania). This approach is simple to implement, and based on an analysis completed for the regulatory impact analysis (RIA), should generally provide protection to human health, including the health of any highly exposed populations, equal to or greater than the level of protection provided by the 1×10^{-4} cancer risk level.

Evidence exists that some individuals in the Great Lakes area (less than 1% of the population) may be consuming up to 150 grams per day of fish, or ten times more than the 15 grams per day of fish that would be used in deriving individual pollutant criteria at a 1×10^{-6} risk level. Assuming that all of the 150 grams of fish consumed contain the maximum residues of pollutants permissible after implementing individual pollutant criteria established at a 10^{-6} risk level for a 15 gram per day consumer ("10^{-6} criteria" for purposes of this discussion), the risk posed to the 150-gram per day consumer as the result of exposure to one chemical would be 1×10^{-5}. If there were two carcinogens in the water at such levels, the total risk to the 150-gram per day consumer would be 2×10^{-5}, assuming the additivity of carcinogenic risk. There would have to be a carcinogenic risk in ambient waters greater than that which exists when ten carcinogens are present at 10^{-6} criteria levels for the additive carcinogenic risk to the 150-gram per day consumer to be greater than 10^{-4}. As discussed, EPA has determined that a carcinogenic risk of 10^{-4} is within a range of risk levels that is protective of human health.

EPA believes based on information in the RIA that it will be unlikely that mixtures of carcinogens in the Great Lakes System will, after full implementation of individual pollutant criteria in the ambient water and individual permits, contain a carcinogenic risk equivalent to that which exists when ten carcinogens are present at 1×10^{-6} criteria levels. It is even more unlikely that those relatively few individuals who consume up to 150 grams per day of fish will catch fish exposed to the few waters containing such high risks. Accordingly, it will be extremely unlikely that after implementing individual pollutant criteria State or Tribal selection of this approach will lead to risks to highly exposed subpopulations that exceed a cumulative cancer risk from exposure to water-borne pollutants of 1×10^{-4}. Additionally, in the event that it is demonstrated that this approach is insufficient to protect human health, including the health of any highly exposed subpopulations, then procedure 1 of appendix F to part 132 provides that States or Tribes must modify the human health criteria to provide additional protection appropriate for these subpopulations. Finally, States and Tribes can adopt any other scientifically defensible approach that will protect humans from the potential adverse additive effects from carcinogens. EPA will need to review any such provisions, on a case-by-case basis when evaluating whether State and Tribes submissions are consistent with procedure 4 of appendix F to part 132.

b. <u>Non-carcinogens.</u>

i. <u>Proposal:</u> As discussed in the preamble for the proposed Guidance and in the 1986 Guidelines for Chemical Mixtures, the use of the additivity assumption for non-carcinogens is most appropriate when the pollutants in a mixture elicit the same type of effect by the same mechanism of action. However, because information on the mechanism of action is normally limited, the 1986 Guidelines for Chemical Mixtures recommended that when two or more compounds produce adverse effects on the same target organ that the effects should be considered additive.

To estimate the potential non-carcinogenic risk from a mixture, the 1986 Guidelines for Chemical Mixtures recommended the use of the Hazard Index (HI) approach. The HI provides a rough measure of likely toxicity. It does not define dose-response relationships, and its numerical value should not be construed to be a direct estimate of risk. The equation used to estimate the HI sums the ratios of the actual exposures to the chemicals to the RfD (see 58 FR 20941). The proposed Guidance requested comments on the use of the hazard index approach.

An alternative approach to the HI discussed in the proposed Guidance and in the Technical Support Document on Risk Assessment for Chemical Mixtures is the use of toxicity equivalency factors (TEFs) approach. This approach involves estimating the potency of less well-studied components in a mixture relative to the potency of better studied components, using data from comparable types of in vitro and short-term in vivo assays. This approach has been used to estimate the toxicity of mixtures of chlorinated dioxins and dibenzofurans by using extensive data on the in vitro activity of these compounds. To date, 17 TEFs for the Chlorinated Dibenzo-p-dioxins (CDDs) and Chlorinated Dibenzofurans (CDFs) have been developed. The data supporting these TEFs are summarized in a monograph of EPA's Risk Assessment Forum entitled "Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans and 1989 Update"(USEPA, 1989), which is available in the public docket for this rulemaking. These interim procedures were reviewed by EPA's Science Advisory Board in 1986 and adopted as interim Agency policy in 1987. These procedures were also adopted for international use by the North Atlantic Treaty Organization.

The two additivity approaches for non-carcinogens presented in the preamble to the proposal differed in the application of these procedures. One approach would require, if adopted, that non-cancer effects be considered additive for those pollutants for which available scientific information supports a reasonable assumption that pollutants produce the same adverse effects through the same mode of action, and for which TEFs could be calculated. Thus, this approach if subsequently promulgated would establish a general requirement for States and Tribes to develop additivity protocols for classes of pollutants when sufficiently supported by scientific information. The second approach, if promulgated, would require the application of this additivity assumption only for those pollutants for which TEFs are set forth as part of the final Guidance. This would initially include CDDs and CDFs, but more pollutants could be addressed through any future revisions to the final Guidance or State and Tribal provisions.

ii. Discussion of Significant Comments.

Comment: Several commenters supported the EPA's proposed approach to limit the assumption of additivity for non-carcinogenic effects to those situations when data are available to demonstrate that the chemicals produce the same adverse effects through the same mechanism of action. Other commenters stated that the Hazard Index approach has little scientific support because pollutants with concentrations below the RfD are considered to have zero risk and summing the ratios from the risk for these pollutants below the RfD should also be zero. Other commenters objected to the use of the HI approach because it fails to incorporate the shape of the dose-response curves for the chemicals. Other commenters supported the use of the HI approach to address additivity for non-carcinogens. Specific comments on the use of TEFs are addressed in section VIII.D.4 below.

Several commenters stated that while neither of the proposed approaches was entirely adequate, the first approach (58 FR 20943) was preferable because it would require regulators to quickly develop new additivity procedures as new scientific information emerges, without waiting for formal revision of the Great Lakes Guidance or State or Federal laws.

Response: Consistent with the discussion above for carcinogens, the final Guidance does not specify an approach for considering the potential adverse additive effects from noncarcinogenic components of mixtures. However, EPA agrees with commenters that the non-carcinogenic effects of individual pollutants should be considered additive only for pollutants for which available scientific information supports a reasonable assumption that the pollutants produce the same adverse effects through the same mechanisms of action. This approach is consistent with the 1986 Guidelines on Mixtures and the proposed Guidance.

EPA carefully considered but does not agree with the comments that the HI approach has little scientific support. The RfD used in the HI equation is an estimate (with uncertainty spanning an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. Because the RfD estimate may span an order of magnitude, the potential risk below the RfD may not be zero as implied by the commenter. EPA does acknowledge, however, that there are several shortcomings with the HI approach as discussed in the Technical Support Document on Risk Assessment for Chemical Mixtures including the problems identified by commenters on defining a dose-response relationship. Because of these shortcomings, EPA does not believe it is appropriate to require States or Tribes to use the HI approach when assessing the effects from multiple non-carcinogenic pollutants.

EPA agrees with commenters who supported the proposed provision that States and Tribes should develop TEFs when sufficiently supported by scientific information. EPA encourages States to adopt this approach to ensure that the most recent scientific information will be used for revising the additivity provisions when it becomes available. The States and Tribes will not have to wait for EPA to develop TEFs for different classes of pollutants or to revise the final Guidance. EPA anticipates that the Clearinghouse discussed in section II of this document will provide a mechanism for sharing information among States and Tribes and in developing TEFs for classes of compounds other than the CDDs and CDFs.

iii. Final Guidance: Procedure 4 of appendix F to part 132 specifies that Great Lakes States and Tribes shall adopt provisions to protect human health from the potential adverse additive effects from the noncarcinogenic components of chemical mixtures in effluents. As with carcinogens, the final Guidance does not specify how States and Tribes must account for the potential adverse additive effects from noncarcinogens. However, as discussed above, EPA believes a reasonable approach for States and Tribes would be to include in their water quality standards that the noncarcinogenic effects of individual pollutants be considered additive for pollutants for which available scientific information supports a reasonable assumption that the pollutants produce the same adverse effects through the same mechanisms of action. EPA continues to support the HI approach as a valid and scientifically credible approach, but EPA considers the use of TEFs as more appropriate in most circumstances because it allows the use of all data to assess the potential risks from non-carcinogens.

7. Toxicity Equivalency Factors/Bioaccumulation Equivalency Factors

a. Proposal: Both approaches in the proposal presented the TEFs for the 17 CDDs/CDFs included in the Risk Assessment Forum report cited above. Both approaches, if adopted, would require that the concentration of each of the 17 CDDs/CDFs in an effluent be converted to a 2,3,7,8-TCDD equivalent concentration by multiplying the concentrations of the CDD or CDF by the appropriate TEF. All resultant concentrations would then be added to produce an equivalent 2,3,7,8-TCDD concentration. Both approaches would require the TEFs to be used to address both cancer and non-carcinogenic effects. The preamble for the proposed Guidance also requested comment on whether TEFs for "dioxin-like" PCBs should be included in the use of any additivity provisions developed to address wildlife effects.

The TEFs for the 17 CDDs/CDFs address the toxicity of various chemicals as compared to 2,3,7,8-TCDD, but do not address differences in bioaccumulation potential between the chemicals. The first approach presented by EPA in the preamble for the proposed Guidance recognized these differences in the bioaccumulation potentials of CDD/CDF by including specific bioaccumulation equivalency factors (BEFs) for the 17 CDD/CDF congeners. These 17 BEFs for CDD/CDF congeners were updated and the new values were provided in an August 30, 1994 notice of data availability for public comment (59 FR 44687). The Committee's approach discussed in the proposal did not include use of BEFs. That approach assumed that BAFs for all CDDs/CDFs were identical to that calculated for 2,3,7,8-TCDD.

b. Discussion of Significant Comments.

Comment: Several commenters supported the use of the 17 TEFs for CDDs/CDFs for human health and wildlife. Others supported the use of TEFs for human health but not for wildlife, stating that it is unclear to what extent TEFs developed for mammalian systems are applicable to avian or other wildlife species. Other commenters advocated also including TEFs for "dioxin-like" PCBs for wildlife due to their adverse impact upon wildlife in the Great Lakes ecosystem, while others stated that there is currently an insufficient scientific basis for the use of TEFs for "dioxin-like" PCBs. Many commenters questioned the use of TEFs in general and argued that the scientific understanding is not sufficiently developed. Other commenters argued that it is not appropriate to assume the effects from the different congeners are additive because it has not been demonstrated that the different congeners affect the same receptor organ and cause toxicity through the same mechanism. Finally, several commenters stated that the TEFs may be appropriate for non-cancer effects, but not for cancer effects because the TEFs were developed from toxicity data, not cancer data.

Several commenters supported the use of proposed BEFs. Other commenters generally opposed any additivity requirements, including the proposed TEFs, but stated if TEFs were adopted, they would support the use of BEFs to account for the congener-specific BAFs of CDD/CDF congeners. Other commenters stated that BEFs should not be used because the data base for development of the BEFs is not sufficiently developed and the BEFs have not been peer-reviewed or widely accepted.

c. Response for Application of TEFs/BEFs to Human Health: EPA carefully considered but does not agree with comments that there is insufficient data to support the TEFs for dioxins and furans for humans. The TEFs for the 17 CDDs/CDFs were developed over several years in collaboration with experts from throughout the world. Adoption of the TEF approach for the 17 CDDs/CDFs for human health risk assessment has also been recommended by the Risk Assessment Forum as discussed above. EPA is aware that the data available from long-term in vivo studies are limited for the majority of CDDs and CDFs. However, a much larger body of data is available on short-term in vivo studies and a variety of in vitro studies. These experiments cover a wide variety of end points; e.g., developmental toxicity, cell transformation, and enzyme induction (aryl hydrocarbon hydroxylase [AHH]). While the doses necessary to elicit the toxic response differ in each case, the data demonstrate that the relative potency of the different compounds compared to 2,3,7,8-TCDD is generally consistent from one end point to another.

This information, developed by researchers in several laboratories around the world, reveals a strong structure-activity relationship between the chemical structure of a particular CDD or CDF congener and its ability to elicit a biological or toxic response in various in vivo and in vitro test systems. (Bandiera et al., 1984; Olson et al., 1989; U.S. EPA 1989; NATO/CCMS 1988a,b). Research has also demonstrated a mechanistic basis for these observations. That is, a necessary (but not sufficient) condition for expression of much of the toxicity of a given CDD or CDF congener appears to be a function of the relative ability of these compounds to bind to a specific cellular receptor located in the cytoplasm of the cell that mediates most, if not all, of the toxic end points for these compounds. This receptor complex then migrates to the nucleus of the cell, where it initiates reactions leading to expression of toxicity (Poland and Knutson, 1982; Safe, 1986; Nebert et al. 1991; Birnbaum, 1994). Further discussion of the demonstrated use of TEFs for these congeners is provided in the preamble for the proposed Guidance (58 FR 20942).

EPA also carefully considered but does not agree with comments that it is inappropriate to assume that the effects from the different identified congeners are additive. As with most chemicals, there is limited data on the effects of interactions of these congeners. However, there is ample evidence indicating that there is a common mechanism of action for the expression of toxicity for the 17 dioxin congeners for which TEFs have been developed. As discussed above and in the 1986 Chemical Mixture Guidelines, in situations where there is a lack of data on the effects of interactions but it can be shown that the chemicals act through the same mechanism of action, then the use of dose addition is a reasonable and scientifically supported mechanism to address potential adverse impacts from multiple pollutants. EPA also maintains that it is appropriate to use TEFs for estimating the dioxin equivalent concentrations for both cancer and non-cancer effects. The mechanistic basis for the development of either cancer or non-cancer effects from 2,3,7,8-TCDD and its associated congeners appears to be the same (Ah receptor mediated). As discussed above, there are a common series of biological steps necessary for most, if not all, of the observed effects of dioxin and related compounds.

Finally, EPA has determined that future State or Tribal program submissions or EPA promulgations implementing the final Guidance should also include the use of BEFs for the 17 CDD/CDF congeners in the final Guidance when a TEF for that congener is used. This decision is supported by scientific studies demonstrating that CDDs/CDFs, other than 2,3,7,8-TCDD, have different and generally smaller bioaccumulation factors. EPA believes it is appropriate to use factors accounting for the different BAFs in converting concentrations of CDDs and CDFs to equivalent concentrations of 2,3,7,8-TCDD. Great Lakes States and Tribes are not precluded, however, from utilizing the more conservative BAF for 2,3,7,8-TCDD for these related congeners as a simplifying approach, as described in the preamble to the proposed Guidance (58 FR 20942). EPA acknowledges that the data base for developing BEFs is limited to data from Lake Ontario, but believes the data is sufficient to develop BEFs for the Great Lakes System. The BEF approach has been peer-reviewed as part of the process of review on the "Interim Report on Data and Methods for Assessment of 2,3,7,8-Tetrachlorodibenzo-p-dioxin Risk to Aquatic Life and Associated Wildlife" (March 1993, EPA/600/R-93/055). The technical rationale for each of the BEFs included in the final Guidance is provided in the "Technical Support Document for the Procedure to Determine Bioaccumulation Factors," which is available in the public docket for this rulemaking.

d. Response to Application of TEFs to Wildlife: EPA agrees that the data supporting TEFs for the 17 dioxins/furans and for the PCBs is not sufficiently developed at this time to require States and Tribes to adopt provisions mandating their use for development of wildlife criteria. This judgement is supported by a report on the March 19-20, 1992, Dioxin Ecotox Subcommittee of the Ecological Processes and Effects Committee of the Science Advisory Board which met to review EPA's research proposals to support the development of an ambient aquatic life water quality criterion for 2,3,7,8-TCDD (USEPA, August 1992 at p.11, EPA-SAB-EPEC-92-024). At that meeting, the Subcommittee addressed the general issue of research needed to support the use of TEFs for aquatic life and wildlife. In their final report, the Committee stated that the TEF approach appears promising for aquatic life and wildlife but more studies are needed to show phylogenetic variability. The Committee concluded that at the present time there are insufficient data available to judge the reliability and the accuracy of the TEF approach for protection of aquatic life and wildlife.

Additionally, it is difficult to evaluate whether the TEFs developed for protection of human health are also appropriate without modification for the protection of wildlife. Although the mechanism of action of CDDs and CDFs for wildlife may be similar to the mechanism for humans, the endpoints of concern for wildlife may be different than those for human health. Because of this uncertainty and the concerns raised by the SAB, EPA believes it is not appropriate at this time to require the use of TEFs for wildlife until further research can be conducted on these issues.

Research is currently underway to develop and evaluate TEFs for "dioxin-like" PCBs, (Safe, 1990; Walker and Peterson, 1991; Devito et al., 1993; Ahlborg et al. 1994). A set of established TEFs for these PCBs similar to the 17 TEFs for CDDs and CDFs, however, has not been adopted by EPA. (See, "Estimating Exposure to Dioxin-Like Compounds" (External Review Draft, June 1994, EPA/600/6-88/005Ca). EPA is continuing research in this area and expects to develop a set of TEFs for "dioxin-like" PCBs in the near future that could be used for risk assessment purposes. Until the science is more fully developed in this area, EPA has determined that it is appropriate to include TEFs in the final Guidance for only the 17 established CDDs/CDFs for protection of human health. This does not preclude States or Tribes, however, from developing TEFs for protection of wildlife for CDDs/CDFs or for the dioxin-like PCBs based on any available supporting scientific data.

e. Final Guidance: For the reasons stated above, EPA has decided to limit the use of TEFs to the protection of human health and to only the 17 CDDs/CDFs included in the proposed Guidance. In addition, the final Guidance allows the use of the BEFs for the 17 CDDs/CDFs with TEFs. The TEFs in Table 1 and BEFs in Table 2 must be used when calculating a 2,3,7,8-TCDD toxicity equivalence concentration in effluent to be used when implementing both human health noncancer and cancer criteria. The chemical concentration of each CDDs and CDFs in the effluent shall be converted to a 2,3,7,8-TCDD toxicity equivalence concentration in effluent by (a) multiplying the chemical concentration of each CDDs and CDFs in the effluent by the appropriate TEF in Table 1 below, (b) multiplying each product from step (a) by the BEF for each CDDs and CDFs in Table 2 below, and (c) adding all final products from step (b). The equation for calculating the 2,3,7,8-TCDD toxicity equivalence concentration in effluent is:

$$(TEC)_{tcdd}=\Sigma(C)_x(TEF)_x(BEF)_x$$

where:

$(TEC)_{tcdd}$ = 2,3,7,8-TCDD toxicity equivalence concentration in effluent

$(C)_x$ = concentration of total chemical x in effluent

$(TEF)_x$ = TCDD toxicity equivalency factor for x

$(BEF)_x$ = TCDD bioaccumulation equivalency factor for x

An equation specifying how to estimate the 2,3,7,8-TCDD toxicity equivalence concentration in effluent was added to procedure 4 of appendix F to part 132 to assist permitting authorities. The 2,3,7,8-TCDD toxicity equivalence concentration in effluent must be used when developing waste load allocations under procedure 3 of appendix F to part 132, preliminary waste load allocations for purposes of determining reasonable potential under procedure 5 of appendix F to part 132, and for purposes of establishing effluent quality limits under procedure 5 of appendix F to part 132.

8. Wildlife

a. Proposal: Both approaches in the proposed Guidance presented additivity provisions for wildlife which were very similar to those proposed for non-cancer human health effects. No additivity provisions were presented for cancer effects because cancer is not a recognized endpoint of concern for wildlife.

b. Comments: As discussed above, several commenters supported the application of the additivity provisions to wildlife, while others opposed the application.

c. Final Guidance: As discussed above, the final Guidance does not include provisions addressing any possible additive effects of pollutant mixtures on wildlife. However, as discussed in section II.G (Implementation of the Endangered Species Act) of this document, EPA, in cooperation with the Fish and Wildlife Service (FWS) will host a workshop on the subject of TEFs for those PCDDs, PCDFs, and PCBs that have been identified as exhibiting toxicity similar to 2,3,7,8-TCDD to wildlife. The workshop will examine existing toxicity data, as it relates to TEFs and research and data needs, and the use of TEFs when establishing total maximum daily loads (TMDLs) or WQBELs. The findings of these workshops will be used to evaluate the feasibility of utilizing TEFs in the development of wildlife criteria. Any methodologies developed by EPA as a result of these efforts will be submitted to the EPA SAB for review and distributed for public comments.

Table 1
Toxic Equivalency Factor Values for CDDs and CDFs

Congener	TEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.5
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.001
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.05
2,3,4,7,8-PeCDF	0.5
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.001

Table 2
Bioaccumulation Equivalency Factors for CDDs and CDFs

Congener	BEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.9
1,2,3,4,7,8-HxCDD	0.3
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.05
OCDD	0.01
2,3,7,8-TCDF	0.8
1,2,3,7,8-PeCDF	0.2
2,3,4,7,8-PeCDF	1.6
1,2,3,4,7,8-HxCDF	0.08
1,2,3,6,7,8-HxCDF	0.2
2,3,4,6,7,8-HxCDF	0.7
1,2,3,7,8,9-HxCDF	0.6
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.4
OCDF	0.02

9. References

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E. Reasonable Potential for Exceeding Numeric Water Quality Standards

The purpose of this section is to define the procedures for determining whether an NPDES permit for discharges to the Great Lakes System must include a water quality-based effluent limitation for a particular pollutant parameter (not including whole effluent toxicity). Considerations related to whole effluent toxicity and the basis for such considerations are addressed separately in section G of this document. This final Guidance requires permitting authorities to follow specific procedures where facility-specific effluent monitoring data are available. Where these data are not available, including when all available effluent data for a pollutant or pollutant parameter are below the applicable analytical detection level, this Guidance does not establish any new or specific requirements, and permitting authorities will continue to follow existing Federal, State or Tribal regulations and guidance. Existing guidance for determination of reasonable potential in the absence of facility-specific effluent monitoring data are discussed in section VIII.E.1 of this document, below.

1. Existing National Rules and Guidance

EPA's existing regulations require NPDES permits to contain effluent limitations necessary to meet applicable technology-based requirements of Federal and State law. These technology-based limitations are derived directly from application of National effluent limitation guidelines or on the basis of the permitting authority's best professional judgment (40 CFR 125.3). States are currently required to adopt regulations consistent with these provisions as part of their approved NPDES State permitting program (40 CFR 123.25(a)(36)). EPA is not, in this final Guidance, addressing the requirements governing the establishment of technology-based limitations.

In addition to these technology-based requirements, EPA's existing regulations require NPDES permits to include water quality-based effluent limitations (WQBELs) to control all pollutants or pollutant parameters which the permitting authority determines are or may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any water quality standard, including numeric and narrative criteria for water quality (40 CFR 122.44(d)(1)). When determining whether a discharge causes, has the reasonable potential to cause, or contributes to an excursion above any State or Tribal water quality standard, the permitting authority must use all relevant available data, including facility-specific effluent monitoring data where available. Additionally, the permitting authority must use procedures which account for existing controls on point and nonpoint sources of pollution; variability of the pollutant or pollutant parameter in the effluent; and, where appropriate, the dilution of the effluent in the receiving water (40 CFR 122.44(d)(1)(ii)). If the permitting authority determines that a discharge has the reasonable potential to cause or contribute to an excursion of an applicable numeric or narrative water quality criterion, it must include a WQBEL for the individual pollutant in the permit (40 CFR 122.44(d)(1)(iii)). In the absence of a numeric water quality criterion for an individual pollutant under these circumstances, the permitting authority must derive appropriate WQBELs from the State or Tribal narrative water quality criterion by: using a calculated numeric criterion for the pollutant that attains the applicable narrative criterion and protects designated uses; establishing effluent limitations on a case-by-case basis using EPA's water quality criteria developed under section 304(a) of the Clean Water Act, supplemented with other information where necessary; or establishing effluent limitations on an indicator pollutant (40 CFR 122.44(d)(1)(vi)).

EPA has provided guidance on how to apply these requirements in the "Technical Support Document for Water Quality-based Toxics Control (TSD)" (EPA/505/2-90-001, March 1991), which is available in the administrative record for this rulemaking. In the TSD, EPA recommends that facility-specific effluent monitoring data be used, where available, to project receiving water concentrations, which are then compared to water quality criteria. This comparison in the TSD guidance is comprised first of calculating the pollutant concentration in the receiving water after considering dilution (if allowed by the water quality standards regulation), the contributions of other point and nonpoint sources, and the potential for effluent variability to justify assuming higher effluent concentrations than have actually been measured; and second, comparing this calculation to the applicable water quality criterion. The TSD guidance allows the permitting authority the flexibility to determine the appropriate approach for assessing reasonable potential. For example, an authority may opt to use a stochastic dilution model that incorporates both ambient dilution and effluent variability rather than use a steady state dilution model with a statistically defined maximum effluent concentration. Also, a permitting authority may develop a WQBEL in the absence of facility-specific effluent monitoring data. Whatever approach is selected by the authority, it must satisfy all requirements of 40 CFR 122.44(d)(1)(ii) summarized above.

One of four outcomes will be reached when using the TSD protocol:

-- Excursion Above the Water Quality Standard. If the permitting authority determines that pollutants or pollutant parameters in a facility's discharge are or may be discharged at a level which causes or contributes to an excursion above a narrative or numeric water quality criterion, it must establish a WQBEL in the permit for those pollutants (40 CFR 122.44(d)(1)(i).

-- Reasonable Potential for Excursion Above the Water Quality Standard. If the permitting authority determines that pollutants or pollutant parameters in a facility's discharge are or may be discharged at a level which has the reasonable potential to cause or contribute to an excursion above a narrative or numeric water quality criterion, it must establish a WQBEL in the permit for that pollutant (40 CFR 122.44(d)(1)(i)). EPA believes that reasonable potential is shown where an effluent, in conjunction with other sources of a pollutant, is projected to cause an excursion above the water quality criterion. This projection is based upon an analysis of available data that accounts for limited sample size and effluent variability. EPA's guidance in the TSD does not, however, constrain the determination of reasonable potential to a projection of an excursion above a water quality criterion based solely on effluent variability. The guidance recognizes that reasonable potential determinations include consideration of the factors in 40 CFR §122.44(d)(1)(ii) and any other appropriate factors based on the professional judgement of the permitting authority. These other factors may include the existing data on toxic pollutants; type of receiving water and designated uses (e.g., high-use fishery); relative proximity of the measured effluent concentrations to the water quality criteria; existing controls on point and nonpoint sources; compliance history of the facility; and type of treatment facility.

-- No Reasonable Potential for Excursions Above the Water Quality Standards. If the permitting authority determines that the pollutants or pollutant parameters in a facility's discharge are not discharged at a level that has the reasonable potential to cause or contribute to an excursion above a narrative or numeric water quality criterion, then a WQBEL for those pollutants is not necessary. In these situations, EPA's guidance recommends that effluent monitoring for the pollutants or pollutant parameters be repeated at a frequency of at least once every five years (see TSD at p. 64). This usually occurs as part of the permit application.

-- Inadequate Information. If a permitting authority has inadequate information to determine whether a discharge contains pollutants or pollutant parameters which are or may be discharged at a level which has the reasonable potential to cause or contribute to an excursion of a narrative or numeric water quality criterion, EPA's existing guidance recommends that the permit contain appropriate monitoring requirements and a reopener clause (see TSD at p. 64). This clause would allow reopening of the permit and establishment of a WQBEL based upon any monitoring results or other new factors which indicate that the effluent causes, has the reasonable potential to cause, or contributes to an excursion above water quality standards.

2. <u>General Requirements of Procedure 5</u>

Procedure 5 of this Guidance provides that the permitting authority would be required to include a WQBEL in an NPDES permit whenever a pollutant is or may be discharged into the Great Lakes System at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value. Procedure 5 of appendix F to part 132 sets forth a two-step process for determining whether the discharge of a pollutant will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value.

First, under procedure 5.A of appendix F, permitting authorities must develop preliminary effluent limitations (PEL) that are calculated such that the discharger, if meeting the PEL, would not cause or contribute to any Tier I criterion or Tier II value being exceeded in-stream after discharge, where there is sufficient data to develop such criteria or values. If such data do not exist, permitting authorities must apply the provisions in procedure 5.C of appendix F to determine whether such data must be generated. Second, procedure 5.B of appendix F sets forth procedures to be followed to determine the projected effluent quality (PEQ) of the effluent that will be discharged and whether a WQBEL must be established based on a comparison between the PEQ and the preliminary effluent limitation. If such effluent data do not exist or if all such effluent data for a pollutant or pollutant parameter are below the analytical detection level for that pollutant or pollutant parameter, permitting authorities will continue to apply existing Federal, State or Tribal regulations and guidance for making reasonable potential determinations. Finally, section F of procedure 5 provides that, regardless of the manner in which the reasonable potential determination is made, all effluent limitations would have to also comply with all other applicable State, Tribal and Federal requirements. In particular, section F specifies that all water quality-based effluent limitations must be consistent with the wasteload allocations calculated as part of a TMDL, or in the absence of a TMDL, consistent with wasteload allocations generated consistent with the provisions specified in the final Guidance and described in more detail below.

This Guidance provides permitting authorities with specific criteria for making reasonable potential determinations based on facility-specific effluent monitoring data consistent with the provisions of 40 CFR 122.44(d)(1)(i), (ii), (iii), and (vi). The procedures of this section do not contain requirements pertaining to whole effluent toxicity. Instead, those requirements are set forth in procedure 6 of appendix F. Furthermore, the procedures of this section do not affect the permitting authorities' existing obligation to implement the regulations at 40 CFR 122.44(d)(1)(vii) which pertain to expression of WQBELs.

As a preliminary matter, before explaining the specific aspects of procedure 5, discussion of two general comments and EPA's responses is necessary.

The first paragraph of procedure 5, appendix F of the proposed guidance contains the following sentence as the last sentence of the paragraph, "In all cases, the permitting authority shall use any relevant information that indicates a reasonable potential to exceed any Tier I criterion or Tier II value." Some commenters suggested that the meaning of the word "relevant" in this statement is unclear and that this statement could be read as implying that relevant data indicating a reasonable potential to exceed a criteria or value is to be used, but that data indicating an absence of reasonable potential should not be used.

In response, in the cited statement, EPA contemplated that a broad scope of data and information could be relevant in determining reasonable potential for a given discharge, including: effluent pollutant concentration data, receiving water background data, ambient fish tissue data, Tier I criteria, Tier II values and in addition, a variety of factors and information when determining reasonable potential where facility-specific effluent monitoring data are unavailable. The variety of factors and information can include: dilution, type of industry, type of POTW, existing data on toxic pollutants, history of compliance problems and toxic impact, and type of receiving water and designated use (See TSD at 50-55.). Any of the above could be "relevant" within the meaning of the final Guidance and, of course the permitting authority must exercise its judgement in determining the relevance of any type of data or information to the discharge and receiving water in question. EPA regulations in some cases define the parameters for the exercise of this discretion. For example, all representative effluent pollutant concentration data--not just data points that alone would trigger the need for a WQBEL--(see 40 CFR 122.41(j)(1)) for a particular discharger are clearly relevant to that discharger and must, under final procedure 5 be used in the determination of reasonable potential. In addition, to clarify the implicit premise in proposed and final procedure 5 that only valid data should be used when determining reasonable potential, EPA inserted the word "valid" into the cited statement immediately prior to the word relevant. EPA's intent is for the permitting authority to exercise its judgement in determining the validity of data and information and their relevance to the discharge and receiving water in question.

Paragraph F.2 of proposed procedure 5 stated that "When determining whether water quality-based effluent limitations are necessary, information from chemical-specific, whole effluent toxicity and biological assessments shall be considered independently." Several commenters suggested that this provision should not be adopted, stating that the policy and philosophy of independent application is flawed, not scientifically valid, and should be replaced by a "weight of evidence" approach to determining the need for WQBELs.

In response, EPA believes that the provision at F.2 of proposed procedure 5 and F.3 of the final procedure 5 requiring independent consideration of chemical-specific, whole effluent toxicity and biological assessments is grounded in the requirements of 40 C.F.R. § 122.44(d)(1), which requires, among other things, that the permitting authority (1) establish chemical-specific permit limits where a discharge has the reasonable potential to cause or contribute to a violation of a numeric water quality criterion, and (2) establish a whole effluent toxicity limit where a discharge has the reasonable potential to cause or contribute to an exceedance of a numeric WET criterion. Under these provisions, if "reasonable potential" is found with regard either of these aspects of standards, then a corresponding permit limit is required. There is no indication in the language of this provision that one type of information (e.g., biological assessment or WET testing) can be used to "negate" a reasonable potential finding based on another type of information (e.g., chemical specific analysis). One principle behind the policy on independent application as it pertains to determining the need for WQBELs is that WET testing does not always measure all potential toxicity in complex mixtures and, likewise, chemical analysis does not always measure toxicity from single components of the effluent. Hence, it is necessary to do both kinds of analysis on effluents and consider the results independently. The regulations do permit, however, the use of chemical-specific limits in lieu of WET limits in cases where there a discharge has the reasonable potential to cause or contribute to a violation of a narrative water quality criterion, provided it is demonstrated that chemical-specific limits are sufficient to attain and maintain applicable narrative and numeric water quality standards.

a. Developing Preliminary Wasteload Allocations

Procedure 5.A.1 of this Guidance describes how the permitting authority must establish preliminary wasteload allocations for purposes of calculating preliminary effluent limitations. Preliminary wasteload allocations are solely for the purpose of determining preliminary effluent limitations that are then compared to projected effluent quality to determine reasonable potential. The preliminary wasteload allocation is an essential component of the reasonable potential analysis and serves no other purpose.

i. Proposal: Procedure 5.A of appendix F of the proposed Guidance provided that the permitting authority would develop preliminary wasteload allocations based upon and consistent with the wasteload allocation procedures defined in procedure 3 of appendix F of the proposed Guidance, and then develop preliminary effluent limitations based on the preliminary wasteload allocations. The proposed guidance did not elaborate on or cross reference the specific wasteload allocation procedures in procedure 3 of appendix F to be used in calculating preliminary wasteload allocations.

ii. Comments: EPA received numerous comments suggesting that the procedures to be used for calculating wasteload allocations (in the absence of a TMDL approved by EPA under 130.7) and preliminary wasteload allocations needed to be clarified. The proposal provided that preliminary wasteload allocations would be calculated in accordance with procedure 3, the TMDL procedure. Some commenters read this to mean that a TMDL would have to be prepared prior to determining reasonable potential, and hence, prior to issuance of any new or revised permit. That was not EPA's intent. Instead, EPA's intent in the proposal was that the same minimum procedures that would be required under procedure 3 for calculating source-specific TMDLs would be used for calculating preliminary wasteload allocations for purposes of determining reasonable potential, and wasteload allocations for purposes of calculating permit limits. The proposal did not acknowledge that reasonable potential determinations often are made, and WQBELs required, in the absence of a TMDL approved by EPA under 40 CFR 130.7. Instead, the proposal suggested that TMDLs would be required for any water receiving effluent from a discharger found to exhibit reasonable potential. This is not the case in the final Guidance. As noted in the final procedure 3 and the accompanying discussion at section VIII.C of this document, the final Guidance specifies the conditions under which a TMDL is required for a waterbody. The final Guidance does not, like the proposal would have, require a TMDL for every water receiving effluent from a discharger found to exhibit reasonable potential. EPA recognizes that, given this change, reasonable potential decisions often will be made, and WQBELs required, in the absence of a TMDL approved by EPA under 40 CFR 130.7. This is currently the case in the national NPDES program.

iii. Final Guidance: Section 5.A of appendix F of the final Guidance clarifies the specific provisions within procedure 3 that would be the basis for determining preliminary wasteload allocations in the absence of a TMDL approved by EPA under 40 CFR 130.7. Section 5.F of appendix F of the final Guidance also specifies that in the absence of a TMDL approved under part 130.7, the permitting authority must use procedures consistent with the referenced provisions of procedure 3 as the basis for determining wasteload allocations for the purpose of deriving WQBELs when the permitting authority determines under this procedure that a WQBEL must be included in a NPDES permit. These specific provisions within procedure 3 that the final Guidance requires permitting authorities to use as the basis for determining preliminary wasteload allocations, and wasteload allocations (in the absence of a TMDL approved by EPA under 40 CFR 103.7) are: 3.B.9, Background Concentrations of Pollutants; 3.C, Mixing Zones for Bioaccumulative Chemicals of Concern, sections C.1.a, C.3, C.4.a, C.5, C.6; 3.D, Deriving TMDLs for Discharges to Lakes when the receiving water is an open water of the Great Lakes, an inland lake or other water of the Great Lakes System with no appreciable flow relative to its volume; 3.E, Deriving TMDLs, WLAs and

Preliminary WLAs, and LAs for Discharges to Great Lakes System Tributaries when the receiving water is a tributary or connecting channel of the Great Lakes that exhibits appreciable flow relative to its volume; and, 3.F, Mixing Zone Demonstration Requirements.

EPA selected the portions of procedure 3 noted above and cross-referenced in 5.A and 5.F of appendix F of the final Guidance (cross-referenced provisions) because they closely parallel the core factors EPA has consistently required be accounted for, pursuant to 40 CFR 122.44(d)(1)(i) and (ii), when determining reasonable potential and wasteload allocations for deriving WQBELs in the absence of a TMDL. Specifically, when determining when a WQBEL is necessary and in setting the limit, these regulations require that existing controls on point and nonpoint sources and dilution where appropriate, be accounted for. EPA has interpreted these regulatory requirements through preamble language (54 FR 23868, June 2, 1989) and through various pieces of Agency guidance (see TSD in particular). EPA has consistently required that, to meet the requirements of 122.44(d)(1)(i) and (ii), permitting authorities must account for ambient background pollutant concentrations in receiving waters and the available dilution in a receiving water that results in mixing of effluent and receiving water. The cross-referenced provisions of procedure 3, which address how to evaluate background concentrations, and available dilution and mixing are therefore now specifically cross-referenced in the reasonable potential section.

It is important to note that the cross-referenced provisions, serve essentially three purposes in the final Guidance. First, outside of the context of developing a TMDL under § 130.7, or in the absence of such TMDL, wasteload allocations for purposes of calculating WQBELs must be determined consistent with the cross-referenced procedures. Second, for purposes of conducting a reasonable potential determination, preliminary wasteload allocations must be determined consistent with the cross-referenced provisions. And of course, third, when a TMDL under 130.7 is being developed, all provisions, including the cross-referenced provisions of procedure 3, apply.

b. Developing Preliminary Effluent Limitations

Procedure 5.A.2 of appendix F of the final Guidance specifies the procedure for developing preliminary effluent limitations based on the preliminary wasteload allocations.

i. Proposal: Procedure 5.A.2 of appendix F of the proposed guidance set out the minimum requirements for developing preliminary effluent limitations and specified that the preliminary effluent limits are required to be developed consistent with these minimum requirements and in accordance with existing State or Tribal procedures for converting wasteload allocations into water quality-based effluent limitations. Procedure 5.A.2 of appendix F of the proposal provided that the preliminary effluent limitations would be expressed as either a single day value, a weekly average, or a monthly average, and would be used in determining if a facility causes, has the reasonable potential to cause or contributes to excursions above water quality criteria by being compared to actual effluent information in procedure 5.B of appendix F of the proposed Guidance. Because the preliminary effluent limitations must be compared with actual effluent information, the proposed Guidance provided that the preliminary effluent limitations would be expressed in the same form that effluent data are typically available to permitting authorities. Effluent information is typically available to permitting authorities either in the permit application or in the Discharge Monitoring Reports (DMR). Both the application forms and DMRs require effluent concentrations to be reported as weekly and monthly averages for publicly owned treatment works (POTWs) and as single day values and monthly averages for non-POTWs. The use of these single day values, weekly averages, and monthly averages allows for direct comparison of preliminary effluent limitations to effluent data without requiring additional manipulations or conversion of the effluent data. In the preamble of the proposed Guidance, EPA discussed its belief that this reduces the burden to the permitting authorities and facilities in reviewing and using effluent concentration data in determining if a WQBEL is necessary.

Each preliminary wasteload allocation has a corresponding preliminary effluent limitation that is based on the criterion (or value) and dilution basis used to develop the wasteload allocation. The preliminary effluent limitation based on wildlife criteria was proposed in section 5.A.2 as a monthly average because the wasteload allocation is calculated using a 30-day (monthly) average flow under proposed procedure 3 of appendix F. The preliminary effluent limitation based on human health criteria was proposed to be expressed as a monthly average because, although the wasteload allocation is calculated using a harmonic mean (annual) river flow, the monthly averaging period is the closest expression of the preliminary effluent limitations to an annual average. The preliminary effluent limitation based on acute aquatic life criteria was proposed to be expressed as a daily value to reflect that the criteria themselves are expressed as one-hour averages and the wasteload allocation is calculated using a one-day (daily) average river flow. The preliminary effluent limitation based on chronic aquatic life criteria was proposed to be expressed as a weekly average value to reflect that the criteria themselves are expressed as four-day averages and the wasteload allocation is calculated using a seven-day (weekly) average river flow. In addition, the preliminary effluent limitation based on chronic aquatic life criteria could, as an option under the proposal, be expressed as a monthly average value to reflect that weekly average effluent data may not be available for non-POTW facilities.

The proposal also explained that dilution, nonpoint sources of pollution, and the potential for effluent variability (all factors required by 40 CFR 122.44(d)(1)(ii) to be considered when determining whether a point source must have a WQBEL(s) in its permit) would be adequately addressed and accounted for under proposed procedures 5.A.1 and 2, and 5.B.

ii. Comments: EPA received few comments on the PEL procedures proposed at 5.A.2 of appendix F. A few commenters suggested that the PEL procedures specify that the PEL for chronic aquatic life protection be specified as a monthly average only and that permitting authorities not be given the option to express this PEL as either a weekly average or monthly average. Commenters noted that such an approach would be more consistent with the PEQ procedures that specify that distribution of monthly averages be used when determining PEQ with respect to protection of aquatic life from chronic effects. In response to this last comment, and as explained in the preamble to the proposal and reiterated above, effluent data for a discharger will not always be readily available to the permitting authority in both the weekly and monthly average format, and for purposes of screening for the need for WQBELs, a comparison of either a weekly or monthly average to a PEQ derived from a distribution of monthly averages is acceptable. Because both formats, weekly and monthly average, reflect averages of daily measurements, EPA does not expect there to be substantial differences between the weekly and monthly average values. As noted above, dischargers often will have data expressed in either one format or the other. In the interest of minimizing the data collection burden on States, Tribes and dischargers, EPA believes it is unnecessary for either new data to be collected to fit a single format or existing average data to be transposed into the other format when existing data is expressed in only one of the two formats.

One commenter expressed concern that the proposed PEL procedure would require WQBELs to be derived such that effluent limits based on human health and wildlife protection would be expressed as monthly limitations; limits based on protection of aquatic life from chronic effects would be expressed as monthly or weekly limitations; and limits based on protection of aquatic life from acute effects would be expressed as daily limitations. The commenter pointed out that such an approach to deriving permit limits would depart from the approach recommended by EPA in the TSD and followed by some states.

In response to this comment, EPA notes that the PEL procedures in the proposal and in the final Guidance do not address how permitting authorities ultimately set WQBELs--that is left to existing State and Tribal procedures. The PEL procedure is simply a component of the larger reasonable potential screening procedure for determining when WQBELs are needed. Similarly, the reasonable potential guidance in Chapter 3 of the TSD does not address how WQBELs should be calculated--Chapter 5 of the TSD provides guidance on that matter.

It is worth noting for purposes of this discussion that the proposed and final PEL procedure refines and expands on the TSD reasonable potential guidance. The TSD guidance for determining reasonable potential, in essence, is a comparison of a projected daily maximum effluent quality, after mixing with the receiving water, to the applicable water quality criteria. Under the TSD guidance, if the projected effluent value, after mixing, exceeds any of the applicable criteria, reasonable potential exists. The proposed and final PEL procedure takes the TSD guidance a step further. The PEL procedures, in essence, are a comparison of a PEQ to a PEL. The PEL essentially is the applicable water quality criterion adjusted to reflect mixing and, most importantly here because it is not a feature of the TSD guidance, the duration of the criterion and the averaging period of the effluent data. The PEL procedures specify that effluent data (PEQ) used for comparison to the PEL be specified in a format that approximates the requisite averaging period of the criterion being protected, and likewise, that the PEL be specified in the same format. So for example, where the chronic aquatic life criterion is the applicable criterion (exposure duration = 4 days), the PEL and the PEQ are to be specified in the format that the data are currently in that best approximates a 4-day averaging period: weekly or monthly average. Similarly, where the acute aquatic life criterion is the applicable criterion (exposure duration = 1 hour), the PEL and PEQ are to be specified in the format that most closely approximates the duration period of the criterion: daily maximum. The TSD guidance, while a technically sound screening approach, is not this refined. It does not provide guidance on specifying the averaging periods of effluent data after mixing to approximate the exposure duration of the applicable water quality criteria when determining reasonable potential. Instead, the TSD recommends a simple conservative screening procedure that compares an observed or estimated maximum daily effluent value with the most stringent applicable water quality criterion. The PEL procedures in the proposed and final Guidance simply take the TSD approach a step further by incorporating a way to more closely match the averaging period of the effluent data with the exposure duration of the water quality criteria.

In response to the comment that the PEL procedures depart from TSD guidance on deriving WQBELS, EPA notes that the reasonable potential screening procedure for deriving PELs differs from the TSD guidance on deriving WQBELs in the same way that the TSD reasonable potential guidance differs from the TSD guidance on deriving WQBELs. This difference is intentional both in the TSD and in this final Guidance. The difference exists because the procedure for determining when a WQBEL is needed and on what basis, and the procedure for deriving the WQBEL are fundamentally different types of procedures. When determining when a WQBEL is needed and on what basis, the PEL procedure specifies that PELs be calculated in different formats (i.e., daily maximum, weekly average, and monthly average) and that these values be compared to PEQ values expressed in the same formats. The resulting analysis, while a screening procedure, does attempt to match effluent averaging periods to the exposure duration of each criterion that applies in the receiving water. Once the analysis is complete, one will know whether a WQBEL is needed, and whether the need for the WQBEL is based on a projected excursion of acute or chronic aquatic life criteria, human health criteria or wildlife criteria. Once the need for the WQBEL has been established, the next step is to calculate the wasteload allocations and generate the actual WQBEL. While the proposed and final guidance contains minimum requirements for calculating wasteload allocations, it is virtually silent on translating wasteload allocations into WQBELs. However, the TSD does contain guidance on this step. The TSD guidance recommends, in short, that the permitting authority calculate the wasteload allocations that will be protective of the various applicable water quality criteria (acute and chronic aquatic life, human health and wildlife), calculate the long term average effluent concentrations that will meet those wasteload allocations, select the most stringent long term average effluent concentration, then translate that long term average into maximum and average WQBELs that, if met by the discharger, will result in protection of all of the applicable criteria.

In summary, the reasonable potential procedures in the final Guidance are a refined version of the reasonable potential guidance in the TSD, but nevertheless still screening procedures. Under these screening procedures, effluent data in each format is compared to each applicable criterion to assess the potential for each type of criterion to be exceeded. In contrast, the WQBEL guidance in the TSD is more precise. Under the TSD WQBEL derivation guidance, once the need for a WQBEL is established, the WQBEL is calculated such that it results in an average effluent concentration that is low enough to be protective of each of the applicable criteria and is expressed in both the maximum and average formats. EPA repeats that this fundamental difference between the two procedures, one a screening procedure and the other a more precise approach to calculating WQBELs, is intentional and appropriate. Were EPA to make the PEL procedure entirely consistent with TSD guidance on deriving WQBELs, and thus a more precise WQBEL derivation procedure, the screening function of the PEL procedure would be entirely lost.

iii. Final Guidance: Procedure 5.A.2 of appendix F of the proposal remains unchanged in this final Guidance. The procedure appearing at 5.A.2 of appendix F of the proposal has been renumbered in the final Guidance and is located at 5.A.3. The procedure in section 5.A.3 of appendix F of the final Guidance is limited to calculation of preliminary effluent limitations for purposes of comparison to projected effluent quality to determine the need for a WQBEL. Except for the provision in 5.E concerning intake pollutants, procedures for converting wasteload allocations into WQBELs and for expressing effluent limitations in NPDES permits shall continue to be governed by existing State, Tribal and Federal requirements and guidance (see 40 CFR 122.45(d) and (e)).

c. Determining Reasonable Potential to Exceed the Preliminary Effluent Limitations Using Pollutant Concentration Data

Procedure 5.B of appendix F of this final Guidance specifies procedures for determining the PEQ for discharges to waters of the Great Lakes System based on facility-specific effluent pollutant concentration data. Available effluent monitoring data includes information from discharge monitoring reports (DMRs), data from NPDES permit application forms 2A and 2C, and other data requested of or submitted by the facility or available to the permitting authority. Sections 5.B.1 and 2 in this final Guidance specify that a statistical procedure must be used to estimate PEQ.

Sections 5.B.2.a-c specify the characteristics that the permitting authority's PEQ procedure must have, which are the same essential characteristics of the proposed PEQ procedures. Sections 5.B.2.a-c provide that the PEQ is to be specified as: no less than the 95th percentile of the distribution of the projected population of daily data; no less than the 95th percentile of the distribution of the projected population of monthly averages; and no less than the 95th percentile of the distribution of the projected population of weekly averages. Sections 5.B.2.a-c do not specify the exact statistical procedure required, leaving flexibility to the States to adopt a PEQ procedure that conforms with the characteristics described in 5.B.2.a-c.

Section 5.B.1 specifies an alternative method for specifying PEQ (i.e. the "TSD" procedure). The TSD procedure is the procedure EPA would promulgate in a permitting authority's program if the permitting authority fails to adopt a procedure consistent with the provisions described 5.B.2.a-c.

i. Proposal: In the proposed rule, the estimated maximum concentration would have been calculated, in most applications, as the upper bound (99th) percentile of the distribution of the projected population of effluent concentrations. The 99th percentile was proposed as a reasonable measure of the maximum effluent concentration. In addition, the proposed rule provided that PEQ would be specified as the maximum observed daily effluent value where the observed maximum is greater than the statistically estimated upper bound (99th percentile) value.

The proposed Guidance also offered a second method, set forth in the proposal at procedure 5.B.1.d of appendix F to part 132, for calculating PEQ. This second method provided that the PEQ could be calculated as the upper 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration data. This statistical procedure is consistent with the procedure described in section 3.3 of the TSD and with the general characteristics of the PEQ procedure required at 5.B.1 of the final Guidance. Each proposed PEQ provision specified that a WQBEL would be required if the PEQ exceeded any of the preliminary effluent limitations developed in accordance with section 5.A.

The proposed guidance also contained a procedure 5.C to address situations where at least one but less than ten data points exist. The proposed statistical procedure at 5.C is essentially the same as the proposed procedure at 5.B.1.d described above, except that, instead of specifying that the coefficient of variation be calculated, the procedure specified that the coefficient of variation is assumed to be 0.6.

Finally, the proposal contained a procedure 5.B.2, described below, specifying a more conservative approach to comparing projected effluent quality (PEQ) with preliminary effluent limits (PEL) for use in low dilution situations that would have required a comparison of PEQ to only one-half of the PEL, instead of the whole PEL.

ii. Comments: EPA received many comments on the reasonable potential procedures using effluent data. Numerous commenters expressed support for the reasonable potential procedures. Many commenters requested various simplifications and clarifications of the reasonable potential procedures, pointing out that there are numerous valid statistical procedures and assumptions, different and less complicated than those proposed by EPA, that could be used to estimate PEQ. Many commenters suggested that States should have more latitude in determining reasonable potential and that best professional judgement should play a more prominent role in reasonable potential assessments. Other commenters suggested that the entire procedure for estimating PEQ should be guidance rather than required procedures. Other commenters expressed strong support for detailed required statistical procedures for determining reasonable potential, suggesting that such procedures are desirable to achieve consistency among the Great Lakes States in the way that reasonable potential determinations are made. Several commenters specifically recommended additional flexibility for determining PEQ using small data sets, while others suggested that small data sets (i.e., fewer than ten data points) should not be used to make PEQ determinations. In contrast, other commenters expressed support for the TSD statistical PEQ procedure, pointing out that it is an improvement over the current approaches of some states with regard to small data sets.

Several commenters suggested that single effluent data points are insufficient to trigger the automatic inclusion of WQBEL in a permit, and that a larger data set should be required. These commenters noted that a single data point for an effluent could be non-representative or an outlier.

Commenters raised the concern that reasonable potential determinations based on a single data point, using the statistical procedure proposed and essentially retained in the final Guidance, will result in conservative projections of effluent quality and unnecessary permit limits.

In response to these comments, EPA notes that the TSD procedure in 5.B.1 of appendix F of the final Guidance and the general characteristics at 5.B.2 of appendix F are designed to estimate the 95th percentile effluent value based upon whatever representative effluent data is available. When a small data set is being used to make this projection, or in the extreme case, where only one data point is being used, the projected effluent quality using the EPA procedure, will be 6.2 times the observed value (assuming a coefficient of variation of 0.6). EPA as well as many of the commenters on the proposed guidance recognize this statistical procedure to be valid, even for very small data sets. However, EPA also recognizes that the more data there are for a discharge, the more accurate the effluent pollutant distribution will be and, generally, the closer the maximum value will be to the projected 95th percentile value. Where dischargers are concerned that the result of the statistical analysis using a single data point will be too conservative, the discharger can certainly remedy the situation. Effluent data in the vast majority of cases becomes available to the permitting authority via reporting by the discharger. In other words, the discharger almost always has the same effluent data that the permitting authority has. Where the discharger has only a single data point, the discharger may always collect and report more effluent samples to the permitting authority prior to permit issuance or reissuance. EPA encourages this practice. However, where the discharger reports only a single data point, EPA's position is that such data must not be ignored. The final guidance provides flexibility to States to adopt a reasonable potential statistical procedure that among other attributes, accounts for and captures long term effluent variability and accounts for limitations associated with sparse data sets. Where a State fails to adopt such a procedure, the final Guidance specifies the statistical procedure EPA would promulgate for a State should it become necessary (procedure 5.B.1. of appendix F). It is essentially the same procedure that was proposed for data sets of ten or less data points. The final guidance leaves room for State procedures to differ from EPA's as long as the basic characteristics outlined in section 5.B.2 of appendix F are adhered to. The procedure at 5.B.1 is offered as one alternative, and would only be required, where a State failed to adopt a PEQ procedure consistent with the characteristics outlined in 5.B.2

With regard to the comment suggesting that only representative data should trigger the need for a permit limit, EPA notes that an implicit and obvious premise in the proposed and final PEQ procedure is that the effluent pollutant concentration data used to project maximum effluent quality are valid data that are representative of the effluent. Permittees should ensure they are reporting valid, representative data (see 40 CFR 122.41(j)(1)). Where the permittee believes certain effluent measurements to not be representative of the effluent, the permittee should bring this to the permitting authority's attention. EPA's position is that valid, representative effluent data must not be ignored. To clarify this point in the final procedure 5, EPA has inserted the word "representative" into the first sentence of paragraph B of final procedure 5. It now reads, "If representative facility-specific effluent monitoring data samples are available for a pollutant discharged from a point source to the waters of the Great Lakes System, the permitting authority shall apply the following procedures:..." Another commenter suggested that EPA Guidance should specify that data obtained prior to and affected by significant treatment, pretreatment, or pollution prevention modifications should not be used for making reasonable potential determinations. The commenter makes the point that effluent data used as the basis for characterizing projected effluent quality should be representative of the discharge and that data obtained prior to installation of treatment, pretreatment or pollution prevention modifications should not be used. In response to this comment, EPA agrees that effluent data used as the basis for effluent characterization should be representative of the discharge under current conditions with current treatment and management practices at the plant. The permitting authority should use judgement in determining whether available effluent data is representative of the current operating conditions at the facility. Where such data is found to be no longer representative of the current discharge, the permitting authority may choose to not use such data based on a determination that the data pre-dates current operating conditions and treatment at the facility.

Several commenters suggested that use of the 99th percentile to specify PEQ would be too extreme and would not be consistent with guidance in the TSD that recommends use of the 95th percentile. Commenters also pointed out that the proposal was unclear about how to calculate the 99th percentile value, some comments simply reflecting confusion about whether EPA intended in the proposal for the 99th percentile value to be the 99th percentile of the observed data points or the 99th percentile of the projected population of data.

Several commenters suggested, as an alternative to comparing a statistically derived "worst case" PEQ to a PEL derived using steady state worst case assumptions, the final Guidance should recognize dynamic modeling techniques which provide probability estimates of receiving water concentrations rather than a single, worst-case condition which rarely occurs. Further, the commenters contended that use of these statistical techniques allows the predicted frequency and duration of exceedances to be directly compared to the duration and frequency associated with the water quality criterion, as described in and EPA's TSD.

Several commenters requested clarification on how to manage effluent data points that are "non-detect" or "non-quantified." Commenters pointed out that there will be cases where all effluent data points are below detection; where some data points are below detection and some are above detection, but below quantitation; where some data points are above quantitation and some are below quantitation, and finally, cases where effluent data points fall into all three categories. Commenters specifically noted that the final Guidance should clarify what values, if any, should be placed on values below detection or quantitation, and on whether such values should be counted as data points when determining reasonable potential.

One commenter questioned the correctness of the statistical procedure for estimating PEQ at 5.B.1.d and 5.C.1 (TSD procedure), stating that the procedure is fundamentally mathematically incorrect. In particular, the commenter states that the two equations presented in the preamble to the proposal at 58 FR 20949, the first for determining P_n and the second for determining the ratio of P_n to the 95th percentile of the projected population of effluent values, contradicted each other. The commenter also suggests that the second equation is incorrect in that it is based on a 99% confidence level rather than as stated in the proposal, the 95% confidence level.

Finally, one commenter suggested that the final Guidance should contain a statistical PEQ procedure that could be applied in all circumstances. EPA interpreted this comment to mean that a single procedure would simplify the provisions for determining PEQ and that a single procedure should be available that would apply to both small and large effluent data sets.

iii. Final Guidance: The final Guidance specifies at 5.B.1, the essence of the procedure for estimating PEQ proposed at 5.B.1.d. This is commonly known as the TSD procedure. The final guidance also specifies, at 5.B.2, more general characteristics of a PEQ procedure. The TSD procedure under 5.B.1 is specified as one option for calculating PEQ. EPA would promulgate this option in a permitting authority's program should it become necessary under 40 CFR 132.5 of this Guidance. EPA has concluded that the procedure proposed at 5.B.1.d, the TSD procedure, and specified in this Guidance at 5.B.1, is consistent with the essential characteristics of a PEQ procedure specified in sections 5.B.2.a-c of this Guidance. In specifying alternative procedures, one specific and one more general, the final Guidance provides the States the flexibility to either select and apply a method for determining PEQ that is consistent with the more general provisions 5.B.2.a-c of appendix F, or the more specific TSD procedure at 5.B.1. EPA believes that either a State method consistent with 5.B.2.a-c, or the specific method specified at 5.B.1 would satisfy the requirements of 40 CFR 122.44(d)(1)(ii) because both require valid statistical procedures to characterize effluent variability in defining a reasonable maximum effluent concentration to characterize the PEQ. Alternative methods may result in different conclusions depending upon the number of data points characterizing an effluent, but neither of the methods will always provide a more stringent basis for determining reasonable potential.

An important change from the proposal is that in the final Guidance, proposed procedures 5.B.1.d and 5.C (The TSD statistical procedures) have been merged and are presented in the final guidance under 5.B.1 The effect of this change is to establish the same PEQ statistical procedures for both large and small effluent data sets. Final procedure 5.B.1, unlike proposed procedures 5.B.1.d and 5.C, does not establish different (PEQ) procedures for when there are 10 or fewer data points and when there are greater than 10 data points. Instead, the final Guidance provides a statistical procedure that is appropriate for use with both small and large data sets (i.e., fewer than ten data points, and greater than 10 data points). EPA notes that the procedure at 5.B.1 is an optional statistical procedure for determining PEQ that EPA believes conforms with the statistical procedures described in section 3.3 of the TSD, proposed at 5.B and C, and the characteristics of a PEQ procedure described at 5.B.2.a-c of the final Guidance. Under this final Guidance, States have the flexibility to adopt a PEQ procedure other than the procedure at 5.B.1, as long as the procedure conforms to the characteristics of a PEQ procedure described at 5.B.2.a-c of the final Guidance. The alternative procedure described at 5.B.2.a-c of the final Guidance is really less a specific procedure than it is a set of required characteristics of a State PEQ procedure. Under 5.B.2.a-c, PEQ is to be specified as the 95th percentile of the distribution of the daily, weekly, or monthly values of the facility-specific effluent monitoring data projected using a scientifically defensible statistical method that accounts for and captures the long-term variability of the effluent quality, accounts for limitations associated with sparse data sets, and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data.

Once the PEQ is determined by the permitting authority, the final Guidance, like the proposal, requires the PEQ to be compared to the preliminary effluent limit (PEL) by the permitting authority to determine the need for a WQBEL.

The changes to the PEQ provisions from the proposal are intended to simplify the proposed PEQ procedures, to maintain the flexibility of the proposal for permitting authorities to select PEQ procedures that fit the essential characteristics of the PEQ procedures proposed by EPA, and to clarify that where EPA determines it is necessary to promulgate a PEQ procedure in a State's program under 40 CFR 132.5, EPA would promulgate the procedure at 5.B.1 of the final Guidance.

Under the method described in section 5.B.1 of this final Guidance, the PEQ is to be specified as the 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration; or the maximum observed effluent concentration, whichever is greater. In calculating the PEQ, the permitting authority would identify the number of effluent samples and the coefficient of variation of the effluent data, obtain the appropriate multiplying factor from Table 1 of procedure 6 of appendix F, and multiply the maximum effluent concentration by that factor. The coefficient of variation of the effluent data would be calculated as the ratio of the standard deviation of the effluent data divided by the arithmetic average of the effluent data, except that where there are fewer than ten effluent concentration data points, the coefficient of variation shall be specified as 0.6. If the PEQ exceeds any of the preliminary effluent limitations developed in accordance with section A.3 of procedure 5, the permitting authority would establish a WQBEL in an NPDES permit for such pollutant.

The PEQ procedures set forth in 5.B.1 account for effluent variability, an important component in determining whether a discharge will cause, have the reasonable potential to cause or contribute to an excursion above a water quality criterion. Effluent quality varies over time. An effluent measurement taken on any given day may or may not be representative of the reasonable upper bound effluent concentration in that particular discharge. The PEQ procedure in the final Guidance (like the proposed PEQ procedures) ensures that PEQ will be estimated as the reasonable upper bound effluent concentration by requiring the PEQ to be specified as the upper bound (no less than the 95th percentile) of the distribution of the projected population of effluent concentrations. The proposal would have provided that the upper bound estimate be specified as the 99th percentile. As noted above, several commenters expressed concern that the 99th percentile was too extreme, and that it could result in estimates of PEQ that were unrealistic. While EPA does not entirely agree with the basis of these comments, EPA also recognizes, as described in chapter 3 of the TSD, that the 95th percentile upper bound estimate of effluent data is an acceptable upper bound for purposes of making reasonable worst case estimates of effluent quality. The 99th percentile would, for practical purposes, be the highest one could specify the worst case estimate. Instead of requiring this estimate to be specified as the 99th percentile, the final Guidance establishes a "floor" at the 95th percentile. States of course have the flexibility to set PEQ at higher levels (e.g., the 99th percentile. Requiring the PEQ to be specified as no less than the 95th percentile is also consistent with EPA's longstanding guidance in the TSD.

Another change from the proposal is that the final PEQ procedure under 5.B.2. differs from the proposal with respect to specifying the PEQ as the greater of the 95th percentile value or the maximum observed value. The final procedure does not, like the proposed procedure, require PEQ to be specified as the greater of the maximum observed effluent value and the projected upper bound value (99th percentile in the proposal) of the distribution of the projected population of daily value effluent values. Instead, as noted above, the final procedure is simplified. It requires the PEQ to be specified as no less than the 95th percentile of the distribution of the projected population of effluent concentrations. It is important to note that while the specification of PEQ as the greater of the maximum observed value or the projected upper bound value would not be required if a State adopts a PEQ procedure under the more flexible provisions at 5.B.2., such a provision is recommended later in this document, and is a feature of the more specific TSD procedure at 5.B.1.

Some commenters expressed confusion over what the proposal meant when it stated that PEQ would be expressed as the greater of the 99th percentile of the distribution of daily values of effluent concentration data or the observed maximum effluent value. Some commenters thought this meant that PEQ would, in some cases, be the 99th percentile of the distribution of "observed" effluent values. EPA's intent in the proposal on this provision was for the permitting authority to compare the maximum observed effluent value with the 99th percentile of the distribution of the "projected" population of daily values, and specify PEQ as the greater of the two. In short, the term "99th percentile" in the proposal referred to a projected, not an actual value. To clarify this point, the final PEQ procedures include the word "projected" immediately prior to the word "population" in the sections 5.B.1 and 2.

In addition, upon further analysis, EPA has concluded that in the vast majority of cases, the statistically projected upper bound value will be greater than the maximum observed value. This relationship is more pronounced with few data points than it is with numerous data points. In other words, the more data points that one has, in general, the closer the observed maximum value will be to the greater projected upper bound value. EPA notes, however, that in rare instances, the maximum observed effluent value will be greater than the projected upper bound value. Under this circumstance, EPA recommends that the permitting authority specify the PEQ as the maximum observed value. EPA makes this recommendation based on the principle that permitting authorities should rely on all valid and representative effluent data, and should not ignore such data where it is available. Where an observed effluent value exceeds a statistically projected upper bound value, EPA believes the observed value should take precedence. In short, the comparison of the observed to the projected values and the specification of PEQ as the greater of the two is recommended by EPA, but not a required feature of State PEQ procedures.

As noted above, the final Guidance retains the TSD approach to calculating PEQ that was proposed at 5.B.1.d. It appears at 5.B.1 of appendix F of the final guidance. The guidance specifies the procedure at 5.B.1 as one option a permitting authority may select in adopting a PEQ procedure, and as the specific procedure EPA would promulgate in a permitting authority's program should it become necessary to promulgate such a procedure in a permitting authority's' program under 40 CFR 132.5. EPA has concluded that the procedure at 5.B.1 of the final Guidance is consistent with the provisions set out at 5.B.2.a-c of the Guidance. Procedure 5.B.1 of appendix F of this Guidance is based on the principles expressed in the TSD guidance document. All effluent assessment approaches for individual pollutants have some degree of uncertainty associated with them. The more limited the amount of test data available, the larger the uncertainty and the lower the precision of the methodology for characterizing the maximum effluent concentration. Because of this uncertainty, EPA developed the guidance in the TSD to provide a statistical approach to better characterize the effects of effluent variability and reduce uncertainty in the process of deciding whether to require a WQBEL for a particular pollutant. The TSD guidance combines knowledge of effluent variability as estimated by a coefficient of variation with the uncertainty due to a limited number of data to project an estimated maximum concentration for individual pollutants in a facility's effluent. The estimated maximum concentration is calculated as an upper bound of the expected lognormal distribution of effluent concentrations at a high confidence level. The information is then used by the permitting authority to determine the need for a WQBEL.

Under procedure 5.B.1 of appendix F, the PEQ is calculated by multiplying the maximum observed effluent concentration value by a factor which represents the uncertainty in the degree of variability in the effluent. The specific value of this factor depends upon the number of effluent concentration values and the variability of the effluent. The final Guidance provides these factors in Table 1 of procedure 6 of appendix F.

The calculation of the factors in Table 1 of procedure 6 of appendix F of the Guidance has two parts. The first is characterization of the highest measured effluent concentration based on the desired confidence level. The relationship that describes this is:

$$p_n \geq (1 - \text{confidence level})^{1/n}$$

where "p_n" is the lower bound ("worst case") percentile represented by the highest concentration in the data and "n" is the number of samples. The second part of this calculation is a relationship between the percentile described above and the selected upper bound of the lognormal effluent distribution.

As noted above, one commenter questioned the correctness of the statistical procedure for estimating PEQ at 5.B.1.d and 5.C.1 of the proposal (TSD procedure), stating that the procedure is fundamentally mathematically incorrect, stating that the two equations presented in the proposal at 58 FR 20949 contradict each other, and suggesting that the second equation is incorrect in that it is based on a 99% confidence level rather than as stated in the proposal, the 95% confidence level. EPA partially agrees and partially disagrees with these comments.

The commenter's analysis concluded that the two equations presented in the preamble to proposed procedure 5, the first for determining P_n and the second for determining the ratio of P_n to the 95th percentile of the projected population of effluent values, contradicted each other. EPA disagrees. The first equation, as noted by the commenter, is correctly presented as:

$$P_n \geq (1 - \text{confidence level})^{1/n}.$$

This equation is used to characterize the percentile of the maximum observed data point. As noted by the commenter, in the second printing of the TSD and in the preamble to proposed procedure 5, EPA replaced the = sign with a ≥ sign in this equation. The commenter takes issue with the second equation, stating that it contradicts the first equation and that the implicit assumption in the second equation is that the maximum value of any set of n samples is exactly equal to and no greater than the p(subscript n)th percentile. EPA agrees that the intent behind the second equation is to set the maximum value in any set of n samples equal to P_n. EPA does not agree that doing so contradicts the first equation. EPA always meant the reasonable potential statistical analysis in the TSD and the proposal to be "worst case." The first equation establishes with a 95% level of confidence the lowest percentile that the maximum observed value reasonably could represent. The second equation sets the percentile to this lowest value thereby establishing the "worst case" assumption. EPA does not believe the equations contradict each other. On the contrary, the equations work in tandem to achieve a statistically sound projection of the 95th percentile effluent quality. The sign in the second equation below therefore remains as it was in the proposal.

The commenter correctly pointed out that the example equation presented in the proposal at 58 FR 20948 (second equation) is based upon the 99% confidence level as shown by the reference to P_n as the 40th percentile of the population and that it should instead be based on the 95% confidence level. EPA agrees and has revised the second equation below. This equation which corresponds to the statistical portion of final procedure 5 is based on the 95% confidence level. The equation now references the 55th percentile instead of the 40th, reflecting that the maximum of five samples represents equal to or greater than the t percentile at 95% confidence. The equation also now contains the normal distribution value for the t percentile (0.126) in the denominator. The commenter will note that the solution to this equation is 2.3, the same value presented in the flawed equation in the proposal. This fact at once demonstrates that the multiplier table at 6-1 of the proposal was correct and that, while EPA correctly presented the solution to the calculation used to determine the ratio of the 95th to the t percentiles at 95% confidence (the multiplier), EPA did not correctly present the equation itself. The multiplier table at 6-1 therefore remains as it was in the proposal.

As explained in the proposal, EPA's industrial treatment effluent data base, which was used by EPA to develop and promulgate effluent limitations guidelines and standards, suggests that the lognormal distribution characterizes effluent concentrations well. For example, if five samples were collected (of which the highest value represents at least the 55th percentile at the upper 95 percent confidence level), the coefficient of variation is 0.6, and the desired upper bound of the effluent distribution is the 95th percentile, then the two percentiles can be related using the coefficient of variation (CV) as shown below:

$$\frac{C_{95}}{C_{55}} = \frac{\exp(1.645\sigma - 0.5\sigma^2)}{\exp(0.126\sigma - 0.5\sigma^2)} = 2.3$$

Where $\sigma^2 = \ln(CV^2 + 1)$, and 1.645 and 0.126 are the normal distribution values for the 95th and 55th percentiles, respectively.

The coefficient of variation (CV) of the effluent data is calculated as the standard deviation of the effluent data divided by the arithmetic average of the effluent data. The CV is, thus, a dimensionless measure of the relative variability of a distribution. Estimates of the CV can be used when the available data set for calculating the CV is small. Typical values of the CV for effluent data range from 0.2 to 1.2. EPA recommends in the TSD that when fewer than ten data points are available, a conservative estimate (assumes relatively high effluent variability) of the CV is 0.6. Section 5.B.1 of the final Guidance specifies that the CV be calculated as described above, except that where there are fewer than ten effluent concentration data points, the coefficient of variation would be specified as 0.6. Section 5.B.2 of the final Guidance, the more general characteristics of a PEQ procedure, do not require the CV to be estimated as 0.6 when there are fewer than ten data points. Section 5.B.2 does, however require the PEQ procedure to account for and capture the long-term variability of the effluent quality. EPA notes that estimating the CV as 0.6 when there are fewer than ten effluent data points is a longstanding EPA recommendation contained in the TSD (chapter 3 and appendix E) and reiterated here.

The assumption that the facility-specific effluent data are lognormally distributed is based on practical experience as discussed in Chapter 3 and appendix E of EPA's TSD. For environmental data, EPA has found the lognormal distribution is usually appropriate. Although the lognormal distribution does not provide an exact fit to environmental data sets in all cases, it usually provides an appropriate and functional fit.

Although the 95th percentile represents a measure of the upper bound of an effluent distribution, the TSD states that other percentiles are acceptable provided they have been demonstrated to provide a similar estimate of effluent variability. Procedure 5.B.1 of appendix F of the final Guidance sets this percentile at the upper 95th percent confidence level and the upper bound of the 95th percentile. EPA recognizes that there is always uncertainty in making decisions based on limited or sparse data sets, and that, under this approach, there is a possibility of requiring a WQBEL where one may not be necessary, as well as not requiring a WQBEL where one is needed. The specific TSD approach at 5.B.1 of the final Guidance minimizes the possibility of not requiring a limitation where one is actually needed by selecting the upper-bound 95 percent confidence level of the 95th percentile or the maximum observed effluent value, whichever is greater. EPA has concluded that use of the upper 95 percent confidence level of the 95th percentile effluent concentration is a reasonable mechanism to assure that the permitting authority will calculate an effluent concentration that appropriately characterizes the PEQ.

Several commenters suggested that the final guidance provide permitting authorities the flexibility to use dynamic modelling techniques to determine when a discharge causes, has the reasonable potential to cause or contributes to and excursion of the applicable water quality criteria or values. EPA has provided substantial guidance, in the TSD and elsewhere, on dynamic modelling techniques for generating WLAs. The essence of wasteload allocation calculations is to understand the distribution of effluent concentrations of a pollutant that can be discharged from a facility over time and not cause the applicable water quality criteria to be exceeded frequently enough to, long enough to, or by amount which would, result in impairment in the receiving water. Dynamic modelling provides a sophisticated probability-based methodology for quantifying wasteload allocations. The same essential concept is at work in understanding reasonable potential. The reasonable potential test, however, is intended to answer whether the distribution of effluent concentrations of a pollutant from a current discharge demonstrates that the discharge will, on occasion, be in amount that could cause the applicable water quality criteria to be exceeded. The calculation of PEQ and its comparison to PEL is designed to answer this question. The PWLA procedures specified at cross-referenced at 5.A.2 of the final Guidance, and specified in procedure 3 of the final Guidance already provide the flexibility to the permitting authority to use dynamic modelling to calculate the PWLA. Because the PEL is based on the PWLA, where the PWLA is determined using dynamic modelling, the PEL also will based on dynamic modelling. EPA notes that the flexibility also exists under the PEQ procedures at 5.B.2 of the final guidance for states to adopt a reasonable potential procedure that uses dynamic modelling techniques to determine whether under worst case effluent concentrations and receiving water flows, there is a reasonable potential for the applicable water quality criteria to be exceeded. EPA notes that the dynamic modelling approach used would need to be consistent with the basic characteristics for specifying PEQ at 5.B.2 of the final Guidance.

As noted above, several commenters requested that the final Guidance provide clarification on how "non-detect" and "non-quantified" effluent data points should be managed for purposes of determining reasonable potential. EPA is currently in the process of developing a national strategy on how to manage such values for purposes of determining reasonable potential, specifying permit limits, and measuring compliance. Because the strategy is under development at this time, EPA is not providing definitive guidance on how "non-detect" and "non-quantified" effluent data points should be managed for purposes of determining reasonable potential. EPA notes that permitting authorities will need to exercise discretion and careful judgement in managing such effluent data points. One option that permitting authorities could exercise is to assign a value of zero to all effluent values below the quantitation level (the Minimum Level [ML] is described elsewhere in this document and the final Guidance as an appropriate quantitation level) and count the values as data points. Another option that permitting authorities could exercise is to assign values, such as one-half the detection level to values below the detection level and one-half the difference between the detection level and the quantitation level to values that fall below the quantitation level, but above the detection level. Another option is to estimate the values below the quantitation level using a statistical model of effluent concentrations. EPA recognizes that there are still other scientifically defensible approaches to managing "non-detect" and "non-quantified" effluent data points for purposes of determining reasonable potential.

d. <u>Determining Reasonable Potential Using Pollutant Concentration Data Where the Effluent Flow Rate is Equal to or Greater than the 7Q10.</u>

Procedure 5.B.2 of appendix F of the proposed Guidance would have established requirements for situations where the effluent flow rate is equal to or greater than the critical low flow of the stream (7Q10). In such effluent dominated discharge situations, the requirements for determining the need for a WQBEL in the proposal were identical to those in procedure 5.B.1 of appendix F with one exception: the upper bound value of daily samples and the upper bound value of weekly and monthly averages were to be compared to 50 percent of the preliminary effluent limitations based on wasteload allocations (instead of to the full 100 percent of the preliminary effluent limitations). The final Guidance does not contain this "low dilution" provision.

i. <u>Proposal:</u> The proposal contained a requirement at 5.B.2 to compare the PEQ to 50 percent of the PEL instead of the entire PEL (low dilution provision). The proposal pointed out that this low dilution requirement would not increase the stringency of a WQBEL; instead it would better ensure that a WQBEL would be included in a NPDES permit in effluent dominated situations in the Great Lakes System. The proposal made the point that because the procedures in section 5.B of appendix F were based on statistical estimates, there was a small potential for a facility to discharge pollutants at higher concentrations that would exceed a water quality criterion. The proposal suggested that this potential is offset in higher dilution waters because the simultaneous occurrence of the high effluent concentration and low stream flow is rare. In contrast, the proposal maintained that there is little substantial ambient stream flow in streams with low dilution capacity. The proposal stated that the 50 percent factor in procedure 5.B.2 of appendix F provided a reasonable level of assurance that a WQBEL would be imposed where appropriate.

The low dilution provision proposed at 5.B.2 also precluded use of the TSD PEQ procedure (proposed at 5.B.1.d and promulgated in this final Guidance at 5.B.1.a) in low dilution waters (where effluent flow is equal to or greater than 7Q10 flow). The proposal explained the basis for precluding the TSD procedure in low dilution waters: that the statistical approach described in procedure 5.B.1.d of appendix F of the proposal, the TSD approach, does not provide a separate explicit mechanism to account for the need for additional assurances in low dilution streams. Rather, the approach addresses this factor implicitly in the selection of the confidence level used. In instances of low dilution streams, a permitting authority could use a higher confidence level to increase the likelihood that a WQBEL will be required and thereby provide the appropriate level of additional assurance. EPA proposed precluding the use of the TSD approach in low dilution waters because the TSD does not include specific guidance on how high to adjust the confidence level in these situations. EPA invited comment on whether the TSD approach should also be available as an option to the permitting authority.

ii. Comments: EPA received numerous comments on the use of only one-half of the PEL for comparison to PEQ in low dilution waters (low dilution provision). None of the comments EPA received on the low dilution provision expressed support for it. The comments generally opposed the low dilution provision proposed at 5.B.2, suggesting that it is excessively conservative, without technical merit, and unwarranted. Commenters pointed out that the PEQ procedure is already conservative and that the extra layer of conservatism of the low dilution procedure would be unnecessary. Commenters also pointed out that the allowable dilution, which is required to be factored into the PEL calculation, automatically results in discharges to low dilution streams being judged differently than discharges to high dilution streams. EPA interpreted this comment to mean that the amount of available dilution in the receiving water is already accounted for when calculating the PEL. Commenters further pointed out that even if the low dilution provision were necessary, and they argued that it is not, reducing the PEL by a factor of two would be arbitrary.

iii. Final Guidance: EPA was persuaded by the numerous comments opposing the low dilution provision. Commenters pointed out that EPA had not shown this extra conservative assumption to be warranted, especially because the available dilution, or lack thereof, is expressly accounted for when calculating the preliminary wasteload allocation. Commenters pointed out, EPA believes correctly, that the actual amount of dilution available in any particular receiving water is specified in the dilution calculations required by procedure 5.A.1-2 of the final Guidance. Where little dilution is available due to the small size of the receiving water, this fact is accounted for in the dilution calculation. Furthermore, the PEQ statistical procedure is, by design, conservative. As noted above, the PEQ will in the vast majority of cases be greater than the observed maximum effluent concentration. Because the PEL calculation includes a dilution factor and because PEL is compared to an intentionally conservative PEQ, EPA is persuaded that the low dilution provision is not warranted as a general practice. EPA believes it is more appropriate to leave to the permitting authority the discretion to adopt a more conservative approach to address, on a case-by-case basis, those rare instances additional caution is warranted, for example when PEQ is less than the actual effluent concentration and dilution is very low.

Therefore, the final Guidance does not require States to adopt the proposed low dilution provision that would require the permitting authority to compare the PEQ to 50% of the PEL when the effluent flow is equal to or greater than the stream seven-day, 10-year flow. EPA notes, however, that States have the flexibility to exercise caution on a site-specific basis where, for example, due to lack of available dilution, there is a possibility that a discharge could result in environmental harm. Where such circumstances exist, State procedures can include the flexibility to make a finding of reasonable potential, where such a finding would not be made using the procedures specified in the final Guidance.

e. <u>Determining Reasonable Potential in the Absence of Facility Specific Effluent Monitoring Data.</u>

i. <u>Proposal:</u> The proposal would not have established any new or specific provisions addressing how to determine the need for WQBELs in the absence of effluent data for a specific facility. Instead, the proposal would have relied on the existing regulations and procedures for determining the need for WQBELs contained at 40 CFR 122.44(d)(1) and guidance in Chapter 3 of the TSD.

The proposal solicited comments on whether existing guidance is sufficient for determining the need for WQBELs in the absence of facility specific effluent monitoring data, and on whether minimum data requirements should be specified in the final Guidance. EPA also solicited comments on any alternative procedures for making the determination of the need for WQBELs in the absence of facility-specific effluent data.

ii. <u>Comments:</u> EPA received a few comments on guidance for determining the need for WQBELs in the absence of facility specific effluent monitoring data. In general, commenters agreed that existing EPA procedures and guidance for determining the need for WQBELs in the absence of facility specific effluent monitoring data are sufficient and provide an appropriate level of flexibility to permitting authorities to use professional judgement.

EPA received one comment suggesting an alternative procedure for making the determination of the need for WQBELs for human health protection in the absence of facility-specific effluent data. The commenter suggested that depending on the extent of data available on a chemical in question, reasonable potential could be determined based on an appropriate surrogate chemical. The commenter suggested that such a determination may be suitable for regulatory purposes, provided there is sufficient certainty that the surrogate chemical will estimate an acceptable environmental concentration for the chemical lacking sufficient data. The commenter suggested that this surrogate chemical approach would not be accurate and defensible enough to use in establishing a specific numeric value for a regulatory purpose, i.e., permit limit, cleanup limit, etc., but that the process would be suitable for determining the necessity of generating further data on the chemical in order to calculate a permit limit, or, to determine if a sufficient margin of safety exists in establishing a permit limit based on another toxicity characteristic of a chemical (e.g., aquatic toxicity), which is sufficiently protective of human health and wildlife. The commenter noted that the determination of the need for additional data collection, and reasonable potential, could be made using an appropriate surrogate chemical provided there is sufficient data, the investigator is qualified, and there is sufficient certainty that the surrogate chemical estimate is an acceptable environmental concentration for the pollutant in question.

EPA agrees that such determinations may be made using data and information other than specific effluent data for the pollutant of concern provided there is sufficient certainty that surrogate chemical data estimate an acceptable estimated concentration of the pollutant in question. The final guidance maintains the provision at 5.C.3 that provides permitting authorities with the flexibility to determine reasonable potential and to incorporate

WQBELs into permits, in the absence of chemical-specific data for the pollutant of concern. In addition, section 5.C.1 of appendix F of the final guidance specifies that permitting authority use all available, relevant information, including Quantitative Structure Activity Relationship information and other relevant toxicity information, to estimate ambient screening values that will protect humans from health effects other than cancer, and aquatic life from acute and chronic effects, for pollutants that a permittee reports as known or believed to be present in its effluent, and for which pollutants, data sufficient to calculate Tier II values for non-cancer human health, acute aquatic life and chronic aquatic life do not exist. The surrogate pollutant approach suggested by the commenter is an approach that could be used to determine the ambient screening values under this provision.

Several commenters raised concerns about using very small effluent data sets as the basis for specifying PEQ. Some commenters suggested that EPA should add minimum data requirements to the final Guidance. Section E.2.c.ii above discusses these comments in more detail.

iii. Final Guidance: Consistent with the proposal, this Guidance does not establish any new or specific provisions addressing how to determine the need for WQBELs in the absence of effluent data for a specific facility. In these instances, the permitting authority must continue to apply existing regulations and procedures consistent with 40 CFR 122.44(d)(1) to determine on a case-by-case basis whether WQBELs are necessary. EPA's existing guidance recommends that the regulatory authority use a variety of factors and information when determining whether or not a discharge will cause, has the reasonable potential to cause, or contributes to an excursion of a water quality standard if facility-specific effluent monitoring data are unavailable. (See TSD at pp. 50-55.) At a minimum, existing regulations require the permitting authority to consider the four factors identified in 40 CFR 122.44(d)(1)(ii) in making a reasonable potential determination regardless of the availability of facility-specific effluent monitoring data.

If the permitting authority, after evaluating all available information on the facility, is not able to determine whether the discharge will cause, has the reasonable potential to cause, or contributes to an excursion above a water quality standard, existing EPA guidance recommends that the authority should require whole effluent toxicity or chemical-specific effluent monitoring to acquire additional data. The permitting authority should require the monitoring prior to permit issuance, if sufficient time exists, or as a condition of the issued or reissued permit. If monitoring is required after permit issuance, the permitting authority should also include a specific reopener clause to allow for subsequent modification of the permit to include a WQBEL if the monitoring establishes that the discharge causes, has the reasonable potential to cause, or contributes to an excursion above a water quality criterion. (See TSD at p. 55)

f. Determining Reasonable Potential for Pollutants When Tier II Values are Not Available.

i. Proposal: Procedure 5.D of appendix F of the proposed Guidance specified procedures for determining whether permitting authorities must generate, or require permittees to generate, data sufficient to calculate Tier II values when pollutants on Table 6 are known or suspected of being discharged into the Great Lakes System, but neither Tier I criteria nor Tier II values have been derived due to a lack of toxicological data. EPA recognized in the proposal that it is preferable to have Tier I criteria available to compute WQBELs in all circumstances. However, the development of Tier I criteria is often costly and time-consuming. In the absence of a Tier I criterion, the permitting authority must have some mechanism with which to interpret and ensure that the narrative prohibition against the discharge of toxic substances in toxic amounts is reflected in permits (40 CFR §122.44(d)(1)(vi)).

The proposed Guidance included the use of a Tier II methodology to derive values in the absence of Tier I criteria. Consistent with this decision, procedure 5.D of appendix F of the proposal contained a methodology for determining whether Tier II data must be generated by the permitting authority or discharging facility to determine the need for a WQBEL for a pollutant in the NPDES permit.

Procedure 5.D.1 of appendix F of the proposed Guidance stated that the permitting authority would use all available, relevant information including Quantitative Structure Activity Relationship (QSAR) information and other relevant toxicity information to develop "ambient screening values" for each of the following water quality criteria categories: aquatic life (acute and chronic); wildlife; and non-cancer human health for pollutants included in Table 6 of the proposed Guidance. These ambient screening values were proposed to be specified at a level which would not be expected to cause an excursion of the narrative water quality standard. The proposal also referenced examples of development of ambient screening values in "Technical Support Document: Establishment of Ambient Screening Values under the Great Lakes Water Quality Initiative," February 1993, which is available in the administrative record for this rulemaking.

The proposed Guidance would have required that the permitting authority apply the appropriate procedure described in procedure 5.A of appendix F of the proposal to calculate a preliminary wasteload allocation and preliminary effluent limitation using the ambient screening value. If, based on this information, the permitting authority concluded the discharge would cause, had the reasonable potential to cause, or contributed to an excursion above an ambient screening value, the regulatory authority, under the proposal, would be required to either generate or require the permittee to generate the data necessary to derive Tier II values for the protection of aquatic life, wildlife, and human health for the pollutant in Table 6. Once sufficient data were generated to calculate a Tier II value, the proposal required the permitting authority to follow the procedures set forth in procedures 5.A through 5.C of appendix F to determine whether a WQBEL must be incorporated into an NPDES permit based on the Tier II value.

EPA proposed procedures 5.D.1 and 5.D.2 of appendix F to implement the existing NPDES regulations at 40 CFR 122.44(d)(1)(vi). These regulations direct permitting authorities, in the absence of an applicable numeric water quality criterion, to establish effluent limitations for pollutants that cause, have the reasonable potential to cause, or contribute to an excursion of a narrative water quality criterion using one or more of the following options: calculate a site-specific numeric criterion; use EPA's water quality criteria (developed in accordance with section 304(a) of the Clean Water Act) supplemented where necessary by other relevant information; or establish effluent limitations on an indicator pollutant.

The proposed Guidance in procedure 5.D.1 of appendix F to part 132 did not require the permitting authority to estimate ambient screening values or to generate or require the generation of data sufficient to develop a Tier II value for human health based on carcinogenic effects.

The proposed Guidance in procedure 5.D.2 of appendix F also did not require the development of a Tier II value for the protection of aquatic life if the permittee demonstrated through a biological assessment that there are no acute or chronic effects on aquatic life in the receiving water and that the whole effluent does not exhibit acute or chronic toxicity based on the requirements in procedure 6 of appendix F. The proposed procedure 5.D.2 of appendix F did not allow this aquatic life Tier II exception for bioconcentratable chemicals of concern (BCCs) as defined in 132.2 of the proposed Guidance, because whole effluent toxicity tests are not designed to measure important impacts from these pollutants resulting from elevated tissue concentrations over time.

Procedure 5.D.3 of appendix F of the proposed Guidance stated that, where there was insufficient information to develop a Tier II value, nothing in procedure 5.D of appendix F would preclude or deny the right of a State or Tribe to determine in the absence of the data necessary to derive a Tier I criterion or a Tier II value, that the discharge of a pollutant will cause, have the reasonable potential to cause or contribute to an excursion above the State's narrative criterion for water quality or incorporate a WQBEL for that pollutant in a NPDES permit. This provision was consistent with section 510 of the Clean Water Act which expressly retains the State's authority to adopt and enforce standards, limitations or requirements more stringent than those in effect under the Clean Water Act. Proposed procedure 5.D.4 of appendix F clarified that if the permitting authority developed a WQBEL pursuant to procedure 5.D.3 of appendix F under other more stringent authority, it would not be obligated to generate or require the permittee to generate the data necessary to derive a Tier II value for that pollutant.

ii. Comments: EPA received numerous comments objecting to several aspects of the Tier II data collection and value generation requirements proposed at 5.D of appendix F. In addition to raising concerns, some commenters requested clarification on the extent to which professional judgement can be the basis for determining when there is sufficient data to generate a Tier II value.

Commenters suggested that requiring the discharger to generate Tier II values for each type of criteria end point regardless of whether the available, relevant information indicates that all of these target populations (i.e., aquatic life, humans, or wildlife) would actually be at risk would be inappropriate. Commenters explained that Tier II values should be developed by the permitting authority only for those target populations which are actually at risk. For example, where screening values clearly show the pollutant to be primarily an aquatic life concern, data to calculate a Tier II human health value should not be necessary.

Several commenters explained that the data collection necessary to calculate Tier II values and the calculation of such values would be expensive and time consuming and as a result, difficult for States to accomplish, especially given that the ambient screening values are loosely defined. Other commenters explained that because Tier II data collection and value generation would be expensive and time consuming, States would tend to pass the responsibility on to the dischargers. Commenters questioned whether the expense of Tier II data collection and value generation should be passed on to dischargers. Commenters also pointed out that the Tier II data collection and value generation requirements would tend to result in duplicative efforts, i.e., multiple states and dischargers would collect Tier II data and generate values unbeknownst to the other states and dischargers. One side effect of this would be that conflicting Tier II values would be generated.

In addition, commenters suggested that the Tier II values should not be used as the basis for permit limits, claiming that the Science Advisory Board did not support use of Tier II values as the basis for permit limits, but rather, supported their use only as screening values to determine when additional toxicity data for a particular chemical needed to be collected. In addition, some commenters suggested that Tier II-based limits would, by design, be overly conservative. Several commenters objected to the proposal that would require dischargers to spend money for additional effluent controls to meet Tier II values that the commenters suggest are overly conservative and in some cases incorrect.

In response to commenters concerns about the scientific validity of ambient screening values, EPA acknowledges that the establishment of ambient screening values involves a considerable amount of judgment by the permitting authority in the face of scientific uncertainty. EPA believes, however, that the mere absence of a Tier II value for a particular pollutant does not take away from the permitting authority the obligation to ensure that a pollutant discharge that has the reasonable potential to cause or contribute to an excursion above water quality standards is subject to appropriate restrictions. See 40 CFR 122.44(d)(1). It therefore behooves the permitting authority to use the best available information to make this judgment. EPA also emphasizes that ambient screening values are just that - "screening" values that do not in and of themselves result in the establishment of any enforceable conditions on the permittee. Rather, the projected exceedance of the screening value is a trigger for the development of more information (Tier II data collection and values) that would enable the permitting authority to determine the need for a WQBEL and derive the WQBEL if necessary. As for the concern about the burden associated with generating Tier II values, as discussed in the section II.C.2 of this document, Adoption and Application of Tier II Methodologies, EPA believes that there should not be a significant number of pollutants for which additional Tier II data will need to be collected, in light of the fact that most of the pollutants of initial focus already have, in EPA's view, enough information available to generate Tier I criteria or Tier II values.

EPA also received a few comments on the exception to Tier II data collection and value generation requirements proposed at 5.D.2 of appendix F (Tier II exception). Commenters generally supported the Tier II exception, noting that it would provide needed flexibility to permitting authorities to utilize bioassessment and whole effluent assessments to characterize impacts to aquatic life in receiving waters. In voicing support for the Tier II exception, two commenters explained that the whole basis of this regulatory program should be the reasonable protection of humans and valued resources. They went on to explain that even though EPA sometimes refers to independent applicability of the various measures of protection, the real measure of the protection is whether there is any instream impact. When considering aquatic life criteria, impact is demonstrated not to exist where whole effluent toxicity testing and biological assessment shows no acute or chronic toxicity. At that point, the goal has been reached. Any additional protection based on statistical procedures and/or aberrations is, according to the commenters, a waste of resources.

EPA does not share the commenters' belief that a measurement of whole effluent toxicity instream is the only valid measure of adverse water quality impacts. Water quality-based permitting requirements are intended, as the commenters suggest, to prohibit discharges that cause environmental impacts such as acute and chronic aquatic life toxicity. Such controls, however, are also intended to prevent environmental impacts "before" they occur. If one is detecting adverse impacts in the receiving water, it often is an indication that the preventative aspect of the program has failed. EPA notes that procedure 5 of appendix F of the final Guidance, like the proposal, is intended to result in WQBELs to ameliorate discharges that are already causing measurable environmental impacts, as well as discharges that demonstrate the reasonable potential to cause such impacts.

EPA notes that the exception to Tier II value generation for aquatic life protection has been retained in the final Guidance at 5.C.2. EPA notes that, as in the proposal, this exception is for aquatic life Tier II values only and that in addition to the WET and biological assessment conditions described in the comment, the third condition that must be met in order to exercise the exception is that there must be insufficient data to calculate a Tier I criterion or a Tier II value for aquatic life. Where such data are available, the exception to Tier II value generation does not apply.

One commenter suggested that the Tier II exception should not be limited to non-BCCs and should be expanded to include BCCs. In response and as noted above, and in the preamble to the proposal, the proposed procedure 5.D.2 of appendix F did not allow this aquatic life Tier II exception for bioconcentratable chemicals of concern (BCCs) as defined in 132.2 of the proposed Guidance, because whole effluent toxicity tests are not designed to measure important impacts from these pollutants resulting from elevated tissue concentrations over time.

iii. Final Guidance: The proposed requirements remain essentially intact in today's guidance and would require permitting authorities to develop ambient screening values, develop PELs based on the ambient screening values, and compare PEQ with PEL for purposes of determining when permitting authorities are required to collect Tier II data, generate tier II values, and develop permit limitations to protect the Tier II values from being exceeded. There is, however, one important change from the proposal. Unlike the proposal, the final Guidance does not require use of the Tier II methodology for wildlife. Like the proposal, 5.C.1.d of the final Guidance provides that the permitting authority, in the absence of a Tier I criterion, would generate or require the permittee to generate data to derive a Tier II value. Like the proposal, the final Guidance provides that the permitting authorities would use the Tier II methodology to generate Tier II values for protection of non-cancer human health, acute aquatic life and chronic aquatic life, but unlike the proposal, use of the Tier II methodology for wildlife protection by the permitting authorities is optional. Likewise, 5.D.1.e of the final Guidance, unlike the proposal, does not require Tier II permit limitations for wildlife.

EPA would like to clarify that States and Tribes may use the scientific defensibility exclusion to avoid the data generation requirements in procedure 5.C.1.d of appendix F for pollutants which are not amenable to toxicological testing as commonly practiced. In these situations, a State, Tribe, or discharger would need to demonstrate experimentally that the chemical is not amenable to testing and provide documentation for this finding. For a more thorough discussion on the use of the Tier II methodology, Tier II data quality assurance, the steps EPA is taking to minimize the burden on States and dischargers in the collection of Tier II data and calculation of Tier II values, and the development of Tier II values for wildlife, see section II of this document on Tier II regulatory requirements and Tier II methodologies.

In addition, an important clarification of the exception from Tier II data collection, value generation and permit limit requirements for the protection of aquatic life ("Tier II aquatic life") is necessary. The final Guidance, at 5.C.2, maintains the exception to Tier II aquatic life contained in the proposal and discussed above. A permitting authority would not be required to generate Tier II data or values, or establish Tier II permit limitations in a permit for an existing discharge, for other than bioaccumulative chemicals of concern if: there is insufficient data to calculate a Tier I criterion or Tier II value for aquatic life for such pollutant; the permittee has demonstrated through a biological assessment that there are no acute or chronic effects on aquatic life in the receiving water; and the permittee has demonstrated in accordance with procedure 6 of this appendix that the whole effluent does not exhibit acute or chronic toxicity.

The preamble to the proposed guidance discussed this three-part test in the context of EPA's existing regulations governing the use of indicator pollutants in establishing WQBELs. Upon further consideration, EPA believes that this discussion in the preamble to the proposal was misplaced and therefore may have resulted in confusion regarding the precise context for the exception under section C.2 of procedure 5. In implementing this provision, EPA believes that the permitting authority would simply determine, in accordance with procedure 6, whether the effluent exhibited whole effluent toxicity. If toxicity was not found (and the other two conditions in section C.2 were met), then the permittee would be exempt from tier II data generation requirements. The discussion in the preamble to the proposed rule of the imposition of a WET limit under section C.2. was therefore besides the point, since such a limit would not be appropriate if the discharge were found not to exhibit whole effluent toxicity.

In order to provide clarification on this point, the condition at 5.D.2.c of the proposed Guidance that would have to be met for a discharge to be excepted from Tier II aquatic life requirements is maintained in the final

Guidance at 5.C.2.c with one change. The condition at 5.C.2.c has been clarified to say that, to fulfill the condition at 5.C.2.c of the final Guidance, the permitting authority must determine in accordance with procedure 6 of the final Guidance not only that the discharge does not exhibit WET, but also that limits for whole effluent toxicity are therefore not required.

Because the preamble discussion in the proposed Guidance discussed the condition at 5.D.2.c (final 5.C.2.c) in the context of EPA's indicator parameter regulation, it was unclear regarding whether satisfying condition 2.c, alone, would exempt the permitting authority from the requirement to generate Tier II data and calculate a Tier II value. EPA intended that the proposed conditions for exemption from Tier II aquatic life at 5.D.2.a-c would "all" have to be met in order for the permitting authority to exempt a discharger from tier II data collection, value generation and limits. EPA received no significant comments suggesting that a WET limit alone, or indicator parameter limit alone, should except a permitting authority from the Tier II requirements. Therefore, the final Guidance, at 5.C.2.a-c, maintains the conditions for exception from the Tier II requirements. Neither a finding of no WET in the discharge, nor use of WET as an indicator parameter limit, alone, is sufficient basis to exempt the permitting authority from Tier II data collection and value generation requirements. The permitting authority can only be exempted from Tier II data collection and value generation requirements by satisfying each of the conditions in 2.a-c. The permitting authority may, as described in the preamble to the proposal, include an indicator parameter limit in the permit in lieu of the tier II limit provided the requirements in the existing regulations at 40 CFR 122.44(d)(1)(vi)(C) are met. EPA notes that the Tier II procedure for aquatic life in the final guidance is the required method for interpreting state narrative criteria that protect aquatic life. Therefore, once a Tier II value is determined for a pollutant of concern, an indicator parameter limit used in lieu of a Tier II-based limit for the pollutant of concern must, in order to be used, be shown to attain and maintain the Tier II value for the pollutant of concern. Such a showing must be made in order to fully meet the requirements of 122.44(d)(1)(vi)(C).

The proposal stated that EPA believes that WET can serve as an indicator parameter under appropriate circumstances. Having received no public comments to the contrary, EPA stands by its statement. EPA notes that WET is by no means the only parameter that can serve as an indicator parameter under 122.44(d)(1)(vi)(C). EPA also notes that whenever an indicator parameter limit is used for a WQBEL, the conditions at 122.44(d)(1)(vi)(C) must be met.

Finally, the proposed guidance specified at 5.D.3 and 4 is retained essentially intact in the final Guidance. These proposed provisions stated that, "3. [n]othing in sections D.1 or D.2 shall preclude or deny the right of a permitting authority to: a. [d]etermine, in the absence of the data necessary to derive a Tier II value, that the discharge of the pollutant will cause, have the reasonable potential to cause or contribute to an excursion above a narrative criterion for water quality; and b. [t]o incorporate a WQBEL for the pollutant into an NPDES permit. 4. If the permitting authority develops a water quality-based effluent limitation consistent with section D.3 of this procedure, it shall not be obligated to generate or require the permittee to generate the data necessary to derive a Tier II value or values for that pollutant." The provision at 5.C.4, (proposed 5.D.4) has been changed to clarify an issue raised by commenters. Commenters pointed out that the proposed provisions at 5.D.3 and 4 seemed to provide maximum flexibility to permitting authorities to derive and require WQBELs using procedures in lieu of the Tier II provisions for generating data and values. The preamble to the proposal explained that the proposed provision at 5.D.4 could only be exercised by a permitting authority where the result would be a WQBEL more stringent than one based on a Tier II value. The change to the language at C.4 of procedure 5 of appendix F of the final Guidance clarifies that an alternative WQBEL under C.4, one not based on a Tier II value, must be shown to be more stringent than a Tier II-based limit would have been in order for such a limit to negate the need for a Tier II-based limit. One effect of this clarification is that it eliminates the possibility that this provision would result in less stringent requirements than would have been obtained under the approach in the final Guidance. Under C.4, a permitting authority could not, for example, choose to forgo generating a Tier II value without showing that the WQBEL derived using alternative procedures under C.3 would be at least as stringent as the tier II-based limit would have been. This would occur where the alternative limit under C.3 is zero. In this example it is clear that the alternative limit is at least as stringent as the tier II-based limit would have been. This clarification is consistent with the principle that States can, under 510 of the Act, be more stringent than EPA.

g. Determining Reasonable Potential Using Fish Tissue Data

i. Proposal: Procedure 5.F.3 of appendix F of the proposal would require that permitting authorities establish a WQBEL if the discharger has a pollutant in its effluent at detectable levels and fish tissue from the water body also contains the pollutant at levels that exceed the tissue basis of the water quality criteria. This provision would apply to instances where proposed procedures 5.B and 5.C of appendix F did not project the reasonable potential of a discharger to cause or contribute to an excursion above a Tier I criterion or Tier II value but tissue data from ambient fish sampling demonstrates an excursion. These instances occur when ambient water concentration monitoring either does not include the pollutant of concern or else the pollutant is present in ambient waters at a level below the ability of analytical chemical methods to detect or quantify. Nevertheless, the presence of the pollutant in fish tissue at levels that exceed the tissue basis of the Tier I criterion or Tier II value demonstrates that the criterion or value is not met. Under NPDES regulations at 40 CFR 122.44(d)(1)(i), a WQBEL is required for that pollutant or pollutant parameter whenever there is information that demonstrates that the discharge of a pollutant causes or contribute to such an excursion. The provisions of proposed procedure 5.F.3 of appendix F would implement the requirements of 40 CFR 122.44(d)(1)(i) with respect to ambient fish tissue data.

ii. Comments: EPA received several comments on the provision proposed at 5.F.3 of appendix F specifying the use of fish tissue data for purposes of determining reasonable potential. Several commenters opposed retaining the provision that would require fish tissue as the basis for reasonable potential determinations, citing various difficulties with the approach. Other commenters supported the use of tissue data, but suggested that the approach needed to be better explained, particularly in the areas of determining the relevance of the tissue data to the discharge and whether the discharge is actually contributing to the tissue contamination. One commenter strongly supported the use of fish tissue data as a required basis for determining reasonable potential.

The commenter that strongly supported the use of fish tissue data as a required basis for determining reasonable potential suggested the provision should be expanded to require the development of numeric permit limits to implement narrative criteria for any discharge of a pollutant that has resulted in or contributed to the issuance of a fish consumption advisory downstream of the discharge (including in the open waters of the Great Lakes). The commenter explained that the issuance of fish consumption advisories by a State, Tribal or federal agency represents, in effect, a determination that the subject waters have not achieved the "fishable waters" goal of the Clean Water Act, i.e. that narrative criteria prohibiting toxic pollutants in toxic amounts are being violated. The commenter concluded that any discharge of such a pollutant is, by definition, contributing to a criteria violation and requires a WQBEL.

Commenters that opposed the use of use of fish tissue data as a required basis for determining reasonable potential explained that using fish tissue data in permitting is technically difficult due to the variability of the data and the difficulty of pinpointing contributing sources. These commenters also suggested that the use of the word "detectable" in the fish tissue provision incorrectly implies that there is no threshold of effect, i.e., one molecule is enough to cause unacceptable bioaccumulation.

The commenters that supported the use of tissue data, but suggested that the approach needed to be better explained, pointed out that permitting authorities should have the flexibility to determine the relevance of tissue data to any particular discharger in question.

One commenter suggested that EPA needed to clarify what is meant by "detectable level" in a facility's discharge, pointing out that some analytical methods are more innovative and sensitive than others. The commenter suggested that EPA should clarify its intent as to whether innovative methods should be employed in a reasonable potential context.

Another commenter requested clarification on whether fish tissue data under proposed procedure 5.F.1 should be obtained through caged or ambient fish tissue studies.

Other commenters suggested that the use of resident fish tissue data is without sufficient scientific basis for use in the reasonable potential procedures. These commenters expressed concern that fish tissue data is unreliable. The commenters also suggested that such data does not lead to those sources which contribute to the problem. The commenters suggested that this procedure, if it is used, should cause permit limits to be generated for those facilities contributing a level of the pollutant high enough to be of concern. The commenters expressed concern that the proposed procedure would result in the generation of many unnecessary permit limits throughout the region resulting in monitoring costs that would squander resources that would better be applied to other uses.

The preamble to the proposal discussed the need for permitting authorities to use care in determining what tissue data are representative of ambient conditions. Care in judgement by the permitting authority should be taken in assuring that the fish tissue data is representative of the ambient conditions in the discharger's receiving water, and relevant to the discharger's effluent.

iii. Final Guidance: This provision on fish data remains essentially unchanged from the proposal and is located in the "Other Applicable Conditions" section at 5.F.4 of appendix F of the final Guidance. However, the words "to that water" have been added to 5.F.4 to clarify that a discharger must discharge detectable levels of the pollutant to the waterbody, the condition of which is reflected by the fish tissue data, to be required to have a WQBEL for such pollutant under this provision. This change simply clarifies the intent of the proposal.

This provision does not exclusively link the need for WQBELs for a discharge to the existence of a fish advisory on the receiving water, but it does require a WQBEL for pollutants found in the discharge that are also found in tissue of fish from the receiving water at levels that exceed the tissue basis of the criteria or values. EPA expects there to be a correlation between fish advisories and tissue levels that exceed the tissue bases for the criteria or values. However, it is possible that a fish advisory could be in place, where tissue data from the receiving water shows the mean tissue value for a particular pollutant to be below the tissue bases for the applicable criterion or value for that chemical. Therefore, the provision at F.4 does not automatically require WQBELs for discharges containing the chemical for which a fish advisory has been issued.

EPA recognizes that the existence of a pollutant at a detectable level in an effluent that is also found in tissue from the receiving water at levels that exceed the tissue bases of the applicable criteria or values is not necessarily an indication that the discharge of the effluent is solely the cause of the fish contamination, or even a substantial contributor of such contamination. However, such a finding is an indication that the discharge of the effluent is a possible contributor of such contamination and therefore exhibits the reasonable potential to cause or contribute to the excursion above applicable water quality standards. EPA notes that the reasonable potential procedures as a whole are intended as a conservative screening procedure to determine where a discharge should contain a WQBEL to either prevent possible future contamination or curtail the contribution to existing contamination. EPA also notes that the reasonable potential procedure, while specifying whether a discharge must have WQBELs, does not specify the actual value of the permit limitation. Hence, where reasonable potential is found under this tissue provision, the permit limit will not necessarily be required to be set at the detection level, but could, as noted in the discussion in section h below, be set at the applicable criteria level, or, through a TMDL at a different level if appropriate.

EPA recognizes that when evaluating reasonable potential under this tissue provision, the permitting authority will need to exercise discretion and careful judgement in determining whether fish tissue data are representative of ambient conditions and in determining the relevance of fish tissue data to any particular discharger. EPA guidance on these considerations is provided in "Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish: A Guidance Manual" (USEPA September 1989, EPA-503/8-89-002), which is available in the administrative record for this rulemaking.

EPA recognizes that there can be wide differences in the detection level of different chemical analytical methods and analysts, and that different methods and analyses for detecting and measuring the same chemical will have different detection levels. EPA notes that the reasonable potential procedures in the final Guidance do not require the generation of effluent data, only that existing effluent data be used when determining reasonable potential. In using existing effluent data, EPA recommends that the detection level of the analytical method employed be recorded in the record of the reasonable potential decision by the permitting authority. In addition, when requiring collection of effluent data for purposes of determining reasonable potential, EPA recommends that the permitting authority specify the use of analytical methods that are sensitive enough to detect in the range of the tissue basis of the criteria or value, or where commonly used analytical methods are not sensitive enough to detect at such level, specify the most sensitive commonly used method.

As discussed in section VIII.C of this document, EPA recognizes that both caged fish and resident fish studies can yield valid results indicating the level of contamination in fish in a waterbody. As noted above, EPA recognizes that permitting authorities will need to exercise careful judgement in determining the scientific validity of any fish tissue study, whether the study results are representative of the condition of the receiving water, and the relevance of the tissue data to any particular discharge.

Procedure 5.F.4 of appendix F compares the geometric mean of tissue samples collected from ambient fish to the tissue basis of the Tier I criterion and Tier II values for human health and wildlife protection. The tissue basis is equal to the bioaccumulation factor that was used to calculate the Tier I criterion or Tier II value multiplied by the Tier I criterion or Tier II value. The tissue basis for the same pollutant may differ for human health and wildlife criteria and values; if any tissue basis is exceeded, reasonable potential exists with respect to facilities discharging detectable levels of the pollutant. The mean of the ambient data is used in the comparison to be consistent with the assumptions of the criteria, that is, wildlife and human consumers of fish eat an assemblage of fish. A mean best reflects this assemblage. The geometric mean is used as the most representative way to reflect the average of environmental samples.

Procedure 5.F.4 of appendix F also recognizes that there may be differences in tissue concentrations between fish samples collected from a specific water body. The reasons for this include differences in lipid content between fish, the ages of fish, and the actual exposure of individual fish. The use of a geometric mean in the comparison serves to overcome some of the inherent variability because the mean reduces the effect of any one sample. However, there may be still be some variability associated with using fish tissue data. Therefore, procedure 5.F.4 of appendix F directs the permitting authority to consider the variability of a pollutant's bioconcentration and bioaccumulation in fish. The assessment of the variability may be accomplished by applying specific factors to adjust for differences in lipid content or age, or by applying an overall factor based on review of the variability in literature or field data. Whatever method is used by the permitting authority must be described in the administrative record supporting the permit decision.

Procedure 5.F.4 of appendix F applies to all facilities that discharge detectable levels of a pollutant into a water body where the pollutant is found in the fish tissue in the water body at levels exceeding the tissue basis of a Tier I criterion or Tier II value. This provision recognizes that all facilities that discharge detectable levels of the pollutant into the water body are contributing the pollutant and therefore meet the requirements of 40 CFR 122.44(d)(1)(i).

h. Basis for Effluent Limitations

As noted in the discussion of general requirements of procedure 5 above, sections C and D of appendix F of the final Guidance provide that, regardless of the manner in which the reasonable potential determination is made, all effluent limitations must comply with all other applicable State, Tribal and Federal requirements. This statement was in the proposal and remains intact in the final Guidance. However, as noted above, EPA has clarified, in response to public comments, the connection between procedure 3 (TMDL procedure) and procedure 5 (Reasonable Potential procedure). The final Guidance omits from procedure 3 the proposed provision that would have required a TMDL under 40 CFR 130.7 for each pollutant (and waterbody) for which there is reasonable potential that a discharge causes, has the reasonable potential to cause, or contributes to an excursion above the applicable water quality standards. Therefore, while a finding of reasonable potential continues to require a WQBEL, it no longer requires a TMDL as the basis of that WQBEL. In light of this change, EPA concluded it was necessary to include in procedure 5 the basis for developing wasteload allocations from which to derive WQBELs in the absence of a TMDL under 40 CFR 130.7. Therefore, the final Guidance contains a new provision at section F.2 in procedure 5 of appendix F. This provision specifies that once the permitting authority has determined in accordance with procedure 5 that a WQBEL must be included in an NPDES permit, the permitting authority shall: 1) Rely upon the wasteload allocation established for the point source as part of any TMDL prepared under procedure 3 of this appendix F and approved by EPA pursuant to 40 CFR 130.7, or, in the absence of such TMDL, calculate wasteload allocations for the protection of acute and chronic aquatic life, wildlife and human health using, at a minimum, the procedures set forth in section A.1 of procedure 5 for developing preliminary wasteload allocations; and 2) develop effluent limitations consistent with these wasteload allocations in accordance with existing State or Tribal procedures for converting wasteload allocations into water quality-based effluent limitations. Similar conforming changes have also been made to procedure 4.C to address TMDLs, wasteload allocations, and preliminary wasteload allocations. In making this clarification, EPA is remaining consistent with its intent expressed in the proposal that WQBELs be consistent with calculated wasteload allocations.

By including a separate provision in the final guidance addressing procedures to be followed in deriving WQBELs in the absence of a TMDL, EPA has not made a substantive change from the approach contained in the proposal. As discussed above, the structure of the proposed guidance would have called for the development of a TMDL for the purpose of deriving wasteload allocations where the permitting authority determined reasonable potential existed. The final Guidance has simply "moved" those procedures into a new subsection, 5.F.2.a., of appendix F of the Guidance. This "move" is necessitated by the fact that, under the final Guidance, the actual development of a TMDL is not a prerequisite to the establishment of a wasteload allocation and permit limits.

Finally, it is important to note that, as discussed in section VIII.C of this document, the final Guidance does not, like the proposal, require wasteload allocations to be set equal to zero in cases where background concentrations of the pollutant in the receiving water exceed criteria or values (non-attained waters), and a multiple source TMDL has not been completed. As noted in section VIII.C of this document, EPA did not include this provision (high background provision) in the final Guidance because setting a wasteload allocation at zero as a default, in the absence of a TMDL, may not be appropriate in many situations. EPA recognizes that many factors need to be considered when background water quality concentrations exceed criteria or values. Furthermore, many commenters objected to a mandate of setting wasteload allocations equal to zero in non-attained waters unless a multiple source TMDL has been completed. Commenters pointed out that such a mandate would, in effect, force all point sources to achieve zero discharge of pollutants to non-attained waters.

Once EPA concluded that it was inappropriate to include the high background provision in the final Guidance, EPA then had to determine if there is an appropriate alternative to the high background provision. Commenters suggested a range of alternatives for setting wasteload allocations for discharges to non-attained waters in the absence of a multiple source TMDL. The suggested alternatives ranged from setting the wasteload allocation to the most stringent applicable criterion up to setting the wasteload allocation equal to the background concentration of the receiving stream. Others suggested that the wasteload allocation be set equal to the greater of the most stringent applicable criterion or the background concentration. EPA examined these suggested alternatives to determine which of them were permissible readings of the national program requirements under the CWA.

Upon review of the alternatives suggested by commenters, EPA notes that in the absence of a TMDL under 40 CFR 130.7, there are several reasonable interpretations of national program requirements under the CWA. One reasonable interpretation of national program requirements is that in non-attained waters and in the absence of a TMDL under 130.7, the wasteload allocation for a pollutant for which the waterbody is in non-attainment, may be set equal to the most stringent criterion or value applicable to the waterbody (criteria end-of-pipe). The concept of a mixing zone to provide for dilution obviously is not relevant where the stream already exceeds the water quality criterion. EPA believes that this approach is consistent with existing regulatory provisions relating to water quality-based permitting, as well as the goals and objectives of the Clean Water Act to restore and maintain the biological integrity of U.S. waters.

EPA's existing NPDES regulations require that, where a wasteload allocation has not been prepared by a state and approved by EPA under 40 CFR 130.7, water quality-based effluent limits must insure that the "level of water quality to be achieved by limits on point sources established under this paragraph is derived from, and complies with all applicable water quality standards." 40 CFR 122.44(d)(1)(vii)(A). Consistent with this provision, water quality based effluent limits set at the water quality criteria end-of-pipe are "derived from" the applicable state water quality standards. Moreover, the water quality that would "be achieved by point sources" will be no greater than the applicable numeric water quality criteria, since all point sources will be limited to discharging at no greater than the criteria end-of-pipe. EPA recognizes that, due to contributions from nonpoint sources and other media (e.g., air deposition of mercury or PCBs), the level of a pollutant in the receiving water from all sources combined may exceed numeric water quality criteria. EPA believes that limiting discharges from point sources to criteria end-of-pipe is nonetheless appropriate in these circumstances, as discussed below.

Numeric criteria are concentration-based standards designed to protect the aquatic ecosystem and humans from the adverse effects of pollutant discharges that would occur at levels above the criteria. Where the background level of the pollutant in the receiving water is greater than the criteria, the stream is in non-attainment and the aquatic environment or human health is adversely impacted. A point source discharging at criteria end-of-pipe in such situations, however, will contain a lower concentration of the pollutant than the receiving water, and therefore will not increase the pollutant concentration in the waterway. Such a discharger may, in fact, cause the ultimate pollutant concentration in the receiving water to decrease. Where the environmental effects of a pollutant on the aquatic ecosystem or on human health are associated with the concentration of the pollutant in the waterway, limiting discharges from point sources to criteria end-of-pipe in these circumstances should therefore result in no further degradation of the waterbody, and may in fact improve the water quality of the waterbody (special environmental considerations are present with regard to bioaccumulative [persistent] compounds, which are addressed separately under the final rule and discussed further below). The Agency therefore believes that establishing limits on point sources under these circumstances at criteria end-of-pipe is consistent with the underlying environmental objectives of the CWA.

The Agency recognizes that establishing limits at the criteria end-of-pipe will not alone result in the attainment of water quality standards in the receiving water for pollutants that are present mainly due to contributions from nonpoint sources and other media. In the absence of a TMDL addressing comprehensively such sources and corresponding controls on such sources, however, the water quality-based permitting process for point sources cannot achieve compliance with standards in such a waterbody. Even if the Agency were, for example, to prohibit discharges from point sources entirely under these circumstances, standards would not be attained in the waterbody. Indeed, where effects on aquatic life or human health are due to the concentration of the pollutant in the water column, allowing discharge at criteria end-of-pipe may actually improve water quality as compared with prohibiting any discharge at all since the former approach may ultimately reduce the pollutant concentration in the receiving water.

For the reasons explained above, EPA believes that, as an interim approach until a TMDL can be developed, establishing WQBELs to meet criteria end-of-pipe is a permissible permitting approach to address adverse environmental and health effects that are due to the concentration of pollutants in the water column in non-attained waters. Allowing such a discharge means that additional mass of a pollutant may be added to the waterbody and consideration of adverse effects due to increases in mass is well suited to the TMDL development process. In the interim before a TMDL has been established, EPA believes that any environmental concerns associated with such additions of mass can appropriately be addressed by the permitting authority through interpretation of the "toxics" narrative criterion contained in state water quality standards. For example, where an addition of mass is, in and of itself, of environmental concern because of the loadings of such pollutants in sediments, the permitting authority could interpret the narrative criterion to require more stringent limitations than criteria end-of-pipe in order to provide a requisite level of protection. Therefore, the permitting authority retains the ability to address circumstances where additions of mass alone may be of environmental concern.

While the Agency recognizes that the criteria end-of-pipe approach may not result in attainment of water quality standards in the near term on some waterbodies, the Agency views this as a reasonable interim approach to water quality-based permitting until a TMDL is developed for such waterbodies. EPA believes that the TMDL process is the appropriate means of effectively addressing ubiquitous pollutants in the Great Lakes basin where background levels exceed standards. Once a TMDL is established, point sources will have to have limits consistent with their wasteload allocation established under the TMDL (which could be lower or higher than criteria end-of-pipe). EPA recognizes, however, that TMDLs have not been established for many waterbodies where background exceeds criteria and that, given the technical difficulties and financial resources it takes to develop some TMDLs, the States will not be able to establish TMDLs everywhere they are needed in the immediate future. Under these circumstances, the Agency believes that setting wasteload allocations equal to criteria provides the best way of restricting additional discharges of pollutants from point sources in the period until a TMDL can be developed.

EPA also examined the approach suggested by commenters to set wasteload allocations equal to background concentrations in non-attained waters in the absence of a TMDL (background end-of-pipe). EPA believes that setting limits at background for discharges to non-attained waters is not an approach that would be consistent with national program requirements under the CWA. EPA notes again that existing NPDES regulations require that, where a wasteload allocation has not been prepared by a State and approved by EPA under 40 CFR 130.7, water quality-based effluent limits must ensure that the "level of water quality to be achieved by limits on point sources established under this paragraph is derived from, and complies with all applicable water quality standards." 40 CFR 122.44(d)(1)(vii)(A). In circumstances where a waterbody is in non-attainment for a particular pollutant, EPA believes that (with the exception of certain discharges of intake pollutants allowed under procedure 5.D and E) it would not be consistent with this provision to establish a WQBEL allowing discharges of the pollutant at levels exceeding the most stringent applicable water quality criterion. On its face, EPA believes that a WQBEL allowing discharges into a waterbody already exceeding such criteria would not ensure that the water quality achieved by point sources was either "derived from" or "complies with" applicable water quality standards. EPA also believes that such a permitting approach would be fundamentally at odds with the water quality-based permitting requirement contained in section 301(b)(1)(C) of the CWA, since such an approach would allow point sources to contribute to the excursion above water quality standards in the waterbody.

3. <u>Consideration of Pollutants in Intake Water</u>

a. <u>Introduction</u>

Appendix F, procedure 5.A-C, provides a means for permitting authorities to determine if a discharge causes, has the reasonable potential to cause, or contribute to an excursion above a State or Tribal numeric or narrative water quality criterion. These procedures require the permitting authority to establish a water quality-based effluent limitation (WQBEL) upon a determination that a pollutant is or may be discharged at sufficient levels to cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value.

The baseline procedures for conducting "reasonable potential" determinations in procedure 5.A-C do not provide special consideration for pollutants contained in a facility's intake water. Procedures 5.D and 5.E of appendix F of the final Guidance provide separate mechanisms for considering the presence of intake water pollutants in a facility's discharge when determining the need for WQBELs and in establishing such limits.

In some situations, the sole or primary origin of a pollutant in a discharge may be the intake water for a facility. For example, the origin of many pollutants in once through cooling water is the water body where the facility obtains the water rather than an industrial process or other activity of the facility itself. Where the intake water contains pollutants at levels that exceed water quality criteria, facilities which use and discharge that intake water may face the need for WQBELS even where the facility otherwise does not contribute that pollutant to the wastestream, unless special consideration of the source of the pollutant is taken into account. As has been emphasized by States throughout development of the GLWQI, and many others during the public comment period, a discharge of pollutants whose source is the intake water is a special circumstance that warrants careful examination in establishing regulatory controls.

Intake pollutants are a particular concern in the Great Lakes region. Concerns mentioned by numerous commenters include: elevated ambient levels of "ubiquitous" pollutants like PCBs and mercury, as well as other common pollutants of concern like copper, zinc, nickel and cadmium, whose continued presence at levels of concern in waters that serve as water supplies is believed to be due primarily to nonpoint sources of pollution such as atmospheric deposition and contaminated sediments; relative lack of regulatory control over nonpoint sources and ability to achieve reductions from nonpoint sources sufficient to relieve point sources of additional reduction responsibilities; increased stringency of water quality criteria, which will increase the number of waters needing protection from pollutant sources; and new analytical methods which may find previously undetected pollutants that exceed WQS.

b. Existing Mechanisms

EPA's NPDES permitting regulation at 40 CFR 122.45(g) currently provides a mechanism for adjusting technology-based effluent limitations to account for pollutants in a discharger's intake water in certain situations. The regulation provides that technology-based limitations shall be adjusted where the applicable effluent limitations guidelines direct that limitations be applied on a net basis, or where the discharger demonstrates that the presence of intake water pollutants prevents compliance with the applicable technology-based limitations despite proper installation and operation of the treatment system(s). The regulation also identifies four specific conditions restricting the use of net credits:

(1) Net credits for generic or indicator pollutants are not allowed unless the permittee demonstrates that the constituents of the generic measure in the effluent and influent are substantially similar or unless appropriate additional limits are placed on process water pollutants.

(2) Credit may be granted only to the extent necessary to meet the applicable technology-based limitation, up to a maximum value equal to the influent value.

(3) Credit is generally limited to discharges to the same body of water from which the intake water is drawn although the permitting authority may waive this requirement if no environmental degradation will result.

(4) Credit is precluded for return of materials generated from the treatment of intake water (e.g., raw water clarifier sludge.)

The provision granting credit only to the extent necessary to achieve a technology-based limitation assures that a discharger uses the appropriate technology-based level of treatment in removing pollutants that originate from the discharger's facility. This provision in essence assures the proper operation of treatment technology.

When promulgating the net credit adjustment for technology-based limits, EPA declined to develop a similar mechanism to adjust water quality-based effluent limitations to reflect credit for intake water pollutants. EPA explained that "[t]he Clean Water Act's requirement to protect and enhance water quality is not conditioned on factors such as intake water quality and it would be inappropriate for EPA to impose such a condition. Eligibility for a net credit under these [technology-based] regulations does not imply any right to violate water quality standards." (49 FR 37998, 38027 (September 26, 1984)). EPA recognized the complexity of water quality-based permitting, however, and indicated that permit writers may take the presence of intake water pollutants into account, as appropriate, in individual permitting decisions. In all cases, EPA noted that permit limits "must be adequate to meet the water quality objectives of the Clean Water Act when considered along with control requirements for other discharges to the stream." (49 FR 38027; September 26, 1984). The existing mechanisms for simultaneously considering control requirements for all dischargers to a single body of water are total maximum daily loads (TMDLs) and NPDES permits written to implement TMDLs. The preamble to the proposed Guidance at 58 FR 20954-6 (April 16, 1993) described in detail the four mechanisms available under existing National regulations and guidance which allow the permitting authority to determine appropriate WQBELs when the receiving water exceeds a water quality criterion. In addition to TMDLs, these mechanisms include: temporary variances to WQS, removal of non-existing uses, and site-specific modifications to water quality criteria. While each of these mechanisms directly or indirectly allows consideration of intake pollutants in deriving permit limitations for individual dischargers by adjusting the standards or wasteload allocations to achieve standards, none is a permit-based mechanism (i.e., based directly on CWA requirements to include WQBELs in NPDES permits necessary to attain WQS).

c. <u>Summary of Proposal</u>

i. <u>Proposed Guidance</u>

In the proposed Guidance, EPA included procedure 5.E of appendix F to provide a new procedure for considering the presence of intake water pollutants in water quality-based permitting decisions in addition to the available mechanisms described above. The proposed Guidance would allow the permitting authority to determine that there is no reasonable potential for the discharge of a particular intake water pollutant to cause or contribute to an excursion above a narrative or numeric water quality criterion, without application of procedure 5.A-D of appendix F of the proposed Guidance, based on the permittee's demonstration of specified conditions. If these conditions are demonstrated, the permitting authority would not be required to include a WQBEL for the pollutant in the facility's permit. If these conditions are not satisfied, the permitting authority would follow the baseline reasonable potential procedures in proposed procedure 5.A-D of appendix F to determine whether a WQBEL is necessary for these pollutants.

Proposed procedure 5.E of appendix F provided a separate mechanism for determining whether WQBELs are necessary for facilities that return unaltered intake water pollutants to the source of the intake water. The underlying premise for this proposal, based on technical considerations of the nature of pollutants and the effects of pollutants on surface water quality, is that determinations whether a discharge of intake water pollutants should be limited by a WQBEL and, if so, the scope of such limitations, must be determined after consideration of site-specific factors. These factors include consideration of the applicable water quality criteria, the quality of the receiving water relative to the criteria, additional pollutant loadings from other point and nonpoint sources, and evaluation of the facility's effluent. As discussed further below, the effect of the discharge of intake water pollutants may also vary substantially depending on the location of the outfall in relation to the intake point, the time interval between intake and discharge , alterations of the pollutant by the wastewater treatment process, synergistic or additive interactions between the intake water and other wastewater pollutants, or the chemical nature of the pollutant in the environment. In proposing this new alternative, EPA acknowledged that States, Tribes, and dischargers had serious concerns about the feasibility of relying on the existing mechanisms for adjusting standards and wasteload allocations described above.

EPA proposed procedure 5.E of appendix F as a reasonable mechanism for evaluating the site-specific water quality effects from the discharge of intake water pollutants. This procedure allowed permitting authorities to conclude that the return of unaltered intake water pollutants to the same body of water under identified circumstances does not cause, have the reasonable potential to cause, or contribute to an excursion above water quality standards and, therefore, WQBELs for that pollutant were not needed. The permittee would be eligible for the reasonable potential procedure in proposed procedure 5.E of appendix F upon demonstration of five conditions.

-- First, the permittee would need to demonstrate that it withdraws 100 percent of the intake water containing the pollutant from the same body of water into which the discharge is made.

-- Second, the permittee would need to demonstrate that it does not contribute any additional mass of the specified intake water pollutant to its wastewater. In other words, the pollutant present in the discharge must be due solely to its presence in intake water from the receiving water body.

-- Third, the permittee would need to demonstrate that it does not alter the identified intake water pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur from the discharge that would not occur if the pollutant were left in-stream. Alterations could occur as long as they do not cause adverse water quality impacts.

-- Fourth, the permittee would need to demonstrate that the pollutant is not concentrated at the edge of any available mixing zone after discharge from the facility.

-- Fifth, the permittee would need to demonstrate that the timing and location of the effluent discharge do not cause adverse water quality impacts to occur that would not occur if the pollutant were left in-stream.

If the permittee demonstrated the five conditions to the satisfaction of the permitting authority, the proposed procedure further identified three conditions that the permitting authority would have to address: (1) the permitting authority must summarize the basis for the determination that there is no reasonable potential for the discharge of an identified intake water pollutant to cause or contribute to an excursion above a narrative or numeric water quality criterion within a State or Tribal WQS in the NPDES permit fact sheet or statement of basis, including an evaluation of the permittee's demonstration of the five specified conditions described above; (2) the permit must require all monitoring of the influent, effluent and ambient water necessary to determine that the conditions of procedure 5.E of appendix F are maintained during the permit term; and (3) the permit must contain a reopener clause authorizing the permitting authority to modify or revoke and reissue the permit if new information indicates that changes in any of the conditions of procedure 5.E of appendix F have occurred.

Finally, the proposed procedure addressed the relationship between the option and any available wasteload allocation (WLA) or TMDL prepared and approved pursuant to 40 CFR 130.7. The proposed provisions of procedure 5.E of appendix F stated that it would not alter the permitting authority's existing obligation to develop effluent limits consistent with the assumptions and requirements of any WLA (which is a part of a TMDL) that is developed and approved in accordance with 40 CFR 130.7. (40 CFR 122.44(d)(1)(vii)). The preamble further explained that the proposed intake pollutant reasonable potential procedure also would not alter a State's obligation to identify water quality-limited segments and establish priorities for conducting TMDLs for those waters under 40 CFR 130.7. The required evaluation of existing and available water quality data to make these determinations under 40 CFR 130.7(b)(5) would include consideration of the information submitted or generated to support permit decisions under procedure 5.E of appendix F.

Procedure 5.E of appendix F was proposed as an alternative to the reasonable potential procedures under proposed procedure 5.A-D of appendix F. Under the proposal, ineligibility of a facility for the simple pass-through determination of procedure 5.E of appendix F did not affect that facility's ability to request the application of existing mechanisms for consideration of intake water pollutants in setting WQBELs (e.g., TMDL, a variance from water quality standards, and modifications to designated uses and criteria).

ii. Other Options

In addition to the proposed alternative reasonable potential determination for intake pollutants, the preamble to the proposed Guidance discussed four other options EPA would consider in developing the final Guidance. Three of the four options, described briefly below, assumed that WQBELS would be needed and addressed how intake pollutants could be taken into account in establishing WQBELs.

(A) Option 1: Option 1 reflected the current National approach. EPA's existing regulations do not provide a specific mechanism to allow special credit or consideration for pollutants present in a facility's intake water when setting WQBELs comparable to the intake credit provision for technology-based limitations at 40 CFR 122.45(g). If the permitting authority determines that a facility's discharge causes, has the reasonable potential to cause, or contribute to an excursion above water quality standards for any pollutant in the effluent, the NPDES permit must include an appropriate WQBEL for that pollutant. Under Option 1, the permitting authority relied on the mechanisms available under EPA's existing regulations and guidance to derive any WQBEL necessary to control discharges of pollutants to receiving waters that exceed water quality standards, including discharges containing those pollutants found in a discharger's intake water. As noted previously, these mechanisms include TMDLs, temporary variances from water quality standards, and changes in the designated use of the water body, or site-specific criteria modifications.

(B) Option 2: Option 2 allowed the permitting authority to directly modify WQBELs to reflect a credit for intake water pollutants if the pollutants are discharged to the same body of water as the intake water. A specified level of credit was allowed under this approach even when the facility contributes an additional amount of the intake water pollutant from its process waste stream. Basically, the discharger would be allowed to discharge an amount of the pollutant equivalent to the mass of the pollutant in its intake water. Removal of the pollutant from the intake water could be offset by increases in the amount added through the facility's process water or other activities. However, credit was precluded under Option 2 if the facility failed to demonstrate the remaining conditions specified in section 5.E.1.a, c, d, and e of the proposed intake pollutant reasonable potential procedure. This option is commonly called the "no net addition" option (and was referred to as Option 2a in the proposal).

The preamble to the proposed Guidance also discussed a variation to the basic "no net addition" option. Option 2b allowed a facility to discharge an effluent containing, at a maximum, the same mass of the pollutant in the intake water after deduction of the amount removed by the facility's raw water, or intake water treatment system . Thus, if a facility removed any of the pollutant originating in the intake water prior to use at the facility, the facility would not be able to offset this reduction. If a facility removed any of the intake water pollutant during the wastewater treatment process, however, it would be able to provide a commensurate increase in the amount of the pollutant contributed in the process wastewater.

As with the proposal, neither Option 2a nor 2b altered the authority of the permitting authority to develop WQBELs to account for the presence of intake water pollutants pursuant to a TMDL, temporary variance, or other allowable modifications to WQS pursuant to State and EPA regulations and the proposed Guidance. The proposed options 2a and 2b did not authorize exceedance of a TMDL or alter a State's obligation to identify water quality-limited segments and establish priorities for conducting TMDLs for those waters under 40 CFR 130.7. EPA specifically asked for comment on whether this option should be limited to one permit term to encourage timely completion and implementation of TMDLs.

(C) Option 3: Option 3 allowed the permitting authority to directly modify WQBELs to reflect a credit for intake water pollutants regardless where the intake water source is located. In other respects, Option 3 was similar to Option 2. The preamble discussed three variations to this Option.

Option 3a allowed a facility to discharge an effluent containing, at a maximum, the same mass of the pollutant that the facility receives from any water source including sources other than the receiving water. If a facility removed any of the pollutant from the intake water, the facility could offset this reduction by increasing the amount of the pollutant contributed by the process wastewater.

Option 3b allowed a facility to discharge an effluent containing, at a maximum, the same mass of the pollutant contained in intake water from any source after deduction of the amount removed by the facility's intake water treatment system (analogous to Option 2a). If a facility removed any of the pollutant originating in any intake water through wastewater treatment, the facility could similarly offset this reduction by increasing the amount of the pollutant contributed by the process wastewater.

Option 3c allowed a facility to discharge an effluent containing, at a maximum, the same concentration of the pollutant that is present in the receiving water. If a facility removed any of the pollutant from the intake water, the facility could offset this reduction by increasing the amount of the pollutant contributed by the process wastewater.

Like the proposal and Options 2a and 2b, Options 3a, 3b, and 3c did not alter the authority of the permitting authority to develop WQBELs to account for the presence of intake water pollutants pursuant to a TMDL, temporary variance, or other allowable modifications to WQS pursuant to State,Tribal or EPA regulations and the proposed Guidance. If a TMDL were developed, effluent limitations derived using Option 3 would need to be adjusted to be consistent with the TMDL.

(D) Option 4: The fourth Option discussed in the preamble to the proposed Guidance was the initial procedure developed by the Great Lakes Technical Work Group and was originally included in the Great Lakes Implementation Guidance as part 11.B (which became, in part, proposed procedure 3 of appendix F to part 132 controlling development of TMDLs). Option 4 represented a combination of Options 2a and 3c. In addition, it applied only when the background level of pollutant in the receiving water exceeded an applicable water quality criterion. Like Options 2 and 3 (and variations), Option 4 required adjustment to limits to ensure consistency with any applicable TMDL. The procedure provided mechanisms for accounting for pollutants in a facility's intake water under two circumstances.

First, when at least 90 percent of the intake water source is from ground water (except ground water withdrawn from a location of contaminated ground water) or a public drinking water supply, Option 4 allowed a facility to discharge an effluent containing a concentration of a pollutant ranging from, at the low end, the water quality criterion, to, at the high end, the concentration of the pollutant in the receiving water. The permitting authority would use its professional judgment and consider reasonable, practical, and otherwise required methods to minimize addition of toxics in deciding where to establish the effluent limitation within the specified range.

Second, when a minimum of ten percent of wastewater is from the same waterbody into which the effluent is discharged, Option 4 allowed a facility to discharge an effluent at a concentration equal to the receiving water or containing a mass of a pollutant equal to the mass the facility receives from the waterbody. This Option would apply even if 90 percent of the wastewater was from the process waste stream or from waters other than the receiving stream. POTWs which discharge to the same surface water from which the public water supply is withdrawn would be covered under this provision as well.

d. Structure of Remaining Discussion

Section 4 below addresses the key features of the Final Guidance and, where applicable, how they differ from the proposed Guidance, including a discussion of and response to major comments. Section 5 addresses EPA's legal authority to regulate intake pollutants. Section 6 explains the relationship between the intake pollutant provisions in today's final Guidance and existing mechanisms to adjust WQBELs. Section 7 addresses other, more detailed aspects of the final Guidance in a similar fashion. In addition, a separate response to comment document, which has been included in the docket for the final Guidance, contains responses to all comments that were received on the intake pollutant procedure in the proposed Guidance, some of which may not be specifically addressed in this document.

4. Summary of Intake Pollutant Considerations in Final Guidance and Overall Rationale

EPA has carefully considered the numerous comments received on the intake credit issue in establishing new mechanisms for considering intake pollutants in water quality-based permitting. Like the proposal, the final Guidance includes a procedure for considering intake pollutants from the same body of water into which the effluent is discharged when evaluating whether a discharge causes, has the reasonable potential to cause, or contributes to an excursion above applicable water quality standards. Unlike the proposal, the final Guidance also establishes procedures for considering intake pollutants in developing WQBELs. The consideration of intake pollutants arises in three factual scenarios, and the final Guidance addresses each of the following circumstances: (1) when the source of the intake pollutants is the same body of water as the receiving water for the discharge; (2) when the source of the intake pollutants is a different body of water than the receiving water for the discharge; and (3) when the discharger has multiple sources of intake water that contain the identified pollutant of concern. These provisions appear under procedure 5.E of appendix F. In addition, the final Guidance defines "same body of water."

a. Intake Pollutant Reasonable Potential Procedure

As described above, the proposed Guidance included a separate procedure 5.E of appendix F for considering intake water pollutants when determining whether a discharge causes, has the reasonable potential to cause, or contributes to an excursion above a water quality standard and therefore needed a WQBEL in the permit ("intake pollutant reasonable potential" procedure). The proposal generated numerous comments as to the details of the procedure and most significantly, to EPA's decision not to propose an additional procedure to adjust WQBELs directly for intake pollutants. However, most commenters supported the need for a reasonable potential procedure that would account for intake pollutants. Support was not universal. Some commenters objected, asserting that TMDLs were the only mechanism authorized by the CWA for allocating loads when waters do not meet standards and that in the absence of a TMDL, discharge of the pollutant(s) exceeding standards either should be prohibited or limited to the most stringent applicable criteria or value.

The final Guidance includes a procedure 5.D of appendix F which is essentially the same as the proposal and allows the permitting authority to determine that a WQBEL is not needed for a particular pollutant when a discharger returns unaltered intake pollutants to the same body of water, and the discharge does not cause adverse water quality effects that would not have otherwise occurred if the pollutants were left in-stream. This procedure represents a comprehensive approach for conducting a site-specific analysis of the potential for a discharge to cause or contribute to an excursion above a water quality standard, which can lead to a decision not to require a WQBEL.

b. No Net Addition Interim Approach for Setting WQBELs

In response to numerous comments and as explained in more detail in section 5.b below, the final Guidance also provides for a direct adjustment to WQBELs when the discharge contains intake pollutants from the same body of water as the discharge and the other requirements for the intake pollutant reasonable potential demonstration are met. The only difference between the no net addition procedure and the intake pollutant reasonable potential procedure is that, under the no net addition procedure, a discharger may add mass of the identified pollutant of concern to its wastestream as long as its discharge contains no more mass of the pollutant than was contained in the intake water. In a sense, the permittee must demonstrate what may be viewed as the functional equivalent of the intake pollutant reasonable potential determination, or simple pass through situation because this procedure establishes WQBELs at a level which ensures the discharge has no greater impact on the receiving water than if the discharger had not removed and returned the intake pollutants to the same body of water.

A major concern expressed by EPA in the proposal about options that would provide for direct adjustment of permit limits for intake pollutants when the discharger contributes additional amounts of the pollutant of concern to its wastestream, and the receiving water exceeds the criteria for that pollutant, was that the availability of a permit-based mechanism would discourage development of TMDLs that meet the requirements of, and are approved or established by EPA in accordance with, 40 CFR 130.7. As discussed in section VIII.E above, TMDLs are a mechanism for determining the assimilative capacity of a waterbody and fairly allocating that capacity among sources of a pollutant. CWA section 303(d); 40 CFR 130.7. Using a permit-based adjustment for intake pollutants imposes an allocation scheme without the assurance that other sources contributing to an exceedance of a water quality standard will be controlled so that the standard is attained, as would be the case with a TMDL.

While EPA does not regard TMDLs as the only available mechanism under the CWA for adjusting point source controls, TMDLs are clearly the preferred mechanism for determining the appropriate load allocation scheme to ensure that a waterbody which does not meet standards is brought into attainment of WQS, particularly when multiple sources contribute the pollutant that exceeds water quality criteria. Indeed, section 303(d) of the CWA requires States to develop TMDLs for waters that are not expected to meet water quality standards despite implementation of technology-based requirements or other existing and planned controls. To address the concern that providing a direct adjustment to permit limits for intake pollutants would discourage development of TMDLs, EPA solicited comments on whether allowing a "no net addition" or other approach for developing WQBELs should be limited to one permit term (i.e., five years). In addition, EPA requested comment on the reasonableness of using one permit term as the maximum duration of relief in this case.

Commenters who specifically addressed this issue supported intake credits based on the premise that dischargers should not be held responsible for the intake pollutants in their discharges. They similarly opposed limiting intake pollutant relief to one permit term. On the other hand, commenters who opposed intake credits asserted that TMDLs should be required from the outset. Commenters supporting intake credits asserted that intake credits should be available as long as the site conditions leading to the need for intake credits existed and that dischargers should not be penalized for a

State's failure to develop a TMDL. In commenting more generally on whether a TMDL could be an adequate substitute for a permit-based approach for considering intake pollutants, commenters expressed skepticism whether TMDLs and, by implication, reductions of the intake pollutant from other sources contributing to background levels specified in the TMDL, could be completed in time to result in limits at or above the background level for a downstream discharger, particularly where pollutant reductions are needed from nonpoint or natural sources.

Consistent with EPA's determination that TMDLs are the preferred mechanism for developing control strategies to bring impaired waters into attainment of WQS, the final Guidance limits the time period for which a permitting authority can use direct adjustment of permit limits for intake pollutants. Under procedure 5.E.2.a of the final Guidance, no net addition limitations may be included in permits for discharges of intake pollutants for a period of up to twelve years after publication of the final Guidance. After that period of time, WQBELs would be based either on: (1) the "baseline" procedures for developing WLAs in procedure 5.F.2 of appendix F; or, when available, (2) WLAs in TMDLs developed and approved in accordance with 40 CFR 130.7; or (3) WLAs contained in an assessment and remediation plan for the receiving water submitted by the State or Tribe and approved by EPA as meeting the requirements of procedure 3.B-F, as provided in procedure 3.A of appendix F and section D.1.c of intake pollutant procedures. EPA remains concerned that the unlimited availability of intake credits through the permitting program could discourage the development of TMDLs where they may be most needed, i.e., for non-attained waters where multiple sources contribute to the exceedance of water quality standards. EPA recognizes that point source dischargers are understandably concerned when their discharge control requirements depend in part on contributions from other sources and, consequently, on the ability and willingness of regulatory agencies and other sources to reduce other loadings that impact water quality. However, an unalterable fact of water quality-based controls is that they will vary depending on the particular condition of the receiving water. The TMDL provides a specific mechanism for determining how best to achieve water quality objectives considering such factors as the ability to achieve reductions from other sources.

EPA has included this time limitation on the availability of no net addition limitations in order to help ensure that States and Tribes are evaluating comprehensively the root sources of non-attainment in the receiving water. As noted previously, EPA believes that, in light of the unique considerations posed by discharges of intake pollutants from the same body water, no net addition limitations are appropriate as an interim measure to help ensure that such point source discharges are not aggravating a waterbody's non-attainment problem. As discussed below, however, such non-attainment is not an acceptable long-term status in light of the requirements and goals of the CWA. Ultimately, it will be critical for EPA, the States and Tribes to address comprehensively the sources of non-attainment in these waterbodies. When these problems are properly addressed, of course, the need for a specialized permitting mechanism to address intake pollutants will no longer be necessary.

As emphasized by EPA in the proposal and elsewhere in the SID, the best means for States and Tribes to address comprehensively the root causes of non-attainment is the TMDL development process. EPA recognizes, however, that States and Tribes may seek to address comprehensively point and nonpoint source contamination in a waterbody through means other than TMDLs.As explained in section VIII.C above, which discusses procedure 3.A of appendix F, EPA recognizes that alternative assessment and remediation plans that meet the requirements of procedure 3 of appendix F can serve the same purpose as TMDLs in providing a holistic assessment of all sources contributing toward a particular water quality impairment problems, identify remediation activities which are reasonably anticipated to result in load reductions that will achieve attainment of WQS within a reasonable period of time, and establishing wasteload allocations for point sources that are consistent with these water quality objectives. Therefore, EPA believes that it is appropriate for the permitting authority to have the flexibility to continue to establish no net addition limitations provided that they are consistent with assessment and remediation plans submitted and approved in accordance with procedure 3.A of appendix F. As described in section I.D.4 of this document, the States and Regions in the Great Lakes basin have undertaken significant assessment and remediation planning efforts through the development of RAPs and LaMPs. Where such assessments and remediation plans are approved by EPA in accordance with procedure 3.A of appendix F, EPA believes that the State or Tribe has demonstrated that non-attainment will not be the indefinite status quo of the waterbody. Under these circumstances, EPA believes, as a matter of policy, that WLAs consistent with those alternative plans, including those that result in no net addition limits, can be an appropriate permitting approach.

For discharges of pollutants for which intake pollutants are not at issue, wasteload allocations would continue to be derived in accordance with procedure 5.F.2 or an EPA approved TMDL or assessment and remediation plan under procedure 3.A of appendix F, where applicable. While commenters addressed generally whether a time limitation on the availability of intake credits was appropriate, none specifically addressed whether one permit term would be a reasonable period of time or suggested specific alternative durations. Upon further consideration of the effort that might be needed to develop TMDLs or comparable assessment and remediation plans in the Great Lakes region, particularly considering that more waters may be in non-attainment based on new water quality criteria adopted pursuant to the final Guidance, EPA has concluded that a one permit term limitation would be unduly restrictive. Therefore, the final Guidance adopts a time limit, which is based on ten years from when States must adopt the Guidance, i.e., 12 years from the publication date of the final Guidance (approximately two permit terms). At the end of this time period, intake pollutant relief in the form of permit limits based on no net addition will no longer be available, unless the limits are consistent with wasteload allocations in an EPA-approved or prepared TMDL under 40 CFR 130.7 or an alternative assessment and remediation plan as provided in procedure 3.A. It is important to note that wasteload allocations in a TMDL, and resulting permit limits, may be more or less stringent than previously allowed under a no net addition approach for establishing permit limits. Because TMDLs or comparable assessment and remediation plans are designed to ensure attainment of water quality standards in the waterbody, such attainment would eliminate the need for special consideration of intake pollutants.

EPA recognizes that developing TMDLs may be a difficult task in the Great Lakes region because water quality problems are widespread, result from numerous sources, many of which have not been extensively regulated, and may be due to past, rather than current, activities. However, the States and Tribes in the Great Lakes region have already undertaken many of the tasks necessary to develop TMDLs through efforts to develop LAMPs and RAPs, as described in section I.D.4 of this document. The final Guidance specifically recognizes these efforts by allowing them to serve in lieu of TMDLs when they meet the fundamental elements of a TMDL as established in procedure 3. The final Guidance also recognizes, in procedure 3.A of appendix F, that comprehensive plans for assessing and remediating non-attainment waters should be tailored in the level of detail and magnitude for the watershed and pollutant being assessed.

In response to commenters' concerns about the difficulties in developing TMDLs in the near term, it is important to realize that under the phased approach, TMDLs can be developed in the absence of complete information and do not necessarily require full implementation of all necessary controls before adjustments to wasteload allocations for point source contributors can be made available. See procedure 3.B.1 of appendix F, which acknowledges that it may not be possible to attain WQS immediately in all cases and that specific controls on individual sources may need to be implemented in stages. The phased approach to TMDLs is described in detail in section VIII.C above. Further, as discussed in more detail in section VIII.E above on the baseline reasonable potential procedures, unlike the proposed Guidance, the final Guidance does not require States to develop a TMDL every time the permitting authority determines that an individual discharger causes, has the reasonable potential to cause, or contribute to an excursion above a water quality standard. Thus, States retain flexibility in determining priorities for TMDL development, consistent with section 303(d) of the CWA and 40 CFR 130.7. The final Guidance provides additional flexibility by allowing States or Tribes to develop appropriate approaches for comprehensively addressing non-attainment in accordance with mechanisms comparable to TMDL (e.g., LaMPs) and use these approaches as an alternative basis for developing WLAs when intake credits are not available (e.g., when the 12-year period allowed for "no net addition" limits ends). Because of this flexibility in the timing of TMDLs, the efforts currently underway to identify the sources contributing to impairment of waters, and the provision recognizing mechanisms comparable to TMDLs, EPA believes that 12 years is a reasonable period of time for States and Tribes to develop TMDLs or comparable approaches.

The final Guidance limits how long permit-based intake pollutant credits are available, but consideration of intake pollutants in setting limits does not necessarily end on March 23, 2007. Within the context of the TMDL or comparable assessment and remediation plan, States and Tribes have considerable discretion to determine how the necessary loading reductions will be achieved. Thus, States and Tribes can continue to provide for consideration of intake water pollutants in establishing wasteload allocations as part of a TMDL or comparable mechanism, provided that the requirements for a TMDL in 40 CFR 130.7 are met (or in the case of a comparable mechanism, the requirements established in procedure 3.A of appendix F are met), most fundamentally the requirement to show that water quality standards will be attained through a combination of load and wasteload allocations, together with a margin of safety. In addition, dischargers may seek adjustment of permit limits through other available mechanisms such as a temporary variance from water quality standards, as addressed in procedure 2 of appendix F and discussed more fully in section VIII.B of this document.

c. Consideration of Intake Pollutants from a Different Body of Water

The proposed Guidance limited intake pollutant relief to instances where the source of the intake pollutant was the same body of water as the receiving water for the discharge. EPA explained that the "same body of water" restriction was appropriate to ensure consistency with the structure and function of State or Tribal water quality standards. Without such a restriction, dischargers could transfer pollutants from one waterbody to another without determining whether the discharge causes, has the reasonable potential to cause, or contribute to an excursion above an applicable water quality criteria based on consideration of site-specific factors, including the condition of the receiving water and contributions by other point or non-point sources.

The preamble to the proposed Guidance also discussed options that would allow intake credits when pollutants were transferred from one waterbody to another. Option 3 allowed consideration of intake water pollutants without regard to waterbody source and based limits on one of two approaches. The first approach (Options 3a and 3b) based limits on the amount of the pollutant in all sources of intake water, with the further option of not extending credit for pollutants removed from the intake water before use at the facility. This approach could result in improved water quality, but could also allow further degradation of the receiving water, depending on the quality of the intake water relative to the receiving water. The second approach (Option 3c) based limits on the concentration of the pollutant in the receiving water. At best, this option would maintain the status quo. Option 4 used a combination of approaches. Under Option 4, where the discharge was to a different body of water, limits would be set at the water quality criteria of the receiving water and could be adjusted up to the concentration of the pollutant in the receiving water if the permittee demonstrated that the concentration of the substance at the point of intake exceeds the applicable standard or criterion for that substance and that reasonable, practical or otherwise required methods are implemented to minimize the addition of the toxic substance to the wastewater.

Several commenters stated that intake credit relief should be limited to the same body of water and if interbody transfers were allowed, the discharge should have to meet the standards of the receiving stream. EPA also received numerous comments supporting intake credits when the source of the intake pollutant is a different body of water. Some commenters favored relief in this situation based on the general notion that dischargers should not be responsible for pollutants originating outside their facilities regardless of the impact on the receiving water. Others, however, endorsed the more limited rationale that interbody transfers of pollutants should be allowed if the discharge would substantially maintain or improve the existing receiving water quality in terms of the concentration of the pollutant in the waterbody. Several commenters supported basing limits on receiving water quality or in instances of net environmental improvement because the "technical work group [composed of the Great Lakes States] could not scientifically conclude whether adding water from another source with lower pollutant concentration helped or hurt the Great Lakes." One commenter suggested dropping the distinction between same and different body of water and advocated instead a requirement that the source and receiving waters have similar concentrations of the pollutant and apply other restrictions to ensure protection of the receiving water from other possible adverse effects of the discharge (e.g., timing and location, chemical and physical alternation, etc.) Others claimed that the distinction was irrelevant because of the application of uniform water quality criteria throughout the basin. Finally, several commenters stated that the distinction between same and different bodies of water in the proposal would unfairly and unnecessarily preclude relief in the many instances where a discharger had multiple sources of intake water.

The final Guidance retains a distinction between situations where the source of the intake water pollutant is the same or different body of water as the waterbody receiving the discharge. (See related discussion on the definition of "same body of water" in section VIII.E.7.iv below.) As explained below in the discussion of EPA's legal authority, EPA does not agree with commenters who argued that the CWA does not authorize regulation of pollutants in a discharge that do not originate with the discharger. EPA maintains, moreover, that requiring consideration of the whole discharge in evaluating whether water quality based limits are needed is essential, as a technical matter. The distinction between same and different bodies of water ensures that each time a particular mass of a pollutant is introduced into a waterbody for the first time (i.e., would not otherwise be in the waterbody but for the discharge), its impact is evaluated to determine whether the discharge of the pollutant would cause, have the reasonable potential to cause, or contribute to an exceedance of the water quality standards applicable to the receiving water, and it is controlled through limits that implement water quality standards where appropriate. Similarly, where WQBELs are found to be necessary, EPA believes that direct adjustment of limits to account for pollutants in the intake water should be restricted to those pollutants that would be in the receiving water with the same effect even if the discharger had not withdrawn and subsequently discharged those pollutants.

EPA recognizes that in some instances discharges from other bodies of water that exceed applicable water quality criteria for the receiving water but have a lower concentration of the pollutant than the receiving water could, theoretically, improve the overall water quality from the standpoint of water column concentrations in the receiving water. These instances could occur if a facility discharges a lower concentration of a pollutant than is present in the receiving water. Although the resulting ambient concentration could be lower, the mass of a pollutant would increase by the transfer of pollutants to a different body of water. Whether this discharge would result in overall water quality improvements would depend on several factors including, the magnitude of the actual decrease in the pollutant concentration in the water column, the lowered concentration in the water column as compared to the water quality criterion, consideration of the factors identified under the proposed procedure 5.E of appendix F (e.g., alteration of the pollutant, concentration at the edge of any applicable mixing zone, and time and location of the discharge), the impacts of the additional mass on pollutant levels in sediment and fish tissue, and the transfer of the additional mass through volatilization and sedimentation into nonpoint sources of atmospheric deposition and sediment resuspension. In particular, the additional mass of a persistent pollutant may offset the environmental benefits of lowering water column concentrations because the additional mass, if cycled through sediments by deposition and resuspension or through the food chain, could negatively impact the waterbody so as to ultimately prolong the non-attainment status of the waterbody. In other words, whether additions of mass, considered alone, will further degrade a receiving water, needs to be considered on a site-specific basis taking into account a comprehensive evaluation of the state of the waterbody, its pollutant sources, and the fate and effect of pollutants within the waterbody, which is the type of evaluation that occurs during development of a TMDL or comparable assessment and remediation plant as provided in procedure 3A.

In the absence of a TMDL or comparable mechanism appropriately considering these factors, EPA is not comfortable with concluding categorically, as advocated by some commenters, that a discharge is by definition environmentally acceptable if it will not cause an increase the concentration of a pollutant in the receiving water. Without such an analysis as part of the TMDL or comparable process, therefore, EPA believes that there is not a sound scientific basis to conclude that such a discharge would never cause, or have the reasonable to cause, or contribute to an excursion above water quality standards. EPA believes, moreover, that such an approach would be inconsistent with the language and structure of the CWA, under which States or Tribes establish water quality criteria to ensure that designated uses are protected. If, as some commenters asserted, the discharge of a pollutant does not pose "reasonable potential" provided it will not increase the concentration of the pollutant in the receiving water, then water quality criteria would be entirely irrelevant to the permitting process. EPA believes such a result cannot be reconciled with the CWA. See CWA 301(b)(1)(C) and 40 CFR 122.44(d).

In the absence of a TMDL or comparable assessment and remediation plan approved under procedure 3.A of appendix F, the permitting authority needs to determine whether the discharge causes, has the reasonable potential to cause, or contribute to an excursion above an applicable WQS, and therefore should have a WQBEL. Evaluating such discharges using the procedures in 5.A-C adequately considers the impact of the discharge on the receiving water. Where "reasonable potential" exists, the permitting authority must develop limits that implement water quality standards.

EPA agrees that maintaining or providing a net improvement to receiving water is preferable to further degradation of the receiving water, but does not agree that "net improvement" is the appropriate standard for deriving WQBELs once "reasonable potential" has been established. Similarly, EPA does not agree that simply maintaining the status quo, as would be the case when limits are based on the background water quality of the receiving water, is appropriate when the source of the pollutants is a different body of water, even if all other requirements applicable to the intake pollutant reasonable potential or "no net addition" approaches for the discharge of the intake water pollutants from the same body of water are met. Instead, EPA regulations at 40 CFR 122.44(d)(1)(vii) require that water quality-based permit limits be derived from and comply with all applicable water quality standards. Also see, CWA 301(b)(1)(C). The fundamental basis for providing special allowance for intake pollutants in the same body of water situation, i.e., that the pollutant would have reached the vicinity of the discharge point despite its removal and subsequent discharge, does not exist when the discharge is from a different body of water. Therefore, procedure 5.E.4 of appendix F of the final Guidance provides that, when the permitting authority finds that reasonable potential exists (using the baseline reasonable potential procedures in 5.A-C), discharges that contain intake pollutants from other bodies of water must meet water quality criteria end-of-pipe when the receiving water exceeds the criteria for that pollutant. In essence, the final Guidance denies the special consideration for intake water pollutants from a different body of water that has been adopted for intake pollutants from the same body of water. EPA's rationale for determining that criteria end-of-pipe, as an interim basis for setting effluent limits in the absence of a TMDL or comparable assessment as provided in procedure 3.A of appendix F, meets CWA and NPDES regulation requirements for WQBELs is explained in section VIII.E.2.h of this document. States and Tribes of course, may require more stringent limits.

Using water quality criteria end-of-pipe as the basis for permit limits when the intake pollutant originates in a different body of water than the discharge, is consistent in part, with Option 4. That option, however, would provide for less stringent limits--up to the concentration of the pollutant in the receiving water--if the intake water exceeded criteria and the permittee could demonstrate that it has implemented reasonable, practical or otherwise required methods to minimize the addition of the toxic substance to the wastewater. In effect, Option 4 would substitute the feasibility of pollution control for consideration of water quality standards as the basis for deriving WQBELs. Comments in support of Option 4 suggest that it could be read to require simply that the discharger has implemented technology-based controls. EPA does not believe, however, that this approach adequately implements CWA requirements to require limits "more stringent" than technology-based limits when necessary to implement State water quality standards. See CWA section 301(b)(1)(C).

d. Combined Approach for Multiple Intake Sources

The proposed Guidance provided for consideration of intake water pollutants only when all such pollutants in the discharge were from the same body of water as the receiving water. As noted above, some commenters objected, asserting that the proposal would unnecessarily deny relief where a facility has multiple sources of intake water which contains the pollutant of concern. Some commenters specifically endorsed a "combined wastestream" approach that would use flow-weighted averages to develop an end-of-pipe limit when a facility had multiple sources of intake water. EPA agrees that it would be reasonable to provide for a combination approach using flow-weighted averages. Accordingly, the final Guidance specifically provides the permitting authority discretion to develop limits using a "combined wastestream" approach. Under procedure 5.E.5 of appendix F, a permitting authority could develop limits by applying the no net addition approach established in procedure 5.E.3 of appendix F, for that portion of the wastestream containing intake pollutants from the same body of water, and applying the criteria end-of-pipe approach established in procedure 5.E.4 of appendix F to that portion of the wastestream containing intake pollutants from a different body of water, and use flow-weighted averages to develop end-of-pipe limits. The permitting authority has the discretion to not use this approach if it determined that development of such limits, or appropriate compliance monitoring, is infeasible. In addition, State or Tribes may impose more stringent requirements pursuant to CWA section 510.

The discussion in section 7.a.v below, addressing the requirement that 100 percent of the intake pollutant be from the same body of water as the discharge as a condition for relief under the intake pollutant reasonable potential procedure and for no net addition limits, also discusses multiple sources of pollutants in a facility's discharge.

5. Legal Authority

EPA received more comments on its authority to regulate intake pollutants than any other aspect of the intake pollutant procedures in the proposed Guidance. While some agreed that EPA had authority to regulate any pollutants in a discharge (and further argued that EPA did not have authority to provide any special allowances for intake pollutants in water quality-based permitting), many commenters who addressed this issue maintained that discharge of intake pollutants was not an "addition" of a pollutant as defined in the CWA and therefore fell outside of EPA's jurisdiction under the NPDES program. Others argued that even if EPA had the statutory authority to regulate intake pollutants, the proposal violated EPA's existing regulations, which require WQBELs only when the discharge causes, has the reasonable potential to cause, or contributes to an excursion above applicable water quality standards.

Evaluating options responsive to commenters' concerns led EPA to examine the appropriate basis for determining the responsibility of a point source discharger when its receiving water exceeds criteria for a pollutant due largely to other sources, its discharge contains that pollutant, and the pollutant originates, at least in part, in the discharger's water supply. Section 101(a) of the CWA establishes the overall objective of the CWA to restore and maintain the chemical, physical,and biological integrity of the Nation's waters. The CWA also establishes a comprehensive scheme for designating uses of surface waters and establishing criteria for pollutants that ensure attainment of those uses (section 303(a)-(c)). Section 303(d) further requires States to identify waters that will not meet water quality standards after implementation of technology-based controls on point source discharges, establish a priority ranking of those waters, and in accordance with the ranking, develop TMDLs which establish the pollutant level that cannot be exceeded in order to protect the applicable water quality standard for that pollutant.

Despite increased recognition of the impact of nonpoint sources on water quality, the CWA scheme for regulating sources of pollutants that can impair water quality focuses on point source controls. Sections 301(a) and 402 of the CWA require limits in NPDES permits for point sources more stringent than technology-based limits when necessary to meet water quality standards. The CWA is silent on how compliance with limits "necessary to meet water quality standards" (CWA section 301(b)(1)(C)) should be determined for a particular discharger, particularly when controls on other sources contributing pollutants to the same waterbody may be necessary to attain standards in the waterbody. While TMDLs provide a mechanism for allocating loadings among all sources in determining how to attain water quality standards, the CWA does not specify how those other sources are to be considered in developing permit limits when a TMDL does not exist.

a. Discharge of Intake Pollutants is an Addition of Pollutants Under the CWA

Some commenters objected to EPA's position articulated in the preamble to the proposed Guidance that release of intake pollutants into waters of the United States, where those pollutants had previously been removed from such waters, constitutes an "addition" of pollutants subject to regulation under the CWA. Commenters asserted that relevant case law (in particular NWF v. Gorsuch, 693 F.2d 580 (D.C.Cir. 1982), NWF v. Consumers Power Co., 862 F.2d 580 (6th Cir. 1988), Appalachian Power Co. v. Train, 545 F.2d 1351 (4th Cir. 1976)) establishes that such activities do not come within the scope of CWA jurisdiction. Some commenters also argued that the release of intake pollutants does not constitute an addition of the pollutants provided that the concentration of the pollutants in the facility's effluent is no greater than the concentration in the waterbody. In the view of these commenters, EPA must look to the environmental effects of a particular discharge to determine whether it is an addition of pollutants. Citing cases relied upon by EPA in the proposal such as U.S. v. M.C.C. of Florida, Inc., 772 F.2d 1501, 1506 (11th Cir. 1985) and Avoyelles Sportsmen's League v. Marsh, 715 F.2d 897, 923-924 (5th Cir. 1983), these commenters contended that a discharge of pollutants must necessarily be accompanied by a fundamental disturbance or substantial alteration to the receiving water in order to be subject to regulation under the CWA.

EPA's basic position, detailed in the preamble to the proposed Guidance at 58 FR 20956-7 (April 16, 1993), that discharge of any pollutant, including those in a facility's intake water, is an addition of pollutants within the meaning of the Clean Water Act, remains unchanged. In EPA's view, the commenters' assertion that the statute narrowly circumscribes the EPA's discretion to interpret "addition" to include the discharge of intake pollutants is without support in the CWA. Several of the cases principally relied upon by these commenters -- Gorsuch and Consumers Power -- in fact support EPA's broad discretion in construing this statutory term. These cases found that the CWA did not speak directly to the question whether dams "add" pollutants within the meaning of the CWA and therefore deferred to EPA's position that dams are not subject to regulation because they do not themselves "physically introduce a pollutant into water from the outside world." See Gorsuch, 693 F.2d at 175. Similarly, there is no evidence in the language or legislative history of the CWA that Congress ever considered the precise question whether the release of intake water pollutants into waters of the United States is subject to regulation under the CWA. As explained below, in deciding that the discharge of intake pollutants is subject to the CWA, EPA has adopted an interpretation of "addition" that the Agency believes is consistent with the language in the statute, and its underlying intent and purposes.

As an initial matter, EPA rejects the notion advanced by some commenters that EPA's statutory authority to regulate a discharge depends on the discharge exceeding a threshold of detrimental environmental effects on the receiving water (however such a threshold is defined). The statute provides simply that "any addition of any pollutant to navigable waters from a point source" is a discharge subject to the CWA (emphasis added). CWA 502(12). EPA does not see how this broad statutory language could be read as mandating that EPA exclude from regulation discharges of pollutants that do not meet a specified threshold of environmental impact on the receiving waters. EPA has never, since the enactment of the CWA, adopted such a constricted view of its statutory authority, and declines to do so now. Certain cases cited by commenters (such as Avoyelles and MCC of Florida) merely noted the detrimental environmental effects of the activities in those cases in the course of determining that they were regulated under the CWA. However, those decisions in no way indicate that such environmental effects are a jurisdictional prerequisite to subjecting an addition of pollutants to the CWA's requirements.

Construing the CWA as mandating such an approach would, moreover, be at odds with the basic structure of the CWA, which contemplates that the environmental effects of a discharge will be evaluated in the context of the permit issuance process. Whether the discharge of a particular pollutant will adversely impact the waterbody is a question appropriately addressed in the context of determining compliance with applicable water quality standards. See CWA 301(b)(1)(C). Requiring such an environmental analysis up front, as a prerequisite to the assertion of any regulatory authority whatsoever over an activity, would turn this statutory scheme on its head.

In EPA's view, whether a pollutant is discharged to waters of the United States turns on a common sense notion of what the term "addition" means: the simple, physical act of introducing a pollutant into a water of the United States from the outside world. Some commenters argued that the regulation of intake water pollutants does not meet this test (which was adopted by the courts in the Gorsuch and Consumers Power cases) because the pollutants had already been contained in the waterbody prior to its removal and use by the discharger as intake water. These commenters contended that regulating intake pollutants therefore reflected a sudden break with EPA's historic policies and practices, and was contrary to these judicial precedents.

EPA's position here is entirely consistent with the legal interpretation advanced by EPA, and upheld by the courts, in these cases. EPA believes that the pivotal fact for determining whether an addition has taken place for purposes of section 402 of the CWA is simply whether a pollutant is physically moved from outside of the waterbody into the waterbody by the discharger via a point source. In EPA's view, the appropriate analytical scope for answering this question need go no further than the end of a facility's discharge pipe. If, immediately prior to the discharge activity, the pollutant was not contained in waters of the United States, then the release of the pollutant into the waterbody is, quite logically, an "addition" of that pollutant to the waterbody. EPA sees nothing in the language of section 502(12) that compels the Agency to look more broadly at the entire life history of the pollutant (i.e., whether the pollutant was in the waterbody at some previous time) in order to answer the straightforward question whether a facility has "added" a pollutant to the waterbody. This interpretation is entirely consistent with EPA's position in the Gorsuch and Consumers Power cases, where the Agency advanced the position that dams did not "add" pollutants because the pollutants never left the waterbody in the course of being diverted by the facilities. (It should be noted that, in the case of discharges of dredged material regulated under section 404 of the CWA, the dredged material is by definition, contained in waters of the United States, and redeposition of such materials can be subject to the permitting requirement even though they are not introduced into the waterbody "from the outside world." See Avoyelles, 715 F.2d at 924, n.43.)

Moreover, adopting an exceedingly broad analytical scope to determine what constitutes an "addition" (to try to trace the ultimate source of the pollutant) would run counter to Congress' goal of effective water pollution control. Such an approach would transform a simple factual inquiry regarding whether a facility has added a pollutant to the waterbody into a more complex analysis of the ultimate source of the pollutant, and its relationship to the receiving water. Ascertaining whether a pollutant in a facility's effluent was originally contained in the receiving water can in some cases be a complicated task subject to uncertainties due to variability of pollutant levels in the intake and effluent, and limitations in available analytical techniques for detecting and quantifying such pollutants at low levels. EPA believes that it would make no sense (and certainly would be inconsistent with the comprehensive nature of the CWA's permitting requirement) to exempt entirely a pollutant discharge from regulation based on such an analysis. Moreover, EPA sees nothing in the text, structure or legislative history of the CWA to support the view that Congress expressly decided to require EPA to undertake this complex technical analysis as a prerequisite to regulating a discharge of pollutants by a point source. EPA believes, rather, that it is far more consistent with the structure and purposes of the CWA to apply regulatory scrutiny whenever pollutants are added by a point source to waters of the United States, and to address the particular environmental issues associated with discharges of intake pollutants through special permitting procedures such as those contained in the final Guidance.

Focusing the "addition" analysis on the narrow factual question whether the pollutant was outside the waterbody immediately prior to its discharge is an approach that has been expressly supported by some of the case law relied upon by commenters challenging EPA's authority to regulate intake pollutants. In Consumers Power, the court found that the entraining of fish by a pumped storage facility did not constitute an "addition" because the facility "never removes the fish from waters of the United States." 862 F.2d at 585. The court contrasted such a situation with seafood processors, which "add" pollutants because they remove the fish from waters of the United States prior to releasing the remains of processed fish. The court in Consumers Power also contrasted releases by dams, where the water containing entrained fish "never loses its status as water of the United States," with diversion of cooling water by industrial steam/electric operations, where removal of pollutants from waters of the United States and their subsequent discharge was subject to the CWA. Id. at 589.

One commenter pointed out that the court's discussion in Consumers Power of steam electric operations focused on the fact that use of cooling water by these facilities results in the absorption of "heat and other minerals produced by the plant or electric generator before being added to waters of the United States." Id. This commenter argued that it was the alteration of the intake water that, in the court's analysis, made its release constitute an "addition" of pollutants subject to regulation, and that therefore this reasoning did not apply to other discharges of intake pollutants by other types of facilities. EPA has two responses to this comment. First, the cooling water process associated with steam/electric facilities is, in EPA's view, typical of industrial use of cooling water generally, as is the effect of this process on the water that is used (i.e., "cooling" water is necessarily heated and can also absorb minerals in the process). Thus, EPA believes that the court's citation of this example provides guidance that use of intake water as cooling water by any industrial facilities generally, and the subsequent discharge of those cooling water, is an "addition" subject to CWA regulation. Second, as discussed elsewhere, EPA does not believe that it is the "alteration" of intake water quality that renders its removal and subsequent discharge an "addition" of pollutants. Rather, the simple fact that the pollutants were withdrawn by the facility so that they were no longer in waters of the U.S. means that the subsequent release of those pollutants into the waterbody is an addition of pollutants from the "outside world." This analysis is consistent with the discussion in Consumers Power, which found that use of cooling water was an addition because the water "loses its status as waters of the United States." In EPA's view, this is the critical fact for determining whether an "addition" has occurred, and this position is consistent with the discussion in Consumers Power.

Consistent with this line of reasoning, EPA maintains its position that, once pollutants contained in intake water are removed from waters of the United States, the pollutants are "outside" such waters, and the subsequent release of those pollutants back into jurisdictional waters via a point source is an "addition" subject to regulation under the CWA. A contrary reading of the statute is not compelled by the language of the CWA and would, moreover, complicate and hamper the administration of the comprehensive permitting scheme created by Congress under section 402 of the CWA.

In light of the growing body of case law finding that EPA has broad discretion to interpret what constitutes an addition subject to the CWA, EPA does not agree with commenters who relied upon the decision in Appalachian Power to argue that EPA is wholly without statutory authority to regulate releases of intake pollutants into waters of the United States. The court in this case found that the withdrawal, use, and subsequent discharge of pollutants originating in the receiving water does not constitute an addition of pollutants. The court based this conclusion on its finding that it is beyond the scope of EPA's authority to require a facility to remove pollutants "other than those added by the plant process." Appalachian Power, 549 F.2d at 1377. For the following reasons, EPA does not agree that this court's decision and reasoning preclude EPA from continuing its longstanding practice of asserting regulatory jurisdiction over the discharge of intake pollutants.

First, as noted in the preamble to the proposed Guidance, several courts have upheld EPA's regulatory approach for considering intake pollutants in establishing technology-based effluent limitations; this approach can in some cases lead to subjecting the discharge of intake pollutants to CWA regulation, but allows for net limits to be established under certain, defined circumstances. (See American Petroleum Institute v. EPA, 540 F.2d 1023, 1034-35 (10th Cir. 1976); Hooker Chemicals and Plastics v. Train, 537 F.2d 620, 633 (2d Cir. 1976)). Second, it is important to note that the Appalachian Power decision predated decisions of the U.S. Supreme Court delineating the appropriate standard of review of agency actions where Congressional intent regarding the meaning of a statutory term is not clear. See, e.g., EPA v. National Crushed Stone Association, 449 U.S. 64 (1980); Chevron U.S.A. v. NRDC, 467 U.S. 837 (1984). Because the Fourth Circuit's decision in Appalachian Power contains no discussion of the deference due to EPA's statutory interpretation, and the court's conclusory analysis does not expressly make a finding that Congress had spoken to the precise question at issue, EPA questions whether the court's analysis is consistent with current legal principles governing review of agency statutory interpretations. As discussed above, court decisions subsequent to Appalachian Power have upheld EPA's interpretation of addition based upon application of the proper, deferential standard of review. See, e.g., Gorsuch, Consumers Power.

Finally, more recent cases, including a case decided by the same court which had issued the Appalachian Power opinion, have not adopted the approach or reasoning of Appalachian Power. For example, as discussed above, the decision in Consumers Power focused on whether the intake pollutants in question had been removed from waters of the United States in order to determine whether the reintroduction of those pollutants into those waters constituted an addition subject to the CWA. That court's analysis was therefore a sharp departure from the reasoning which some commenters read into the Appalachian Power case (i.e., that pollutants contained in the waterbody can never be subject to CWA regulation, even when they are withdrawn from those waters and subsequently discharged into waters of the United States via a point source).

In a recent decision in U.S. v. Law, 979 F.2d 977 (4th Cir. 1992), the Fourth Circuit itself adopted a line of reasoning similar to EPA's approach here. This case involved an appeal of a criminal conviction of a mine operator for violating the CWA by discharging pollutants into waters of the United States from a water treatment system that had collected contaminated run-off from the mining operation. The defendant challenged his conviction on the grounds that the CWA imposes liability only upon the generators of pollutants, and not upon persons over whose property pre-existing pollutants pass before flowing into navigable waters. Arguing that the headwaters of the receiving stream were already polluted prior to entering his treatment system, the defendant cited Gorsuch, Consumers Power, and Appalachian Power to argue that he had no duty to remove pre-existing pollutants. The Fourth Circuit held that the discharge of pollutants from the facility's water treatment system was subject to the CWA's permitting requirement because the water treatment system was not part of waters of the United States. Because the "origin of pollutants in the treatment and collection is therefore irrelevant," the court found that release of pollutants from the treatment system into waters of the United States required a permit. 979 F.2d at 979.

While the Law case addressed pollutants contained in surface run-off (as opposed to intake pollutants originating from the receiving water), the Fourth Circuit found in this case that the critical fact for determining whether an addition of pollutants has occurred is whether the pollutants were already in the waters of the United States at the time of discharge through the point source and therefore not being added to waters of the United States. Since, in this case, the water treatment system releasing pollutants was not part of waters of the United States, the ultimate origin of those pollutants was irrelevant, and the discharge of those pollutants constituted an "addition" for purposes of the CWA. This is precisely the line of reasoning that EPA advocated in the "dams" cases, and continues to adopt here. Under this mode of analysis, EPA asserts that reintroduction of intake pollutants that have been withdrawn from waters of the United States clearly constitutes an addition of pollutants. Thus, notwithstanding how some commenters may construe the reach of the Appalachian Power decision, EPA maintains that its position that discharges of intake pollutants by point sources are subject to the CWA is consistent with the current state of the law in the Fourth Circuit.

Numerous commenters also argued that the proposed Guidance was inconsistent with the court's decision in American Iron and Steel Institute et al. v. EPA, 526 F.2d 1027 (3rd Cir. 1975), which held that EPA was required to adjust technology-based effluent limitations if it could be shown by a discharger that it was unable to meet the limitations due to significant amounts of pollutants in intake water. The court stated that "[s]uch an adjustment would seem required by due process, since without it a plant could be subjected to heavy penalties for circumstances beyond its control." 526 F.2d at 1056. EPA believes that this decision does not undercut the final Guidance's intake pollutant provisions. First, under appropriate circumstances, the final Guidance authorizes a special reasonable potential determination procedure and the adoption of "no net addition" limitations that, in effect, would not hold the permittee responsible for pollutants that had been in the waterbody prior to use of the intake water by the facility. Second, the focus of the American Iron and Steel decision was on technology-based limitations which, by definition, can only require permittees to take all technologically and economically feasible steps to reduce pollutants in its discharge. See CWA § 304(b). If, as the court noted, a discharger is simply unable to meet such limitations due to the presence of intake pollutants, then an adjustment of those limitations is appropriate, and EPA's permitting regulations recognize this fact. See 40 CFR §122.45(g). Under section 301(b)(1)(C) of the Act, however, limitations necessary to meet state water quality standards must be included in NPDES permits, without regard to economic or technological feasibility. See U.S. Steel Corp. v. Train, 556 F.2d 822, 838 (7th Cir. 1977) ("It is clear from §§ 301 and 510 of the Act, and the legislative history, that States are free to force technology . . . . If the States wish to achieve better water quality [than can be achieved through technology-based controls], they may, even at the cost of economic and social dislocation caused by plant closings."). Thus, in determining the appropriate limitations on discharges of intake pollutants necessary to meet the requirements of section 301(b)(1)(C) of the Act, the feasibility considerations relied upon principally by the court in American Iron and Steel are not legally relevant.

Finally, as to the statement in the court's opinion that adjustment of limitations would seem required by due process, the precise legal analysis supporting this conclusion is unclear. Notably, the court in that case did not analyze the process by which intake credits would have been determined for permittees subject to the regulations at issue in that case, and whether that process would meet constitutional requirements. See Mathews v. Eldridge, 424 U.S. 319, 333 (1976) ("The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner."). EPA believes that procedural protections satisfying the requirements of the due process clause are afforded to NPDES permit applicants, since the applicant has the right to receive notice of draft permits developed by the permitting authority and to comment on the contents of the draft permit. See 40 CFR §124.10. Thus, any permit conditions relating to the discharge of intake pollutants would only be adopted by the permitting authority after the permittee has had a timely opportunity to provide comments on the permitting authority's decision. In EPA's view, these procedures provide an opportunity "to be heard in a meaningful time and in a meaningful manner." Mathews, 424 U.S. at 333.

Underlying the court's conclusion in American and Iron and Steel was the concern that a permittee could be held responsible for circumstances beyond its "control." As discussed above, to the extent the notion of "control" reflects concerns about technological feasibility, such considerations are not legally germane to determining water quality-based effluent limitations. EPA disputes, however, the notion advanced by some commenters that facilities do not have any "control" over discharges of intake pollutants, and that the discharge of such pollutants is a wholly "passive" act which should never subject dischargers to regulatory requirements or legal liability for their discharge. While it is true that a point source does not necessarily have control over the background level of pollutants in surface waters used as a source of intake water by the facility, this does not mean that the source automatically does not have any control of the pollutant levels that it discharges. The process of withdrawing intake water from surface waters for use by a facility is unquestionably an affirmative, volitional act by the facility. It reflects an affirmative decision by the point source to use intake water from waters of the United States instead of utilizing other water sources (e.g., public water supply). While such decisions may reflect reasonable economic calculations (i.e., it may be more expensive to obtain the necessary intake water from the public water utility), it can hardly be argued that such decision-making is wholly passive in nature. Moreover, once the facility has decided where to obtain its intake water, the facility's use of the water as part of its processes makes it impossible, in EPA's view, to argue that the water is not subject to the "control" of the facility. It is not uncommon for facilities to pretreat their water to make it suitable for use by the facility, and EPA's technology-based intake credit regulations recognize, and require, that intake pollutants be reduced through treatment to the extent feasible. See 40 C.F.R. § 122.45(g) (allowing credit "only to the extent necessary to meet" technology-based limitations). EPA acknowledges commenters' concerns that treatment of intake pollutants may in certain cases be difficult or costly. This does not mean, however, that discharges of such pollutants are wholly outside the discharger's "control." EPA also recognizes that removal of intake pollutants may not be necessary to meet water quality standards in certain cases, and accordingly has included appropriate provisions in the final Guidance that would allow such discharges when appropriate environmental safeguards are met.

b. EPA's Authority and Rationale for Establishing Interim Permitting Procedures Allowing "No Net Addition" Limitations for Intake Water Pollutants

In contrast to commenters who argued that EPA has no jurisdiction to regulate intake pollutants, some commenters argued the intake provision in the proposed Guidance, as well as the other options discussed in the preamble to the proposal, were outside EPA's legal authority under the CWA. In the view of these commenters, section 301(b)(1)(C) of the CWA, which requires that dischargers achieve any "limitation . . . necessary to meet water quality standards," does not authorize EPA to allow intake pollutants to be discharged at a level exceeding water quality standards. These commenters maintain that section 301(b)(1)(C) flatly precludes the permitting authority, under any circumstances, from finding that a discharge of pollutants into non-attainment waters at levels above applicable water quality criteria "meets" water quality standards under the CWA.

EPA disagrees with these commenters that EPA is without statutory authority to provide for the establishment of special permitting procedures for the discharge of intake pollutants being discharged into the "same body of water" as defined the final Guidance. EPA believes that it has the legal authority to adopt the "no net addition" permitting procedures contained in the final Guidance. The Agency believes, moreover, that it is appropriate, as a matter of policy, that these procedures be followed for an interim period of time (i.e., 12 years from publication of the Guidance) to provide an opportunity for States and Tribes to develop TMDLs or comparable assessment and remediation plans as provided in procedure 3.A of appendix F which ensure attainment of water quality standards in the waterbody.

EPA agrees with the general principle that section 301(b)(1)(C) narrowly limits permissible discharges into waters of the United States to those which meet water quality standards. Consistent with this statutory requirement, EPA's regulations require the imposition of WQBELs that are derived from, and comply with, all applicable water quality standards. See 40 CFR 122.44(d)(1)(vii)(A).

While section 301(b)(1)(C) clearly requires that all dischargers meet water quality standards, the CWA does not expressly address the specific technical question of how EPA should determine whether a particular discharge is, in fact, meeting such standards. Ascertaining a discharger's compliance with water quality standards is a technical determination that is necessarily made on a case-by-case basis, based on consideration of the pollutants in the discharge, as well as the discharge's relationship to, and interaction with, the conditions in the receiving water. In the case of intake pollutants discharged into the same body of water from which they originated, there is a highly unique relationship between those discharged pollutants and the receiving waterbody. In some cases, discharge of such a pollutant merely transfers the pollutant downstream to a location that the pollutant would have reached in any event, and the environmental impact of such a discharge may be no different than that which would have occurred had the pollutant remained in-stream.

EPA believes that, to ascertain accurately whether, and under what conditions, such a discharge meets water quality standards, a site-specific evaluation of the relationship between the discharge and the waterbody is necessary. Where it can be demonstrated that particular intake pollutants in a discharge meet all conditions necessary to ensure that the discharge would have no different impact on the receiving water than the impacts that would occur in the absence of withdrawal and discharge of the pollutant, EPA believes that, as a matter of policy, it has the authority to authorize the permit writer to account for the presence of that pollutant in determining a discharger's compliance with water quality standards, and in deriving limitations that are necessary to meet such standards. Further, for the reasons explained below, EPA believes that it is appropriate for this special allowance of intake pollutants to be effective only for an interim period, to provide continued incentives for the permitting authority to develop comprehensive solutions necessary to reduce background concentrations of pollutants in non-attainment waters. However, EPA believes that accounting for such pollutants in making a determination of compliance with water quality standards must only result from a rigorous, case-specific inquiry carefully evaluating the relationship of the intake pollutant discharge with the waterbody, and a finding that the presence of the discharge does not alter the impacts that would have occurred in the absence of the discharge.

A case-specific inquiry is required in the final Guidance, which provides that, in order to be eligible for "no net addition" limitations, the permitting authority must find that the intake pollutant is discharged into the same body of water from which it originated, and that the facility does not increase the mass or concentration of the pollutant, alter the pollutant chemically or physically, or cause any increased adverse effects due to the timing and location of the discharge. In light of the clear mandate in section 301(b)(1)(C) that all discharges meet water quality standards, EPA believes that it would be necessary for a discharger to meet all of these conditions in order for the presence of intake pollutants to be accounted for in determining whether a discharge meets water quality standards and in deriving WQBELs. Only when these conditions are met is EPA satisfied that discharge of a particular pollutant would not result in any impacts that would not have occurred if the pollutants had remained in-stream, and that discounting of the pollutant in the standards compliance determination may be therefore appropriate, as a matter of policy, on a case-by-case basis.

Some commenters argued that intake pollutant relief should also be available where a facility has intake pollutants from a different body of water (or from other sources allegedly not the "responsibility" of the discharger), provided that the concentration of the pollutant in the discharge is no greater than the concentration in the receiving water. In the view of these commenters, such a discharge should be allowed on the grounds that it does not worsen the condition of the waterbody. The relevant test for determining consistency of a water quality-based permitting approach with the requirements of the CWA is not, however, whether a discharge worsens existing conditions, but whether the discharge "meet[s] water quality standards." CWA section 301(b)(1)(C). EPA does not believe that there would be any basis, either legally or technically, to account for the presence of pollutants in a discharger's effluent where those pollutants only reach the receiving water because of the presence of the discharge. Since the introduction of such pollutants into waters of the United States is precisely the type of activity that the CWA is intended to regulate, EPA does not believe that accounting for the presence of such pollutants in determining a discharger's compliance with water quality standards and in deriving effluent limitations would be permissible under section 301(b)(1)(C) of the CWA.

Since EPA has determined that the presence of intake pollutants can, as a matter of policy and under certain circumstances, be accounted for when determining what limitations are necessary to meet water quality standards, the question arises as to how to derive the appropriate WQBEL that implements section 301(b)(1)(C). One option considered by EPA would have allowed a straight "credit" for intake pollutants. Under this option, an initial WQBEL would be derived following the normal permitting procedures, and that limitation would then be adjusted upwards to allow the facility to discharge any additional amount of an intake pollutant meeting all the conditions specified in the final Guidance. Thus, for example, if the permitting authority were to determine that the appropriate WQBEL for a discharge into a non-attainment water would be criteria end-of-pipe (in the absence of intake pollutants), the discharger would receive a limitation corresponding to that limitation plus the amount of the intake pollutant (assuming all other conditions in the final Guidance were met). EPA rejected this option because facilities would be allowed to discharge pollutants into non-attainment waters at levels exceeding the background level of the pollutant in the receiving water. Such a discharge would therefore actually be making the quality of a non-attainment water worse, a result that cannot be reconciled with the requirement in section 301(b)(1)(C) that dischargers meet water quality standards, or with the CWA's goal of restoring and maintaining the integrity of the nation's waters.

Therefore, as discussed in previous sections, EPA decided that the appropriate method of taking account of intake pollutants in developing WQBELs would be to establish limitations based on the concept of "no net addition." Under this approach, the permitting authority would establish limitations allowing the facility to discharge the amount of the intake pollutant, but not any additional amount. EPA recognizes that, under this approach, a facility without pollutants in its intake water may be permitted to add an additional amount of the pollutant from its process (e.g., a concentration based on criteria end-of-pipe) whereas a facility with intake pollutants would be precluded from adding to the total net amount of the pollutant discharged. However, rectifying this difference by allowing a facility with intake pollutants to add an additional amount to the total loadings in the effluent would not, as noted above, be consistent with section 301(b)(1)(C), or the goals of the CWA.

While EPA believes it has discretion to account for the presence of intake pollutants in deriving WQBELs under certain circumstances, EPA believes that it is vital that this discretion be exercised in a manner that advances the underlying objectives of the CWA: to restore the integrity of the nation's waters. CWA section 101(a). Therefore, as discussed in previous sections, the final Guidance only allows the "no net addition" approach for a period of approximately two permit terms. After that time, WQBELs in a non-attainment water would be based on the WLAs in an EPA-approved TMDL or comparable assessment and remediation plan approved under procedure 3.A of appendix F. In the continued absence of a TMDL or comparable plan, WQBELs would be developed without special consideration for intake water pollutants in accordance with the provisions in procedure 5.F.2 of appendix F. (See section VIII.E for a discussion of deriving WQBELS for discharges to non-attainment waters in the absence of a TMDL.)

While EPA believes that "no net addition" limitations are appropriate as an interim measure for dealing with intake pollutants in the permitting process, EPA recognizes that this approach contributes to the mere maintenance of status quo for waterbodies that are currently out of compliance with water quality standards. This status quo is not an acceptable long-term result under the CWA. As has been discussed extensively during the development of the Guidance, the root causes of non-attainment with water quality standards in the Great Lakes basin are complex, and for some pollutants of concern, non-attainment may be due predominantly to nonpoint sources of pollution. The best, indeed in some cases the only, means of bringing such waterbodies into compliance with standards is to address comprehensively all the relevant sources of contamination. The CWA mechanism for comprehensively evaluating these sources is the TMDL development process, which establishes wasteload allocations for point sources and load allocations for nonpoint sources in order to calculate the pollutant reductions from point sources necessary to achieve water quality standards in the waterbody. Section 303(d) of the CWA requires States to identify waters that are not attaining water quality standards and in accordance with the State's priority rankings, develop TMDLs for those waters. As discussed above, States may also undertake other efforts that identify sources causing or contributing to a water quality impairment and develop load reduction activities for those sources as necessary for attainment of water quality standards. When these efforts satisfy the provisions of procedure 3.A of appendix F, they may serve in lieu of a TMDL as the basis for developing WLAs for discharges of intake pollutants from the same body of water after the time period for "no net addition" limits ends.

By limiting the time period during which the "no net addition" permitting approach will be available, EPA is establishing incentives for States and Tribes to develop TMDLs or comparable assessment and remediation plans that will comprehensively assess all of the causes of non-attainment in the affected waterbody and establish a plan for achieving attainment, a step which EPA believes is critical if the objectives of the CWA are to be met. As to the appropriateness of precluding intake pollutant relief after this interim period, it is important to emphasize that EPA does not view the CWA as mandating that special allowance be made for intake pollutants. EPA is, rather, allowing such consideration by the permitting authority for an interim period of time as a matter of policy, for the reasons explained above. Dischargers do not, as some commenters asserted, have a "right" to discharge intake water pollutants since EPA believes that the discharge of intake pollutants by a point source constitutes an "addition" of pollutants subject to regulation under the CWA. Among the many policy options available to address intake pollutants, EPA believes that allowing the no net addition approach where the discharge is not altering the impact of the pollutant on the waterbody, but limiting the time period during which this procedure is available so that the root causes of non-attainment can be addressed through TMDLs or comparable assessment and remediation plans, best complies with the mandates of the CWA and will most effectively achieve its goals.

6. Continued Availability of Existing Mechanisms

In the preamble to the proposed Guidance, EPA stated that existing mechanisms could adequately address intake pollutants, particularly in non-attainment waters, and provided numerous examples. See 58 FR 20953-56 (April 16, 1993). At the same time, EPA proposed the new reasonable potential procedure addressing intake water pollutants in recognition that States and dischargers had concerns about administrative burdens associated with existing mechanisms, including increased paperwork, permit issuance delays, and increased costs for both dischargers and the States. Numerous commenters echoed these concerns, with several asserting that the environmental result would be the same regardless of which mechanism were chosen to adjust the limits. Some commenters also objected to the use of existing mechanisms on the grounds that they may not be available under existing State laws, and even if they were, would be discretionary with permit writers, and none of them would necessarily offer relief considered by these commenters to be adequate.

The final Guidance addresses many of these practical concerns with existing mechanisms by adopting an alternative reasonable potential procedure that focuses on intake pollutants and by establishing methods to consider intake pollutants directly in developing WQBELs. The intake credit provisions in the final Guidance are designed to provide for consideration of intake water pollutants through the NPDES permit program in certain circumstances, but do not replace the need for other mechanisms to address the underlying problem, i.e., waters that do not meet water quality standards. Indeed, one of EPA's major concerns with adopting a permit-based mechanism to adjust WQBELs for intake pollutants was that it could discourage the development of TMDLs. When non-attainment is due largely to significant loadings from nonpoint sources or historical contamination, as is the case for some pollutants in many of the waters in the Great Lakes basin, a TMDL is the mechanism best suited for characterizing the problems and possible solutions, and establishing a comprehensive plan to bring the water into attainment. Other mechanisms may accomplish this same objective as TMDLs and thus serve in lieu of TMDLs as described above. To provide incentives for comprehensively evaluating sources contributing to excessive background levels of a pollutant and identifying steps necessary to reducing those levels to acceptable levels, EPA is limiting the availability of no net addition limits to 12 years after the publication date of the final Guidance.

A TMDL is the preferred mechanism for identifying all sources of a pollutant to a waterbody and devising a load allocation scheme to achieve attainment of water quality standards throughout the waterbody. In all cases, TMDLs should be considered initially when the background concentrations in the waterbody exceed applicable criteria before turning to intake credits. Indeed, section 303(d) of the CWA requires States to identify waters that do not meet water quality standards after implementation of technology-based controls on point sources discharges, establish a priority ranking of those waters, and prepare TMDLs. A phased approach to TMDL development, described more fully in section VIII.E of this document, provides flexibility in cases where data are limited.

All options discussed in the preamble to the proposed Guidance preserved the paramount role of TMDLs in allocating load reductions among various sources of pollutants, as reflected in the requirement to implement limits consistent with a TMDL. The final Guidance retains this feature. The provision addressing the relationship between the intake pollutant procedures and TMDLs has been moved to the front of the procedure and reworded slightly to highlight the fact that when a TMDL exists, it governs wasteload allocations for individual point sources and intake pollutant procedures do not apply. See procedure 5.D.1.c of appendix F of the final Guidance. This section also now recognizes that assessment and remediation plans approved in accordance with procedure 3.A of appendix F may serve in lieu of TMDLs as the basis for establishing WLAs. Where such a plan has been approved, it would be used instead of the intake pollutant procedure to determine WQBELS. The TMDL or comparable plan itself may take into account the presence of intake water pollutants in determining the appropriate load allocations for nonpoint sources, wasteload allocations for point sources, a margin of safety required by CWA section 303(d), and any reserved allocation for future growth determined desirable by the State or Tribe. Nothing in the final Guidance alters a State's or Tribe's existing responsibility to identify and provide priority ranking for waters that do not meet water quality standards in accordance with section 303(d) of the CWA and 40 CFR 130.

Some commenters argued that the final Guidance should require States or Tribes, in developing a TMDL, or permit writers in implementing a TMDL, to grant intake credits despite the existence of a TMDL that allocates loads differently than would the intake credit procedures. These comments are consistent with other numerous comments that dischargers should not be responsible for pollutants in their discharge that originate in the intake water. One suggestion was that WQBELs in waters exceeding WQS not be more stringent than the larger of the criterion or the background concentration.

Another suggestion was that, given the number of conservative assumptions in addressing scientific uncertainty in developing criteria or values and TMDLs, the WQBEL calculation becomes unworkable without considering that intake waters frequently are "contaminated" with trace concentrations; and stated further, since trace levels are being proposed to be unacceptable i.e., the new GLI criteria), reality demands a sound procedural solution for this phase of national water quality protection.

EPA does not agree that States and Tribes should be constrained by the intake credit provisions when establishing TMDLs or comparable assessment and remediation plan designed to achieve water quality standards in the waterbody. Nothing in the CWA constrains the authority of EPA or the States to require whatever load reductions are necessary to attain water quality standards. As a matter of policy in implementing the NPDES program, EPA has established intake credit procedures to restrict the load reduction responsibilities for individual dischargers in the absence of a TMDL or comparable plan. Historically, State flexibility in allocating load reduction responsibilities has been a key feature of the TMDL process. However, imposing mandatory intake credit provisions on a State TMDL or comparable process would eliminate the flexibility to apportion available loadings among sources in a manner which best achieves CWA objectives, accounts for sources that cannot feasibly be reduced, and meets State policy goals such as cost-effectiveness and reserving loading capacity to accommodate future growth. This same flexibility would allow a State to consider the presence of intake water pollutants in establishing wasteload allocations for point source dischargers, as long as controls on other sources are sufficient to attain water quality standards and provide a margin of safety. Consideration of intake water pollutants within the context of a TMDL or comparable plan could result in wasteload allocations, and resultant permit limits, that are more or less stringent than limits developed under the intake pollutant procedures in the final Guidance.

EPA acknowledges that meeting the CWA requirement for TMDLs to attain standards with a margin of safety may be difficult in some cases given stringent new standards and significant loadings from nonpoint sources. States face difficult choices in determining priorities for TMDL development and for devising a workable mix of load allocations, wasteload allocations, and margin of safety necessary to attain water quality standards when establishing a TMDL. It would be inappropriate (and inconsistent with CWA section 510 and EPA regulations at 40 CFR 122.44(d)(1)(vii)(B)) for EPA to limit States' or Tribes' flexibility in undertaking this task or to undermine decisions made through the TMDL process by adopting a permitting policy that ignores WLAs established by a TMDL.

Waters may exceed standards for numerous reasons and all available mechanisms should be considered to determine which provides the most suitable approach to addressing a particular situation. A common feature of all intake credit options discussed in the preamble to the proposed Guidance was the continuing availability of existing mechanisms for adjusting standards or load allocations that would allow adjustment to WQBELs and provide relief to dischargers using polluted intake water. In addition to TMDLs, these mechanisms include site-specific modifications to criteria, temporary variances to water quality standards, and changing the designated use of the waterbody. Also, in certain circumstances, a permittee may qualify for a compliance schedule in its permit, which does not adjust the limits but rather provides a period of time to come into compliance with new effluent limits, under procedure 9 of appendix F. Under the final Guidance, these mechanisms continue to be available and are discussed in detail elsewhere in this document. States and Tribes, of course, may choose to be more stringent under section 510 of the CWA, and restrict the availability of these mechanisms. Depending on the circumstances, application of these mechanisms at the outset could preclude the need for WQBELs. For example, a site-specific modification to criteria under procedure 1 of appendix F may result in the waterbody attaining standards at the existing levels and projected discharges from a facility may not be at levels determined to cause, have the reasonable potential to cause, or contribute to an excursion above the newly modified standard. In some cases, a combination of mechanisms may be necessary. For example, a facility with intake pollutants from a different body of water that discharges to a waterbody which exceeds standards for a pollutant in the discharge does not qualify for "no net addition" limits and if the discharge causes, has the reasonable potential to cause, or contribute to an excursion above State or Tribal water quality standards, WQBELs for that facility will be based on the most stringent applicable criteria for the pollutant of concern (see procedure 5.E.4 of appendix F) or, where the facility has multiple sources of intake water pollutants, on a flow-weighted combination of "no net addition" and criteria end-of-pipe approaches (see procedure 5.E.5 of appendix F). WQBELs derived from these procedures in the final guidance may be more stringent than those in the facility's existing permit. In this situation, the facility may qualify for a compliance schedule (see procedure 9 of appendix F). Alternatively, the facility may be eligible for a temporary variance under procedure 2 of appendix F).

7. Final Intake Credit Provision and Response to Major Comments

a. General Issues

This section discusses issues common to the reasonable potential determination and qualifying for limits based on no net addition.

i. Pollutant-by-Pollutant, Outfall-by-Outfall Analysis

In the preamble to the proposed Guidance, EPA explained that the intake pollutant procedures would apply on a pollutant-by-pollutant, and outfall-by-outfall basis. The reasonable potential analysis need only be done for pollutants in the intake that, absent special consideration for their origination in the same body of water, could potentially cause or contribute to an excursion above the water quality standard applicable to the receiving water. The presence of an intake pollutant of concern in the discharge would not require automatic submission of data and an analysis of, or limits for, all other pollutants in the discharge. Similarly, if a facility used receiving water for cooling purposes that exceeded criteria for copper, for example, and also added copper to a separate process stream, the added copper to the process stream would not be relevant to the no additional mass requirement or for the reasonable potential procedure for the cooling water stream if the process and cooling water streams were discharged from separate outfalls. Each discharge should be evaluated separately.

Despite the discussion in the preamble to the proposal, some commenters appeared confused on this point. One commenter requested clarification to avoid problems during implementation. EPA agrees that clarification in the Guidance is appropriate because misunderstanding could be costly. Although treatment of one pollutant in a discharge might incidentally remove other pollutants, as several commenters pointed out, treating different pollutants could also require installation of new or different technology at significant expense. Accordingly, EPA has added language in procedure 5.D.1.a which states that the determination made under the intake pollutant provisions shall be made on a pollutant-by-pollutant and outfall-by-outfall basis.

ii. Pollutants Covered

The final Guidance, as did the proposed Guidance, provides that Great Lakes States and Tribes may, at their discretion, apply any of the implementation procedures to the pollutants and pollutant parameters listed in Table 5 of part 132 ("Pollutants Subject to Federal, State and Tribal Requirements," referred to as the "excluded" pollutants in the proposal). EPA solicited comments on whether the pollutants eligible for intake pollutant relief should be more or less inclusive. Specifically, EPA stated that application of proposed intake pollutant reasonable potential to the pollutants in Table 5, including generic pollutant parameters (e.g., biochemical oxygen demand and total suspended solids), is technically feasible as long as the proposed requirements of procedure 5.E of appendix F are demonstrated. EPA asked for comment on whether any intake pollutant procedures should be applied to all pollutants, including identification of pollutant characteristics that may prevent demonstration of any of the proposed requirements of procedure 5.E. In addition, EPA requested comments on whether any procedures in the final Guidance that provided for direct adjustment of permit limits for intake pollutants should be restricted only to those pollutants that, due to nonpoint source contributions such as atmospheric deposition, are present throughout the Great Lakes basin at about the same concentration, and that concentration already exceeds the water quality criterion. With respect to Option 3, which would allow relief for pollutants from other bodies of water, EPA asked whether such a provision should be limited to non-BCCs.

EPA received few comments on this issue. Some commenters stated that no distinctions should be made based on the type of pollutant because regulating intake pollutants was not legal or equitable for any pollutant . Similarly, some commenters asserted that any option chosen should be applicable to all pollutants subject to regulation by the final Guidance, not just non-BCCs, because EPA had no sound legal, policy or other reason to limit intake credits in that manner. With regard to limiting relief to ubiquitous pollutants, some commenters stated that such an approach would not be scientifically justified because background concentrations will vary considerably throughout the basin, as will sediment contributions to background concentration, which are limited to a few specific areas. Several commenters submitted data showing varying levels of background pollutants, in many cases at levels above the proposed criteria. Another commenter added that limiting relief to ubiquitous pollutants would be meaningless anyway, because any additional treatment necessitated for the remaining pollutants would likely remove the ubiquitous pollutants as well.

Commenters who generally opposed intake credits favored efforts to limit the availability of intake pollutant relief based on the type of pollutant. One commenter stated that although intake pollutant relief for BCCs generally would be contrary to the purposes of the GLWQA and the CPA to advance "virtual elimination" of those pollutants; nevertheless, relief would be appropriate where, because of atmospheric deposition, the pollutant is present throughout the Great Lakes at similar levels. One commenter advocated a prohibition on the transfer of pollutants to another medium for intake credits, e.g., an intake credit for atmospheric deposition must not be allowed, unless provisions are written that guarantee that industry will not benefit by burning toxics in order to get an intake credit.

The final Guidance is the same as proposed with respect to the pollutants covered by the intake credit procedures. That is, States or Tribes can adopt the intake pollutant procedures in procedure 5 for any pollutant for which the State or Tribe determines that such procedure is appropriate. Although certain pollutants are excluded from the Guidance under Table 5, EPA believes that States and Tribes can choose to apply the intake pollutant procedures to any of the Table 5 pollutants, where the State or Tribes believes that application of those procedures is appropriate. Moreover, States and Tribes can elect not to adopt intake pollutant procedures for any pollutants, since the final Guidance does not mandate that these procedures be adopted by States or Tribes. States and Tribes can, of course, choose to adopt intake pollutant procedures that are more stringent than the procedures in the final Guidance, consistent with section 510 of the CWA.

While EPA believes that it has discretion to develop different approaches based on the nature of the pollutants, it declines to do so in this instance. The reasons supporting EPA's decisions on intake pollutant relief do not readily support distinctions among different types of pollutants, e.g., BCCs vs. non-BCCs. Ubiquitous pollutants, particularly PCBs and mercury, are of concern when considering intake pollutant relief, but available data suggest that it would be difficult to support a finding that any pollutant occurs at roughly the same level throughout the Great Lakes. EPA believes that the intake pollutant procedures in the final Guidance are defensible on legal and technical grounds regardless of the pollutant at issue. When the source of the intake pollutants and the discharge are within the same body of water, the final Guidance provides relief when the permittee can demonstrate that the pollutant of concern in the discharge essentially has no effect on the receiving water quality greater than would occur if the pollutant were left in-stream. When the source of the intake water pollutant is a different body of water, EPA does not believe that intake pollutant relief cannot be reconciled with the requirement to establish limits that implement water quality standards, even if the pollutant of concern can be characterized as "ubiquitous." Relief might be appropriate through other mechanisms, however, such as variances from water quality standards, as provided in procedure 2 of appendix F.

Few comments specifically addressed whether intake pollutant relief would be appropriate or inappropriate for pollutants on Table 5. The only objection to making intake pollutant procedures available to Table 5 pollutants are that they are not needed for those types of pollutants. Because States have discretion in this matter, no changes have been made, which would limit a State or Tribe's ability to apply the intake pollutant procedures in the final Guidance to pollutants on Table 5. However, as a practical matter, EPA does not expect much demand for intake pollutant relief for many of these pollutants because they biodegrade quickly in water or are relatively easy to treat and thus do not present the same problems as BCCs, for example.

iii. Required Demonstration

The proposed Guidance required the permittee to demonstrate that it met each of the five requirements for intake pollutant relief. The permitting authority was required to document how this demonstration was made in the fact sheet or statement of basis for the permit and to establish monitoring to ensure that the requirements continued to be met throughout the term of the permit.

Most comments on the necessary demonstration focused on the specific elements that needed to be demonstrated and are addressed in the sections addressing those requirements. In addition, several commenters objected generally that the intake pollutant procedures were cumbersome and onerous, put an unfair burden on permittees and, because of the "absolute nature" of the required demonstration, effectively denied any relief. These commenters requested that permitting authorities be given more discretion to exercise their best professional judgment in making the reasonable potential determination. The most extreme application of this approach, advocated by some, was to simply state that intake pollutants may be considered in WQBEL development and leave it up to States to determine how. Others, in contrast, urged relative specificity because consistency among the Great Lakes States is a major goal of the CPA and the Guidance.

In the final intake pollutant procedures, EPA has balanced the goal of consistency with flexibility for permitting authorities to exercise judgment in making the ultimate determination of whether WQBELs are needed. EPA recognizes that determining whether a discharge causes or has the reasonable potential to cause or contribute to an excursion above a WQS is a complex determination based on site-specific factors and calls for the exercise of judgment, particularly in ascertaining the impact of a particular discharge in light of other sources and stressors on the receiving water . At the same time, leaving all aspects of this determination to the permitting authority could lead to very different results in comparable situations, a result the Guidance was intended to minimize. EPA also recognizes that while many aspects of this evaluation are site-specific, there are bounds which can be prescribed for conducting such an evaluation. EPA has balanced these competing considerations by providing a general framework for assessing the impact of intake pollutants on a case-by-case basis that considers the possible impacts resulting from the discharge while providing discretion to the permitting authority to determine the details of how the required demonstration can be met. This decision is reflected in the discussion below of each of the conditions necessary to establish eligibility for special consideration for intake water pollutants.

EPA does not agree with numerous comments that a discharger should not be required to demonstrate that its discharge meets the conditions in procedure 5.D of appendix F. Section 301(b)(1)(C) of the CWA requires that NPDES permits include any limitation necessary to meet state water quality standards. Here, a facility seeks to discharge an effluent containing a pollutant at levels above the applicable water quality criteria into a receiving water that may not be in compliance with WQS. Despite these circumstances, EPA has found that such a discharge does not have the reasonable potential to cause or contribute to a violation of an applicable WQS provided certain conditions are met. In light of the potential for harm to the aquatic environment if those conditions are not met, and in view of the strict statutory prohibition against discharges that do not meet water quality standards, EPA believes that it is entirely appropriate to require dischargers to demonstrate that they qualify for special consideration of intake pollutants under procedures 5.D or E.

These demonstrations may not be as onerous as some commenters believe, since information already on hand may be used. The permitting authority can look to available data, such as permit application data, in deciding whether the demonstration has been made adequately, rather than requiring the permittee to supply additional data. In all cases, however, the discharger bears responsibility for establishing eligibility for special consideration of intake water pollutants in procedure 5.D and E. The permitting authority's responsibility is to document the basis for the determination in the fact sheet or statement of basis for the permit.

Additionally, EPA believes the intake pollutant procedures generally are less burdensome than those associated with existing mechanisms for addressing intake pollutants, e.g., variances, downgrading uses. The level of effort needed to make the required demonstration for special consideration of intake pollutants will vary depending on the characteristics of the effluent and the receiving water. Where the intake water contains numerous pollutants at high concentrations in relation to the water quality criteria, the demonstration may require analysis of numerous pollutants. The final Guidance allows the permitting authority to require the use of the baseline reasonable potential procedure (procedures 5.A-C) before intake pollutant relief is considered. Using procedures 5.A-C as a relatively simple screening process has the advantage of limiting the number of pollutants needing fuller analysis (particularly since most applicants are required already to provide a comprehensive characterization of their effluents in the permit application and effluent characterization is the major information needed for the baseline reasonable potential determination.) Similarly, the procedures for adjusting permit limits for consideration of intake water pollutants apply only to pollutants that exceed water quality standards in the background of the receiving water. This limits the number of pollutants for which the demonstration is required.

iv. Definition of Same Body of Water

Special allowance for intake water pollutants under the final Guidance depends on whether the source of the intake pollutant of concern is from the same body of water or a different body of water than the receiving water. If the intake pollutant is from the same body of water, the discharger may be eligible for two types of intake water pollutant consideration: (1) a finding that its discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above water quality standards when the intake water is the sole source of the pollutant and; (2) if the discharger additionally contributes that pollutant to the wastestream during its operations, it may be eligible for limits based on "no net addition." When the pollutant originates from a different body of water, WQBELS will be based on the most stringent applicable water quality criterion if the discharge causes or has the reasonable potential to cause or contribute to an excursion above water quality standards.

Consistent with the approach taken with the intake credit provision for technology-based limits, the proposed Guidance did not define "same body of water." However, the preamble discussed two options for defining more specifically "the same body of water": (1) define as water segments designated in State or Tribal water quality standards; and (2) define "same body of water" on a case-by-case basis. The preamble further solicited comments on what factors should be taken into account when using the case-by-case approach, including whether the intake and outfall points are within the same water segment identified in State or Tribal water quality standards; whether the discharge is upstream or downstream from the intake point in flowing waters or in close proximity to the intake point in open lake waters; whether the intake pollutants would reach the outfall point within a reasonable time period in the absence of the removal and discharge back to the receiving water; or whether the water chemistry (e.g. hardness and pH) are similar.

One option discussed in the preamble to the proposed Guidance provided a different approach for distinguishing between relief available based on the source of the pollutant. Option 4 provided for "no net increase" limits when the source of more than 10 percent of the wastewater for any discharger is from the same receiving water and for POTWs which discharge to the same surface water from which the public water supply is withdrawn. "Same receiving water" was not defined. Under this option, different limits might apply when the source of at least 90 percent of the wastewater is from ground water or a public drinking water supply system (except where groundwater is contaminated).

The following discussion addresses three aspects of defining "same body of water:" (a) general issue of whether and how "same body of water" should be defined in the Guidance; (b) whether intermediate use of the water should preclude intake pollutant relief, i.e., whether dischargers who receive their water from the water supply system rather than directly from the receiving water should be eligible for intake pollutant consideration; and (c) whether, and to what extent, ground water should be considered as "the same body of water."

(A). General. Commenters took divergent positions on whether, and how, same body of water should be defined. One position was that a definition was needed in order to provide consistency throughout the Great Lakes System and to make the distinction meaningful. Further, in these commenters' view, "same body of water" should be defined to preclude any requests where the discharge is not to the same designated segment from which the intake water is drawn, to require dischargers to demonstrate environmental equivalence of the source water and the receiving water, and to preclude any allowance for intake water pollutants in complex hydrological situations, such as discharges to the open Lakes or to rivers, such as the lower Fox River and St. Louis River, that experience seiche events, essentially wind-induced tides, or where there is no consistent unidirectional flow. Other commenters who advocated defining "same body of water" urged broader definitions including: the entire Great Lakes Basin (to be consistent with the basin-wide approach taken generally in the Guidance and because relatively uniform water quality standards would apply throughout the basin) or the same watershed as defined by the State. Several commenters advocated finding same body of water whenever the background concentrations of the source water and receiving water were similar. This approach would prevent discharges of relatively polluted intake waters to cleaner receiving waters and therefore prevent further degradation.

Another position taken by several commenters was that permit writers should have discretion in making this determination, with some commenters advocating that permit writers should have the same discretion to determine that the same body of water restriction need not apply as they do when technology-based limits are at issue. In contrast, some commenters argued against the case-by-case approach because it would be difficult to administer given the site-specific nature of the determination and could lead to inconsistency among the States, which is contrary to the intent of the CPA. In these commenters' view, no definition could be adequate, because a discharge may have adverse water quality effects due to differences in aquatic communities, differences in the physical and chemical characteristics of the affected waters apart from the pollutant in question, or simply because of increased loading in the receiving water, whether the discharge was from the same or different body of water; therefore, a better approach, in the commenter's view, would be to drop the distinction and address these possibilities through the requirement that the permitting authority consider whether any adverse water quality impacts will occur due to the "location" of the discharge.

As discussed above, EPA's position is that intake pollutant relief generally should be available only when the discharge containing the identified intake pollutant of concern effectively has no impact on the receiving water that would not otherwise occur if the pollutant were left in-stream. This requires an evaluation of the receiving water and the discharge's impact on that water which is necessarily site-specific. Any definition of "same body of water" should reinforce and facilitate this approach. For this reason, EPA disagrees with commenters who argued that the distinction between same and different body of water should be dropped or that "same body of water" should be defined broadly to include the entire Great Lakes basin. Application of uniform standards across the basin is not relevant in this context, because receiving water quality is not necessarily uniform across the basin. Thus, EPA disagrees that defining same body of water on a watershed basis is appropriate. Also, how States define watersheds may differ and may be based on administrative considerations, such as units of manageable size, rather than solely on hydrological considerations. Similarly, definitions that focus narrowly, such as only on comparisons of background concentrations of the intake and receiving waters, could be over- or under-inclusive in identifying situations EPA considers appropriate for relief, i.e., where the discharge of the intake pollutant has no different impact that would occur if the pollutant had remained in-stream.

In the preamble to the proposed Guidance, EPA discussed using water body segments as a way to identify the same body of water. Commenters did not support this option as the sole way to define same body of water. However, some commenters advocated requiring the intake source and receiving water to be within the same water segment as a minimum requirement. EPA has not adopted the stream segment approach for two reasons. First, as stated in the preamble to the proposal, the way in which States designate segments may vary, which could lead to inconsistency in how the "same body of water" determination is made. Second, as with other narrow approaches, relying solely on stream segment designations could be over- or under-inclusive for purposes of defining when the discharge of the intake pollutant has no different impact that would occur if the pollutant remained in-stream. The stream segment designation can be a useful factor to consider, however, in making the same body of water determination. In some instances, stream segment designations correlate to the boundary determinations made by States in establishing the use of a particular body of water (and thus, the water quality criteria that apply to that waterbody). In this situation, the permitting authority could find that a "same body of water" determination would be inappropriate because, for example, the use designation of the waterbody and corresponding criteria applicable to the intake water source is less stringent than the use designation applicable to the receiving water. In this case, not only could the concentrations of the intake and receiving water differ (potentially allowing discharges of water that contain higher levels of the pollutant of concern than the receiving water), but a finding of the "same body of water" would undermine the standards setting scheme established by States or Tribes and required by the CWA.

The "same body of water" definition in procedure 5.D.2 of the final Guidance balances the need for consistency with the flexibility to consider factors on a site-specific basis by defining the basic scope of the same body of water determination and listing factors the permitting authority must consider on a case-by-case basis in making that determination. The same body of water definition in the final Guidance is structured as follows. First, procedure 5.D.2.b states the underlying definition of same body of water: an intake pollutant is from the "same body of water" if the pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period of time had it not been removed by the permittee. In order to determine whether this underlying definition is met, the Guidance provides that the permitting authority must consider the three specific factors listed in procedure 5.D.2.b.i-iii (discussed below), and may consider other site-specific factors relevant to the fate and transport of the pollutant. This structure to the same body of water definition is designed to provide clear guidance to the permitting authority as to the underlying finding that must be met in any finding of "same body of water," but preserves flexibility in the factors that the permitting authority can consider in making this determination.

Under procedure 5.D.2.b.i-iii, the permitting authority may find that an intake pollutant is from the same body of water if all three of the following conditions are met: (i) the background concentration of the pollutant in the receiving water (excluding any amount of the pollutant in the facility's discharge) is similar to that in the intake water; (ii) there is a direct hydrological connection between the intake and discharge points; and (iii) water quality characteristics (e.g., temperature, pH) are similar in the intake and receiving waters. When these three factors exist, the permitting authority may make a same body of water determination.

EPA selected these factors from those listed in the preamble and suggested by commenters as those conditions which reflect that an intake pollutant would have reached the outfall area within approximately the same time frame and, to a lesser extent, with approximately the same effect, as would have occurred if the pollutant had been left in-stream. EPA also decided to include these factors in order to simplify the process for the permitting authority in making a same body of water finding, since these factors should be relatively easy to determine based upon easily obtainable monitoring information.

The definition in procedure 5.D.2.c also allows the permitting authority to consider other site-specific factors related to the transport and fate of the pollutant that may be relevant in determining whether the intake pollutants would have reached the receiving water in any event within a reasonable period. "Reasonable period" is site-specific and may vary depending on the type of pollutant; therefore, determining a "reasonable period" is left to the permitting authority's best professional judgment. Procedure 5.D.2.c of the final Guidance is related to procedure 5.D.2.b in several ways. First, even if all three conditions listed in procedure 5.D.2.b are met, the permitting authority retains the discretion to conclude, based on other site-specific factors, that the underlying definition of "same body of water" has not been satisfied. While EPA believes that such circumstances are relatively unlikely, the Agency did not want to preclude the permitting authority from considering all relevant site-specific conditions in making the underlying "same body of water" determination required by procedure 5.D.2.b For example, the discharge point may be upstream of the intake point. In this case, although the three factors in procedure 5.D.3.a have been satisfied, the permitting authority could find that the intake pollutant is from a different body of water because water generally does not flow upstream and the basic showing that the pollutant would have reached the outfall area in any event would not be met. Similarly, unusual hydrological characteristics such as seiche events mentioned by one commenter may be appropriate to consider in making the required determination. As discussed above, stream segment designations may be a useful factor to consider in certain situations.

Second, under procedure 5.D.2.c, the permitting authority could based, on site-specific factors relating to the fate and transport of a pollutant, find that an intake pollutant is from the "same body of water" even if one or more of the criteria listed in procedure 5.D.2.b is not met. For example, in a case where the intake point is upstream from the discharge point, but there is a tributary that joins the waterbody between the two points, the permitting authority could conclude that the pollutant would have reached the outfall point within a reasonable period of time, even though the concentration of the pollutant at the outfall point differs from the intake point due to the confluence of the waterbodies. In this circumstance, the absence of one or more of the conditions listed in paragraph 5.D.2.b. would not necessarily preclude the permitting authority from deciding that the underlying definition of same body of water is met. In order to apply the intake pollutant procedures in this circumstance, however, the permitting authority must still find that other applicable requirements in procedure 5.D.3 been met, e.g., that the timing and location of the discharge or chemical or physical changes to the intake water pollutants that occur at the facility would not cause adverse water quality impacts to occur that would not occur if the pollutant had been left in-stream.

Some commenters advocated creating an exception to the same body of water requirement similar to the one found in the intake credit provision for technology-based limits. That provision allows the permitting authority to waive the same body of water requirement if he or she determines that no environmental degradation would result (see 40 CFR 122.45(g)(4)). EPA disagrees that this exemption is appropriate when intake pollutant relief from WQBELs is at issue. When it promulgated 40 CFR 122.45(g), EPA explained that it could justify providing this exemption because protection of the receiving water could occur, in part, through imposition of WQBELs where necessary to meet applicable water quality standards (49 FR 38026, September 26, 1984). In other words, WQBELs are a "safety net" which protect receiving water quality when intake credits are considered for technology-based limits. There is no comparable safety net when intake pollutant relief is considered for WQBELs. As explained previously, EPA believes that special allowance of intake pollutants can only be squared with the water quality-based requirements of the CWA where it is demonstrated that the discharge of the pollutant does not alter the environmental impact of leaving the pollutant in-stream. If this condition is not met, EPA believes that a discharge into a non-attainment water can be permitted only if it does not exceed water quality criteria. These are the applicable requirements under the water quality program, not the more general standard of "environmental degradation" provided under 40 CFR 122.45(g)(4). Therefore, an exemption from the "same body of water" requirement comparable to the one available for technology-based limits is not appropriate.

(B). Intermediate Use/Public Water Supply. The proposal was silent on whether intermediate use of intake water would preclude a discharger from seeking intake credit relief. Numerous commenters endorsed Option 4 because it specifically provided for situations where a facility used a public water supply rather than drew its water supply directly from the receiving water. Many commenters stated that intake pollutant relief should be available in this situation as well because a discharger should only be responsible for pollutants it originally introduces into the wastestream and not be required to clean up its source water. Others claimed that it would be inequitable to treat direct and indirect users of the same water differently, which would be the case if intermediate use disqualified a discharger from eligibility for intake pollutant relief. A trade association representing industries which use significant amounts of cooling water suggested that smaller industries could be disproportionately impacted because they were more likely to use public water supplies than large industries which could draw from the rivers or lakes directly. Another commenter stated: "Virtually all of the water provided by a public water supplier is ultimately discharged to ground or surface water. It is inequitable to hold a limited number of dischargers responsible for removing pollutants from such water while leaving other dischargers of the same water unregulated. Such pollution should be controlled at the source, the water utility, or by a general limit adjustment granted to all dischargers of such water." Several commenters noted that, unless intermediate use was taken into account, all POTWs would be ineligible for intake pollutant relief because a POTW's "intake" water comes from users of the POTW's system.

EPA agrees that indirect users of the receiving water should be eligible for special consideration of intake water pollutants to the same extent as direct users. As long as all requirements of the intake pollutant provisions are met, EPA can find no reason for excluding indirect users of the receiving water from intake pollutant relief. As noted above, however, EPA rejects the theory that dischargers generally should not be responsible for pollutants in their dischargers that they do not themselves add to the wastestream. The final Guidance addresses the intermediate use issue in two ways. First, 5.D.2.e. states that intake pollutants include those withdrawn from the waters of the United States by any facility supplying the discharger with intake water (e.g., public water supply). Thus, users of such waters supplies are eligible for intake pollutant relief to the same extent as direct users of surface waters. In applying the criteria in section 5.D.2.b to determine whether a user of a public water supply is discharging to the same body of water, the permitting authority would compare the surface water where it is withdrawn from the waterbody by the water supplier with the user's outfall location.

The final Guidance addresses intermediate use more specifically in 5.E.2.c, which details how no net addition limits would be developed for water supply users. That section states that intake water shall be determined at the point where the raw water supply leaves the waters of the United States, except that it shall be the point at which the water enters the water supplier's distribution system where the water treatment system removes any of the identified pollutants from the raw water supply. This provision further specifies that, for purposes of establishing limits, the applicable concentration of the pollutant should be determined at the intake point, and that the mass of the intake pollutant will be determined by multiplying the applicable concentration times the facility's influent flow from the public water supply.

By defining the intake point as the point where the water leaves its source in waters of the United States, this provision does not extend intake pollutant relief to pollutants added at the water treatment plant or in the distribution system. To allow relief for pollutants added after the intake water leaves the same body of water would be inconsistent with the rationale for allowing special consideration of intake water pollutants, i.e., that special consideration is appropriate only for those pollutants whose discharge has no different impact than the impact that would have occurred had the pollutants been left in place, which is in part reflected by the fact that the pollutant would have reached the discharge point in any event. Obviously, pollutants which are introduced by a public water supply or during distribution to its users are not initially present in waters of the United States. At the same time, EPA does not think it is appropriate to extend relief automatically to water supply users for pollutants removed by the water supply system before reaching the user.

Several commenters requested relief for pollutants added as part of water treatment. Some commenters noted that water which meets drinking water standards may not be of sufficient quality to meet water quality standards. For the reasons discussed in previous sections, EPA disagrees that complete relief is required for any pollutant in a facility's water supply or that generally it should hold water suppliers, rather than users, responsible for pollutants in the water supply. However, if the water supplier adds pollutants for purposes of water treatment into a water of the United States (e.g., a dammed impoundment or other waterbody meeting the CWA definition of a water of the United States), and the permitting authority finds that the impoundment and the discharger's receiving water are the "same body of water," the mass and concentration of the pollutant for purposes of the intake pollutant procedures could include the pollutants added by the water supplier to the impoundment (which should have been subject to an NPDES permit). This is no different than a situation where the background concentrations of a pollutant in a facility's intake water includes pollutants due to other discharges to waters of the United States subject to the NPDES permit program.

In most cases, however, treatment of the water supply occurs after the water is removed from waters of the United States. As noted earlier, pollutants added during treatment or in the distribution system are not from the receiving water initially and therefore would not reach the receiving water except for the discharge by the water supply user. While not providing a special intake pollutant allowance in this instance may impose an additional burden for the users of the water supply who do discharge to waters of the United States, EPA does not believe, for the reasons stated above, that special consideration of intake pollutants is appropriate in this circumstance. Likewise, EPA does not agree that the fact that water quality standards may be more stringent than drinking water standards is a reason to provide special consideration of intake water pollutants. Providing intake pollutant relief based on the difference between drinking water and surface water quality standards would not be appropriate in the context of ensuring that the requirements of the CWA are met. EPA encourages users to work with their water suppliers, as they would other suppliers of raw materials, to minimize pollutants of concern in the water supply. For example, one POTW, which experienced difficulty in meeting zinc limits in its NPDES permit, successfully worked with the water supply managers to substitute sodium metaphosphate for zinc orthophosphate for purposes of addressing problems created by an aggressive water supply.

(C). Ground water. As with intermediate use, the proposed Guidance did not specifically address whether pollutants in ground water would be eligible for intake pollutant relief. Option 4, however, specifically included ground water by providing limited relief (limits based on water quality criteria with the possibility for limits up to background in specified circumstances) when the source of at least 90 percent of the wastewater is from ground water or a public drinking water supply system (except where ground water is contaminated).

EPA received numerous comments advocating intake pollutant relief for ground water, echoing the argument that dischargers should not be responsible for pollutants already in their intake water. Several commenters objected that the proposal would preclude any relief if the discharger used any amount of ground water for its water supply. Some commenters who supported providing relief for pollutants in ground water also stated that it would be appropriate to distinguish between ground water naturally contaminated and that contaminated by human activity. In addition, commenters argued that relief for pollutants was appropriate because ground water may be hydrologically connected to the surface water into which the pollutants are discharged and therefore are, in effect, the same body of water.

EPA does not agree with commenters who advocated intake credits for all pollutants in ground water even with suggested limitations, such as not allowing credit for pollutants added by human activity, or including ground water if there is any hydrological connection to surface water. However, EPA agrees that relief for intake pollutants in ground water is appropriate for situations that fall within the general rationale for relief, i.e., when the pollutants would have reached the vicinity of the outfall in approximately the same period of time, in the natural course of things regardless of removal and use by the discharger. Thus, the final Guidance specifies in procedure 5.D.2.d that the permitting authority can find that ground water is the same body of water as the receiving water using the test specified in 5.D.2. EPA also agrees that ground water contaminated by human activity should not be considered for relief because it would simply transfer the problem without abating it. By human activities, EPA means activities conducted by industrial, commercial, and municipal entities resulting from operations, disposal actions, or treatment processes. Thus, ground water at CERCLA remediation sites would not be eligible for intake pollutant relief. EPA would also consider contaminated ground water that has been intentionally diverted to form a direct hydrological flow to surface water to be covered by this restriction. This restriction may avoid the potential for a discharger to obtain relief for pollutants added as a result of the discharger's activity (e.g., when ground water has been contaminated by mining activities and the ground water serves as the mine's water supply).

v. 100 Percent Requirement

Related to the definition of "same body of water" is the requirement in the proposed Guidance that 100 percent of the intake pollutant is from the same body of water as the discharge in order to be eligible for a finding that WQBELs are not needed. The purpose of this requirement, as explained in the preamble to the proposed Guidance, was to avoid inter-waterbody transfers of pollutants without making a reasonable potential determination and developing appropriate WQBELs. The preamble also clarified that multiple sources of water did not preclude a discharger from relief automatically. However, if the discharge included water from a different body of water which contained the pollutant of concern, intake pollutant relief was not available, and reasonable potential would be determined by the proposed baseline procedures in 5.A-D of appendix F. Two other options discussed in the preamble were less limiting. Option 3 applied intake pollutant relief regardless of the source of water. In Option 4, the provisions applicable to same body of water scenario applied as long as at least 10 percent of the wastewater was from the same body of water.

According to many commenters, the practical implication of this requirement would be to deny relief in many situations because dischargers commonly use multiple sources of water, especially smaller facilities. Of particular concern to some commenters was the situation where the discharge was primarily non-contact cooling water from the same body of water but also included process wastewater or pollutants added by the infrastructure. Alternative approaches suggested for this situation included changing 100 percent to "substantially all" and categorically excluding non-contact cooling water from the reasonable potential determination. Several commenters also asserted that EPA had no scientific basis for taking a different approach than that contained in Option 4, i.e., using a no net addition approach in situations where the discharges had other sources of water, such as ground water and public water supplies. Some commenters supported Option 4 in this regard as a reasonable interim measure and asserted that States and EPA always have the authority to impose tighter limits if they believe they are needed to protect the designated use of a water which provides a sensitive habitat. Some commenters went further, objecting to limiting Option 4 to situations where at least 10 percent of the wastewater was from the same body of water. One commenter stated that the proper test should be whether or not the discharge, taken as a whole, has a negligible impact on the receiving water.

In the final Guidance, EPA has retained in procedure 5.D.3.b.i the requirement that 100 percent of the intake pollutant come from the same body of water to qualify for a determination that a WQBEL is not needed. EPA's rationale for distinguishing between the same and different bodies of water in the intake pollutant context has been discussed previously. The 100 percent requirement in 5.D.3.b.i implements this decision. However, unlike the proposal, the final Guidance provides additional flexibility where a facility has multiple sources of the pollutant of concern in two respects. First, as explained in more detail elsewhere, procedure 5.E.5 allows the permitting authority to apply a flow-weighted average approach for deriving limits when the pollutant of concern in the discharge originates in both the same and different bodies of water. Second, if the facility that has intake water containing the pollutant of concern from the same body of water and the facility also introduces additional amounts of the pollutant to the wastestream, e.g., from process waste, 5.E.4. of the final Guidance authorizes the use of a no net addition approach. These changes will address many of the situations identified by commenters as warranting relief.

EPA does not agree that non-contact cooling water should be categorically excluded from any reasonable potential determination because it would deny relief if the facility co-mingled its non-contact cooling water with other wastestreams containing the pollutant of concern, as asserted by some commenters. EPA is not aware of a factual basis for determining that non-contact cooling water, co-mingled with other wastestreams, as a class of discharges, will not have the reasonable potential to cause or contribute to an excursion above water quality standards. In some cases, such discharges may have a detrimental impact on the receiving water, for example, because pollutants are added to those in the intake water via the cooling water wastestream (e.g., through corrosion or water treatment) or concentration of the pollutants occurs due to evaporation. Likewise, the mass and concentration of the pollutant of concern that may be contributed by the co-mingled, non-cooling water wastestream, and consequently the impact of the discharge on the receiving stream, will vary from facility to facility. Evaluating such circumstances and determining whether a discharge poses "reasonable potential" must necessarily be made on a case-by-case basis. Nonetheless, EPA believes that the underlying concern of commenters--that some allowance for intake pollutant be allowed where non-contact cooling water is commingled with other wastestreams--is addressed through the provision in the final rule allowing "no net addition" limits.

vi. <u>No Increase in Concentration Requirement</u>

To qualify for special consideration of intake pollutants, the proposed Guidance required the discharger to demonstrate that the identified pollutant of concern is not concentrated at the edge of any available mixing zone after discharge from the facility. The preamble explained that facilities which further concentrate pollutants at the edge of a mixing zone may contribute to the excursion above water quality standards. If no mixing zone is allowed by a State's water quality standards, the appropriate comparison is instead to the point of discharge. EPA further explained that proposed procedure 5.E of appendix F allowed consideration of increased concentrations at the edge of any allowable mixing zone to accommodate water conservation, as consistent with the proposed provisions in procedure 3 of appendix F that allowed the continued use of mixing zones for BCCs when water conservation measures resulted in an overall reduction in mass loading even though higher concentrations occurred. EPA invited comment on all aspects of this provision including the interpretation of "no concentration"; whether a particular statistical methodology for measuring "no concentration" should be included in the final Guidance; and whether any provision in the final Guidance for intake water pollutants should allow consideration of a maximum increased concentration resulting from evaporation of cooling water.

EPA received numerous comments opposing the "no increased concentration" requirement based on competing policy considerations but none on the grounds that the requirement was inappropriate on the basis of water quality considerations. Some commenters disputed whether the water quality impacts were sufficiently significant to justify the condition. As with the no additional mass requirement discussed below, numerous commenters advocated a general exemption from the no increase in concentration requirement for de minimis additions of mass. Similarly, some commenters advocated an exemption for slight increases due solely to evaporation (but did not define "slight.") Others requested a blanket exemption for cooling water, both once-through and recycled. Several commenters asserted that a "no increased concentration" requirement would effectively preclude recycled cooling water from relief because concentration of pollutants is inherent in the design of cooling towers; furthermore, relief would be denied for BCCs where it was most needed, even if mass were not increased (a result that would be further exacerbated by the proposed phase-out of mixing zones for BCCs). Commenters suggested that mass limits only be used to avoid concerns about concentration. Another suggestion was to limit this requirement to situations where adverse water quality impacts would occur.

EPA has retained the "no increased concentration" condition in the final guidance with minimal changes from the proposal. It appears at 5.D.3.b.iv. EPA is retaining the "no increased concentration" requirement because it is integral to its rationale for allowing special consideration of intake pollutants, i.e., that the removal and subsequent discharge of intake pollutants would not create adverse water quality impacts that would not have occurred if the pollutant were left instream. Discharges which are more concentrated than the receiving water will increase the degree to which the waterbody exceeds the applicable criterion for that pollutant, thereby exacerbating the any non-attainment problems. For this reason, EPA rejects suggestions that imposing mass limits only is appropriate. For waters already attaining water quality standards, increases in concentration in the discharge that do not result in an increased concentration of the pollutant at the edge of the mixing zone would be allowed where mixing zones are available under State provisions. This scenario could occur only for purposes of the intake pollutant reasonable potential procedure. Applying the "no increased concentration" requirement at the edge of the mixing zone allows for dilution of the pollutant in the receiving water and therefore for some increased concentration in the discharge itself. In the final Guidance, EPA has also clarified that, in the attained water scenario, an increase in concentration at the edge of an available mixing zone is allowed if the concentration at the edge of the available mixing zone does not cause or contribute to an exceedance of an applicable WQS.

Allowing increased concentrations in these limited situations does allow discharges that potentially cause adverse effects in the receiving water quality that would not occur if the pollutant were left in-stream. However, prohibiting increased concentrations at the edge of an available mixing zone that result in an exceedance of the applicable WQS when applying the intake pollutant reasonable potential procedure is consistent with EPA's and States' use of mixing zones in the water quality standards program and with limiting "reasonable potential" finding to situations where the discharge causes, has the reasonable potential to cause, or contribute to an exceedance of an applicable WQS. EPA believes that the final Guidance adequately addresses the circumstances under which an increase in pollutant concentration within the mixing zone would itself be of environmental concern by precluding the application of the intake pollutant reasonable potential procedure if the timing and location of the discharge would cause adverse effects that would not occur in the absence of the removal and discharge of the pollutant. See procedure 5.D.3.b.v of appendix F. EPA also believes this approach adequately defines when an increased concentration is significant enough to preclude special consideration of intake pollutants (i.e., when it causes or contributes to an exceedance of the criteria at the edge of an available mixing zone) and therefore has not adopted some commenters' suggestion that the "no increased concentration" requirement be modified to apply only when the increased concentration creates adverse effects that would not occur if the pollutant were left in-stream.

Applying the "no increased concentration" requirement may differ depending on whether eligibility for the intake pollutant reasonable potential test or eligibility for "no net addition" limits is at issue. Because availability of "no net addition" limits in the final Guidance is limited to situations where the level of the pollutant in the background water exceeds the criteria for that pollutant, mixing zones will be unavailable when evaluating whether increased concentration has occurred. Application of a mixing zone assumes that water is available to dilute the discharge so that compliance with water quality standards is determined at the edge of the mixing zone rather than within the mixing zone. As noted by some commenters, dilution to meet a standard in-stream for a particular pollutant is not possible when the pollutant already exceeds the criteria in the background waters. In short, mixing zones do not exist for non-attainment waters, i.e., where background waters exceed criteria even, if a State has a policy which allows mixing zones. Unavailability of mixing zones when background pollutants levels exceed the criteria also means that the exemption from the "no increased concentration" requirement due to competing water conservation considerations, which is based on the mixing zone provisions in procedure 3 of appendix F, would necessarily be unavailable when "no net addition" limits are at issue.

EPA recognizes that States or Tribes may develop TMDLs which project attainment of WQS for a water body currently in non-attainment. In this instance, a mixing zone can be allowed as long as it is consistent with the provisions and assumptions of the TMDL or comparable remediation and assessment plan approved under procedure 3.A of appendix F. Since "no net addition" limits assume the absence of a TMDL or comparable plan, the possibility of mixing zones in non-attainment waters, where no TMDL or comparable plan approved under procedure 3.A of appendix F exists, is not relevant.

Also, explained above, increased concentration beyond the edge of an available mixing zone may be allowed when the intake pollutant reasonable potential procedure is being applied and the receiving water meets in-stream standards, if the increase does not cause or contribute to an exceedance of an applicable WQS. When the receiving water already exceeds an applicable WQS, however, as is the case when "no net addition" limits are at issue, in an ideal sense, any increase in concentration exacerbates an existing problem and therefore is unacceptable because it contributes to an exceedance of the standard.

The "no increased concentration" requirement is necessary to implement the modest interim goal of holding discharges to non-attainment waters at a level that maintains the status quo and does not aggravate a situation that already is inconsistent with the CWA's goals.

As with the other conditions, the final Guidance does not establish how "no increased concentration" should be determined and leaves this to the discretion of the permitting authority. Language has been added to the final Guidance to clarify that the permitting authority has this discretion. As a general rule, increases in concentration can be determined easily by comparing measurements of intake levels of the pollutants with those in the effluent to determine whether there is any statistically significant difference. This approach can incorporate principles of averaging (provided, of course that the averaging period is appropriate for the circumstances) and also can have the end result of accounting for relatively insignificant mass increases or "slight" increases due to evaporation where such differences are not statistically significant. In addition, increases due to evaporation that cannot be measured or are not statistically significant, as discussed below, adequately account for "insignificant" increases due to evaporation.

EPA is aware that measurable increases in concentration due solely to evaporation may require some dischargers to remove intake pollutants or take other appropriate measures to ensure that intake water pollutants are not concentrated at the point of discharge. However, EPA believes that such measures are necessary to ensure that discharges at levels exceeding water quality criteria into non-attainment waters are allowed only in those instances where such a discharge has no greater adverse effect on the receiving water than that which would occur if the pollutant were left in-stream. Furthermore, these increases would need to be larger than those allowed by the permitting authority as they use their approach to assess increased concentrations.

EPA has not adopted the numerous suggestions for categorical exemptions for certain types of discharges, particularly recycled cooling water blowdown, that would be more concentrated than the intake water. As discussed above, EPA believes that an increase in pollutant concentration caused by a discharge of intake pollutants generally should disqualify a discharger from receiving a special allowance for intake pollutants. EPA has no basis to conclude that certain categories of discharges will not cause increased concentrations of pollutants in a waterbody. The impact of discharges that have increased concentrations of pollutants as compared to the intake water must therefore be evaluated on a case-by-case basis.

vii. Chemical/Physical Alteration Requirement

The proposed Guidance also required that the permittee demonstrate that it does not alter the identified intake water pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur from the discharge that would not occur if the pollutant were left in-stream. Only alterations that cause adverse water quality impacts would be prohibited under this requirement. Simple removal of a pollutant, which could be considered a chemical or physical alteration, would not be considered to cause adverse effects. The purpose of this requirement was to exclude from relief situations where changes in the pollutant occur within the facility that could render the pollutant more harmful to the receiving water than before its removal by the facility. For example, a change in pH or temperature that affects the structure or valence of some intake pollutants contained in non-contact cooling water could increase the toxic effects associated with the pollutants in the discharge. EPA invited comment on all aspects of this provision including: the interpretation of "chemical and physical alteration; " the interpretation of "adverse water quality impacts;" the specific environmental and pollutant parameters needing evaluation for making this determination; the use of statistical methods to make this determination; whether minimum parameters for consideration, such as hardness, pH, total vs. dissolved fractions, should be specified in the final Guidance; and whether the final Guidance should specify the maximum extent to which these parameters can change without causing an adverse impact on water quality.

EPA received numerous comments on this provision. The comments generally did not dispute the validity or need for the condition, but rather focussed on the details of how it would be applied. Some commenters stated that the burden should be on the permitting authority to demonstrate that a physical or chemical alteration that adversely affects water quality has occurred, rather than on the permittee to demonstrate that it has not occurred. One commenter requested that "chemical and physical alteration" be defined with sufficient flexibility to permit adequate consideration of site-specific factors, such as the comparative qualities of intake and receiving water and the nature of the discharger's activities so as to avoid disqualification due to altered pollutants that result in less toxic impacts. Several commenters advocated recharacterizing this condition as "no net increase in pollutant bioavailability" as protecting receiving water while providing necessary flexibility to deal with different situations reasonably (e.g., where a facility softens water before use, which may increase the toxicity of pollutants, but rehardens the water before discharging). Similarly, several commenters suggested requiring whole effluent toxicity tests or water effects ratio tests to meet this demonstration. With respect to chemical-specific testing, some commenters suggested measuring the bioavailable form of the pollutant to determine if changes have occurred (as well as basing criteria on the bioavailable form), but other commenters noted that it would be difficult to measure the bioavailable form of pollutants at low levels. Other commenters expressed concern that changes such as increases in temperature that result when water is used for cooling purposes, or evaporation that might increase concentration would eliminate them from relief. A municipality expressed concerns about how this requirement might be applied to POTWs: "With a sewage treatment plant as our 'end of process,' we would never be able to argue that the physical, biological, and chemical processes we employ did not change the chemical form of the pollutant...."

The final Guidance in procedure 5.D.3.b.iii retains the requirement for the permittee to demonstrate that the identified intake pollutant of concern will not be altered chemically or physically in a manner that would cause adverse water quality effects that would not occur if the pollutant were left in-stream. This provision is necessary to identify instances where use of the intake water at a facility alters the pollutant sufficiently to cause additional adverse impacts on the receiving water. Although several commenters seemed to read this requirement to prohibit any alteration of the pollutant (and even of the chemistry or other characteristics of the discharge), EPA's intent, as reflected in the final Guidance , is to address only physical or chemical alterations to the pollutant that would cause increased adverse water quality effects as compared to that pollutant in the intake water before removal and use by the facility, i.e., "adverse water quality impacts...<u>that would not occur if the pollutants were left in-stream</u>" (emphasis added). In this sense, the requirement already focuses only on "net" changes as advocated by some commenters. Temporary changes within the facility that do not affect the pollutant as discharged are not prohibited. For example, temporary increases in the toxicity of metals due to water softening would not fail this condition if the toxicity were reduced to the same level as in the intake water by hardening of the water before discharge. For this reason, the discharger need not demonstrate that no changes have occurred to the pollutant at the facility as feared by a municipal commenter, but only whether "net" changes have occurred that create an adverse effect in the receiving water that would not have occurred if the pollutant had been left in-stream. The focus of this requirement is on changes to the form of the pollutant. It does not duplicate the requirement prohibiting increases in concentrations or mass, which apply independently of the "no chemical or physical alteration" requirement.

EPA has not included additional specificity in the Guidance on what data are necessary to demonstrate this requirement. As with the other conditions, what data are appropriate will vary with the pollutant of concern, the facility processes, other pollutants entering the wastestream, and characteristics of the receiving water. No one test will capture all possible alterations that could create additional adverse affects for the receiving water. As noted by one commenter, toxicity or water effects ratio measures could indirectly measure changes in toxicity but could not provide information on specific pollutants, such as BCC effects on human health. Flexibility is also important because EPA expects that scientific advances in understanding the effects of, and ability to measure pollutant alterations, will change over time. EPA is aware that lack of specificity may create uncertainty from the permittee's perspective. However, as addressed in the discussion on demonstrating that the "no additional mass" requirement under the intake pollutant reasonable potential procedure is met, uncertainty should not create unknown liability as some commenters feared. For this reason, EPA encourages permitting authorities to develop a strategy or additional guidance on what is needed to make this demonstration. As discussed in section VIII E.7.a.iii above, EPA believes that it is appropriate to require the permittee to establish eligibility for special consideration on intake pollutants.

viii. <u>Timing/Location Requirement</u>

The final condition in the proposed Guidance that the permittee had to demonstrate to be eligible for intake pollutant relief is that the timing and location of the effluent discharge does not cause adverse water quality impacts to occur from the simple pass-through of an intake water pollutant that would not occur if the pollutant were left in-stream. EPA explained that it did not expect the timing or location of the discharge to cause adverse water quality impacts in most instances, but that the possibility should be considered in each instance to ensure protection of the receiving water. An example where timing could adversely affect the receiving water would be if intake water were withdrawn at high flow conditions and discharged at low flow conditions or withdrawn at high tide and discharged at low tide. EPA invited comments on all aspects of this condition including whether the final Guidance should specify a maximum distance between the intake and outfall or a maximum time interval between intake and discharge to be eligible for the proposed intake pollutant relief.

Although EPA received several comments on this condition requesting additional guidance on its application, no commenter advocated more specificity in the final Guidance, particularly with regard to identifying the maximum location between the intake and outfall points. One commenter advocated against the timing and location condition as regulation or guidance because its purpose was purely for protection of the stream from ill effects from the withdrawal and discharge of the water not associated with industrial processes. For similar reasons, another commenter noted adverse affects due to timing and location of the discharge is likely to be a very site-specific phenomena; therefore, rather than adopt a firm rule, require consideration solely of whether there is an adverse change.

The final Guidance at 5.D.3.b.v. is the same as the proposed. EPA agrees with commenters that determining whether timing or location cause adverse impacts that otherwise would not occur requires consideration of site-specific factors that cannot be easily reduced to a general rule. EPA does not agree that the site-specific nature of making this determination is sufficient reason not to require the analysis. Similarly, EPA does not consider the fact that the "timing/location" requirement focuses on an aspect of the discharge not directly related to an industrial process to be sufficient reason to disregard potential adverse effects caused by the timing or location of the discharge, especially for deciding whether the discharge causes or has the reasonable potential to cause or contribute to an excursion above an applicable WQS.

ix. Relationship Between this Section and Other Reasonable Potential Sections

The proposed Guidance included the reasonable potential procedure for intake pollutants as an alternative to the reasonable potential procedure in proposed sections 5.A-D of appendix F (the baseline reasonable potential procedures). In discussing options for considering intake pollutants that addressed limit derivation (options 2, 3 and 4), the preamble did not separately address the question of reasonable potential. In other words, these options assumed that reasonable potential would exist and WQBELS were necessary.

In most cases where the final Guidance now allows for consideration of intake pollutants in limit derivation, reasonable potential will be found to exist regardless whether the baseline reasonable potential procedure or the intake pollutant reasonable potential procedure is used. However, in some cases where intake pollutants are at issue, the baseline reasonable potential test may find that reasonable potential does "not" exist, even in non-attainment waters where the pollutant of potential concern is present in the discharge. An example is where the discharge contains extremely low concentrations of the pollutant of concern, the discharge has a high flow rate when compared to the receiving water flow rate, and the impact of the discharge on the receiving water is sufficient to bring it back into attainment with the applicable WQS. This result is most likely in the different body of water scenario, but could occur in the same body of water scenario if the facility has a significant source of clean water (i.e., without the pollutant of concern) that contributes to the discharge or its treatment system removes most, but not all of the pollutant. The intake pollutant provision is intended to be an exception to the usual reasonable potential procedures in appropriate circumstances; therefore, it would not make sense to require WQBELs in those situations where reasonable potential would not be found under the baseline reasonable potential procedures notwithstanding the result that would be reached under the intake pollutant procedures.

Under the final Guidance, States and Tribes have the discretion to make both reasonable potential procedures available or, alternatively, to determine the order in which they apply the baseline and intake pollutant reasonable potential procedures. States may also opt not to require a separate reasonable potential determination before imposing WQBELs in those situations covered by the intake pollutant limit derivation procedures (i.e., background of the receiving water exceeds criteria and the discharge contains the pollutant for which criteria is exceeded). Where the discharge does not qualify for special consideration of intake water pollutants under procedure 5.D.3.b, e.g., the intake water pollutants are from a different body of water, procedure 5.D.3.d provides that "reasonable potential" will be determined using the procedures in 5.A-C of appendix F.

b. Issues Specific to the Intake Pollutant Reasonable Potential Procedure

i. No Mass Added Requirement

The proposed Guidance limited the intake pollutant reasonable potential procedure to those situations where the presence of the pollutant of concern in the discharge was due solely to its presence in the intake water from the same body of water as the discharge (sometimes referred to as the "simple pass through scenario). Proposed procedure 5.E.1.b stated that the facility must not contribute any additional mass of the identified intake water pollutant to its wastewater. The preamble further explained that this determination should be made based on monitoring data and information on the kinds of pollutants generated by the particular type of facility.

The question whether contributing additional mass of the pollutants should preclude intake pollutant relief absolutely generated many comments. As discussed above, EPA carefully considered these comments and the final Guidance provides intake pollutant relief in situations that are environmentally the functional equivalent of the simple pass through scenario outlined in the proposal. That is, where all requirements for a finding of "no reasonable potential" are met, but the facility additionally contributes the pollutant of concern to the wastestream, the permitting authority may establish limits based on a "no net addition" principle. Thus, a facility can contribute additional mass of a pollutant to its wastestream in any amount, but permit limits will be set to ensure that the discharge contains no more mass of that pollutant than had been in the intake water.

Where a facility is simply "passing through" a pollutant taken from the waterbody and other conditions under the final Guidance are met, discharge of intake pollutants may not cause or contribute to violations of water quality standards. Where, however, a facility is adding some of the pollutant of concern to its wastestream, and the effluent as a whole contains levels of pollutants that exceed applicable criteria, then EPA believes that it is reasonable to conclude that the facility is or may be contributing to the exceedance of water quality standards in the waterbody. EPA believes that the latter conclusion is reasonable as a logical matter: i.e., a contribution by a facility of some amount of a pollutant to a wastestream exceeding applicable criteria into a waterbody that is in non-attainment can reasonably be viewed as contributing to the continued violation of the standards for the waterbody.

EPA also believes that this conclusion is appropriate as a technical and policy matter. EPA's regulations provide that WQBELs must be established for all pollutants that "are or <u>may be</u> discharge at a level which will cause, have the reasonable <u>potential</u> to cause, or <u>contribute to</u>" a violation of water quality standards. 40 C.F.R. § 122.44(d)(1)(i) (emphasis added). The emphasized language in this regulation underscores the cautionary nature of the reasonable potential inquiry, which necessarily asks the questions whether there may be a possibility that a discharge will cause or contribute to a violation of standards. Such a cautionary approach is consistent with the protective nature of the CWA, and EPA does not believe that it would be consistent with the statutory scheme to establish an unduly high threshold for the reasonable potential determination, and require certainty that a particular discharge will cause or contribute to a violation of water quality standards prior to impose a water quality-based effluent limitation. Where the permitting authority determines that, in fact, a particular discharger is not contributing any additional mass of a pollutant to a wastestream containing intake pollutants exceeding water quality standards but is simply "passing through" those pollutants, EPA believes there is a reasonable degree of certainty that the discharge of the facility will not contribute to further exacerbating the non-attainment in the waterbody. Where, however, it is demonstrated that the facility is adding some amount of the pollutant to its wastestream, EPA is not comfortable concluding that the facility will not ever contribute to a violation of water quality standards. Even if particular monitoring results indicates that the total amount of a pollutant in the discharge is no greater than the amount in the intake water (because, for example, the facility has both added and removed some of the pollutant of concern), the fact that the facility is itself contributing some amount of that pollutant to the effluent creates a reasonable possibility that the effluent may exceed the amount of the pollutant in intake water under some circumstances. In the latter case, EPA believes that the prudent and reasonable approach is to impose a WQBEL to ensure that this eventuality does not occur.

Most comments on the "no additional mass" requirement focussed on the fundamental issue whether an addition of mass should preclude all intake pollutant relief. These comments are addressed above. However, the question whether the facility contributes additional mass remains important for purposes of determining whether or not a WQBEL is necessary. In the preamble to the proposed Guidance, EPA solicited comments on several aspects of determining how this requirement should be demonstrated, including: how "contribution of no additional amount" should be interpreted; what data would be needed; the use of statistical information; and whether the final Guidance should specify minimum data required. Commenters suggested a variety of approaches for determining whether additional mass has been added. Some endorsed the idea of using statistical procedures to compare influent and effluent data. One commenter submitted a detailed statistical methodology, supported by several other commenters, for making this determination and another commenter specified that long-term averages should be considered in this analysis. One commenter suggested that the requirement be changed to no "quantifiable" addition. In a related vein, a commenter stated that procedures for handling non-detects must be established, especially considering that detection limits may differ between intake and effluent data sets. Commenters were divided on whether the Guidance should establish minimum data requirements. Some stated that more specificity was needed to provide adequate notice of what was expected of dischargers, as well as their potential liability for failure to act. Others commented that "adequate" data was the type of determination best left to the permitting authority's discretion.

Another group of comments involve suggestions for different interpretations of "addition" to exclude certain types of additions from a reasonable potential determination, i.e., to exclude certain discharges from the need for WQBELs. Many of the suggested categories overlap. The broadest categories suggested were "de minimis" additions (defined in numerous ways) and cooling waters in general, although most commenters would only accord special consideration for non-contact cooling water. Some commenters put limitations or conditions on excluding cooling waters, such as allowing only "tiny amounts" of metal-based algicides, or allowing exemption from WQBELs only when all State technology-based requirements or industry design standards to minimize corrosion have been met. Other suggested categories for an exemption from WQBELs included: pollutants added as result of corrosion or erosion, with several suggestions that EPA use the approach adopted in the amended effluent guidelines for Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) (57 FR 41836, 9/11/92) for constituents due to corrosion or materials of construction that are not reasonably avoidable; pollutants not added "intentionally" or "voluntarily," including "trace" amounts of pollutants in raw materials; increases in mass due solely to evaporation; additions of mass that do not increase concentration; and automatic determination of "no reasonable potential" for all pollutants but those added by the facility as part of normal operations.

The final Guidance, in procedure 5.D.3.b.ii, retains the requirement that the discharger not add additional mass of the identified pollutant of concern in order to qualify for a determination that its discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable WQS and therefore does not need a WQBEL. When the receiving water exceeds standards for a pollutant, WQBELS are reasonable to ensure that there are no additional loadings of the pollutant to the receiving water beyond that already in the intake water. Requiring that WQBELS be established in cases of additions of mass is consistent with the CWA goal of restoring non-attainment waters. For this reason, EPA disagrees with the comment that additions of mass should be allowed as long as concentrations do not increase. EPA also rejects the suggestion that additions of mass due to evaporation be excluded because evaporation does not increase mass (although it may be easier to detect mass when concentration is increased).

As reflected in the comments, "addition" can be determined in a number of ways depending on the situation. In some cases, knowledge about a facility's process and infrastructure is enough to determine that an addition will occur. For example, dioxin is a known by-product of certain processes used in pulp and paper mills and it would be reasonable for a permitting authority to find that dioxin is added even if it is not detectable in the effluent. For these situations, a reasonable approach would be to rely on application data describing the processes used at the facility. Similarly, as noted by many commenters, certain metals are known to enter a wastestream through corrosion or erosion when particular materials are used in a facility's infrastructure. Applying best professional judgment to make an addition determination in these situations has the advantages of simplicity and avoiding expensive monitoring. Similarly, knowledge that certain industrial processes do not use a particular pollutant and that the pollutant would not be added in other ways also may be a sufficient basis for concluding that a pollutant is not added. In many cases, however, it may not be known whether a pollutant is added. In these cases, a statistical approach using commonly acceptable procedures may be the best approach. To provide flexibility to deal with a variety of situations, the final Guidance does not establish the minimum data needed to determine whether the "no addition" requirement has been met. The permitting authority must determine the most appropriate approach, using its best professional judgment. EPA expects that this flexibility will allow permitting authorities to minimize the burden on dischargers in many instances. EPA strongly encourages permitting authorities to develop a policy addressing how "addition" determinations will be made. This policy can serve as advance notice to dischargers of what is expected for them to demonstrate that the "no addition" requirement is met. Note, however, that EPA does not agree that leaving the question of demonstrating addition to the discretion of the permitting authority deprives permittees of adequate notice of what is expected of them with regard to their discharge activities and associated liability. Such notice would be provided through any requests for information made by the permitting authority authorized by existing regulations, e.g., 40 CFR 122.21(e) and 122.41 (h), and/or by the terms of the permit.

EPA declines to adopt the many suggestions for categorical exclusions of certain types of discharges from the reasonable potential determination and would not approve these if included in a State or Tribal submission under part

132. All these suggestions acknowledge that the discharge contains additional contributions of the pollutant beyond that already in the intake water, but argue that these contributions should nonetheless be excluded from consideration for water quality-based controls for various reasons. Because these suggestions, in some cases, argue that additions by the permittee should not be regulated, such suggestions are not, in fact, related to the intake pollutant issue. Many of the suggestions seem based on the principle that some discharges, while having an impact on the receiving water, are so insignificant that they should be ignored. EPA disagrees that it is appropriate to judge certain discharges as "insignificant" on a categorical basis. Instead, "significance" needs to be evaluated on a site-specific, discharge-specific basis, considering such factors as the status of receiving water and other loadings of the pollutant, which will obviously vary. Existing procedures available to the States, such as the baseline reasonable potential procedures, already take into account the significance of the level of the pollutant in the discharge in relation to receiving water quality. EPA and the States have acquired significant experience in determining "reasonable potential" based upon the policies and procedures reflected in the TSD and similar guidance, and this general approach is reflected in the baseline reasonable potential procedures in procedure 5.A-C in appendix F of the final Guidance. EPA does not believe that it would be appropriate to graft onto these technically sound procedures the additional evaluations of whether a particular discharge would cause "significant" environmental effects. As demonstrated by the widely varied views of commenters about when and what types of discharges would cause such effects, a "significance" test that is acceptable, objective and detailed would be difficult to craft. In EPA's view, the baseline reasonable potential procedures provide the appropriate mechanism for determining whether the discharge is environmentally significant in the sense that it causes, has the reasonable potential to cause, or contribute to an excursion above an applicable WQS. As noted previously, further consideration of the discharge's significance and related questions of appropriate load reduction responsibilities are best evaluated through the TMDL or comparable process, as provided in procedure 3.A of appendix F. With regard to pollutants added to the discharge because of corrosion and erosion, EPA is not aware of a factual basis, nor was one provided by commenters, for concluding that pollutants added through processes such as corrosion and erosion or in cooling water have less of an impact than the same pollutants added in other ways, or that their amounts are necessarily small in all cases. This further supports EPA's decision not to categorically exclude such pollutants from water quality-based controls.

Suggestions that exclusions or de minimis determinations should be based on the discharger meeting existing State technology-based standards or industry standards to minimize leaching of metals from corrosion or erosion are inconsistent with the fundamental premise of the CWA that more stringent limits are required if technology-based limits are not sufficient to attain water quality standards. Similarly, suggestions that EPA adopt the approach for regulating "incidental" metals used in the OCPSF technology-based guidelines are not appropriate when WQBELs are at issue.

Other suggestions for categorical exclusions, including those arguing for exclusion of pollutants found in raw materials or added unintentionally, not deliberately, or outside the normal operations of the facility, are variations on the argument that dischargers should not be responsible for certain pollutants in their discharge because they would be difficult or costly to control. As reflected by the allowance in the final Guidance for limits based on "no net addition" and based on a "combined wastestream" approach when pollutants are added from other bodies of water, EPA agrees that the addition of such pollutants should not preclude intake pollutant relief in all situations. EPA believes, however, that the other circumstances cited by commenters should not exempt discharges containing these pollutants from the need for WQBELs if they pose "reasonable potential" under procedure 5.A-C. As discussed elsewhere, EPA does not believe that the intent of the discharger or other factors cited by these commenters relieve in any way the responsibility of the discharge to comply with section 301(b)(1)(C) of the CWA. In all cases cited by commenters, facilities would be adding pollutants to a waterbody that would not be there but for the action of the discharger.

EPA agrees that questions regarding measurements when the levels of pollutants in the wastestream are below detection are important and may be significant both when determining whether reasonable potential exists and when determining compliance with permit limits. These issues have become increasingly common as criteria below analytical detection levels have been adopted and more permits include WQBELs, some of which are below detection levels. However, there is nothing unique to the intake pollutant situation that would require a different approach to these issues. Procedures to manage data when values are above and below detection levels or levels of quantification are addressed elsewhere in the final Guidance and this document. For example, procedure 3 of appendix F, discussed in section VIII.C of this document, addresses these issues when determining whether the ambient background water exceeds criteria. Section VIII.E addresses these issues when determining whether a discharge causes, has the reasonable potential to cause, or contribute to an exceedance of WQS. Procedure 8 of appendix F, discussed in section VIII.H of this document, addresses WQBELs below the levels of quantification.

ii. Other Requirements

The proposed Guidance included three additional requirements for intake pollutant relief imposed on the permitting authority. First, the permitting authority must summarize in the NPDES permit fact sheet or statement of basis the reason for determining that there is no reasonable potential for the discharge of an identified intake water pollutant to cause or contribute to an excursion above a applicable narrative or numeric water quality criterion, including an evaluation of the permittee's demonstration of the five specified conditions in the proposed Guidance. Second, proposed procedure 5.E of appendix F required that the permit require all monitoring of the influent, effluent and ambient water necessary to determine that the required conditions are maintained during the permit term. Third, the proposal required that the permit contain a reopener clause authorizing the permitting authority to modify or revoke and reissue the permit if new information indicates changes affecting any of the required conditions, e.g., obtaining a different source of intake water or relocating the discharge to a different body of water.

(A). Documentation. EPA received few comments on the requirement to document the basis for the reasonable potential determination in the NPDES permit fact sheet or statement of basis. Commenters stated that the proposed intake pollutant reasonable potential procedure would deny the public an opportunity to review and comment on decisions that would relieve dischargers of pollution control obligations because it does not require an opportunity for public comment on any of the proposed required demonstration, nor does it require public participation in the decision to grant an exemption; rather, according to this commenter, the proposal merely required an after-the-fact notice to the public of the agency's determination and its basis. Commenters further objected that EPA does not explain how this public notice will be provided when the discharge contains only intake pollutants.

The final Guidance at procedure 5.D.3.c.i retains the requirement to document the intake pollutant reasonable potential finding in the statement of basis or fact sheet, as proposed. This requirement is consistent with existing requirement at 40 CFR 124.7 and 124.8 to document all calculations and the rationale for the conditions in a draft permit. The requirement to document the intake pollutant reasonable potential determination ensures that the fact sheet or statement of basis explains why certain limitations may not be in the permit that would otherwise be expected absent special consideration for intake pollutants (i.e., WQBELs for pollutants that would be found to cause, have the reasonable potential to cause, or contribute to an excursion above applicable water quality standards under the baseline procedures).

Procedure 5.D.3.c.i only applies to the reasonable potential determination. Existing procedures governing development of NPDES permits and supporting documentation sufficiently cover instances where intake pollutants are considered in developing permit limits in accordance with today's final Guidance.

Contrary to commenters' assertion, the proposed, and final, provision addressing the fact sheet and statement of basis ensures that the public receives advance notice of a proposed finding that WQBELS will not be required for particular pollutants. Existing NPDES regulations require the permitting authority to prepare a fact sheet (40 CFR 124.8(a)) or statement of basis (40 CFR 124.7) for each draft permit and make them available to any requester. Further, the permitting authority must public notice the preparation of the fact sheet (40 CFR 124.10(a)(ii)) and, in addition, send the public notice to any person requesting to be on a State's mailing list (40 CFR 124.10(a)(ix)). The public notice must include the name of the person to contact to obtain further information, including copies of the draft permit, the statement of basis or fact sheet, and the application (40 CFR 124.10(d)(iv)). Existing regulations at 40 CFR 122.7(b) and (c) also require that certain information such as the permit application be publicly available. All interested persons have an opportunity to comment on the draft permit (40 CFR 124.11) and to submit oral or written statements at any public hearing (40 CFR 124.12(c)). These procedures apply even if the permit does not include permit limits for all pollutants in the discharge.

(B). Monitoring. The preamble to the proposed Guidance explained that monitoring is necessary to ensure that the conditions supporting a finding of "no reasonable potential" continue to be met throughout the term of the permit. Appropriate monitoring is necessary, for example, to identify changes in the mass or concentration of an intake water pollutant or to identify a new source of the pollutant of concern from a facility's processes. The proposed Guidance left the selection of appropriate monitoring parameters and frequencies to the discretion of the permitting authority to allow consideration of the individual circumstances at each facility or within the receiving water. EPA also invited comment on whether the final Guidance should specify minimum monitoring requirements for all facilities, whether permitting authorities should be required to consider specified factors in making this determination, or whether other permit conditions would be adequate in lieu of the proposed monitoring provisions.

EPA received comments on two aspects of the monitoring requirement: whether more specificity was needed in the Guidance and what appropriate monitoring methodologies should be. Several commenters endorsed the approach in the proposed Guidance to leave the details of monitoring requirements to the discretion of the permitting authority so that individual circumstances could be considered. One commenter requested that the permitting authority be given discretion to remove the influent and receiving stream monitoring requirements after the permittee demonstrates it is not responsible for the pollutant. Other commenters requested that the Guidance specify that monitoring be based on a statistical comparison of the influent and effluent, as opposed to straight comparisons of influent and effluent based on single samples, to account for normal variability in analytical methods, particularly when values are close to the detection limit.

EPA has finalized the monitoring requirement as proposed. EPA agrees that factors such as variability and detection limits are important considerations in establishing appropriate monitoring requirements. However, establishing a set approach in the Guidance would unduly hamper the ability of permitting authorities to determine appropriate monitoring for a variety of situations. EPA also declines to adopt the suggestion to specifically allow the permitting authority to remove monitoring requirements when it determines that the permittee is "not responsible" for the pollutant. As discussed elsewhere, it is EPA's view that a discharger is "responsible" for whatever pollutants are in its discharge. While special allowances may be appropriate under certain circumstances for intake pollutants, EPA does not endorse the view that the reasonable potential finding and related monitoring provisions should be adjusted generally based on the facility's "responsibility" for the pollutant. Moreover, the final Guidance gives considerable discretion to the permitting authority to determine the appropriate requirements regarding monitoring parameters and frequency. The purpose of monitoring is to ensure that the conditions for intake pollutant relief will continue to be met throughout the term of the permit. Traditionally, such factors as historical data on the consistency of effluent quality and whether conditions affecting the discharge are static, or subject to change, are considered in developing appropriate monitoring frequencies. Permitting authorities continue to have discretion to consider such factors under the final Guidance.

The monitoring provisions at 5.D.3.c.ii in the final Guidance apply only when the permitting authority has determined that the permittee's discharge does not cause, have the reasonable potential to cause, or contribute to an exceedance of applicable water quality standards, i.e., when WQBELs are not included in the permit. Existing NPDES regulations govern development of monitoring and reporting requirements when permit limits developed under procedure 5.E.3-5 of the final Guidance are included in the permit (see, for example, 40 CFR 122.41, 122.44, and 122.48). Also, see procedure 5.E.3.a of appendix F with respect to compliance monitoring for "no net addition" limits and related discussion in section VIII.E.7.c.iii of this document.

(C). Reopener. EPA received no comments on the proposed requirement to include a reopener provision in the permit to allow the permitting authority to modify or revoke and reissue the permit if changed conditions at the facilities require different permit limits or conditions. For example, a facility may obtain a different source of intake water or may relocate its discharge into a different receiving water. In these instances, limits may be needed in accordance with procedures 5.E.3-5. Similarly, monitoring may demonstrate that an intake water pollutant is altered by some change in the process wastestream subsequent to permit issuance. Here, also, a WQBEL may be appropriate given the changed circumstance. The final Guidance includes the reopener provision as proposed to ensure that permitting authority can take steps necessary to evaluate new information and adjust permit requirements for changed conditions without waiting for the permit term to expire. This reopener provision is consistent with the authority to modify permits because of new information under 40 CFR 122.62(a)(2).

As with the documentation and monitoring provisions, the reopener provision at 5.D.3.c.iii is specific to the situation where the permitting authority has determined that a WQBEL is not needed for an intake pollutant in a facility's discharge. Existing NPDES regulations require reporting of changed conditions (40 CFR 122.42(l)(1)) and allow inclusion of a reopener provision in the permit, which authorize the permitting authority to modify or revoke and reissue the permit if changed conditions warrant new or different permit requirements (40 CFR 122.62). These existing regulations would govern permits that include permit limits based on the procedures in 5.E.3-5.

c. Issues Specific to Consideration of Intake Pollutants in the Derivation of WQBELs

i. Availability Only for Non-Attainment Waters

Of the options discussed in the preamble addressing development of WQBELs, option 2 was silent on whether it was restricted to situations where the background concentration of the receiving water exceeded criteria, while option 4 was specifically restricted to these situations. Some commenters endorsed limiting intake credits to situations where the intake water exceed criteria, with some stating this was appropriate when the intake source was the same body of water as the receiving water while others did not make this distinction. Other commenters who generally favored option 4 stated that it should not be limited to non-attainment waters and requested the same relief for waters close to exceeding the criteria. Commenters further explained that the basis for this request was that conservative assumptions used in determining reasonable potential meant that WQBELs could be required in some cases even if the receiving water was in attainment, and that relief in this situation was needed to avoid compliance problems dealing with variability and to avoid requiring dischargers to remove pollutants they did not add. Another commenter stated that it may be legitimate to impose a permit limit or condition restricting an increase in the discharge beyond that contained in the intake water, except where the pollutant concentration in the intake water is below the applicable water quality criterion, in which case, the discharger should be allowed to increase the pollutant load up to the criteria and a WQBEL will not always be justified. Finally, several commenters argued in effect that WQBELs should not be required at all in non-attainment waters because "the technology-based limits would become essentially useless because, in addition to dealing with its own pollution, the facility would be required to have technology to combat many forms, and varying degrees, of pollution without workable industry standards to guide them."

The intake pollutant reasonable potential procedure can be used regardless of the status of the receiving water since it looks solely to whether a pollutant discharge that originates in the same body of water has any adverse effect that would not have occurred if the pollutant were left in-stream. Whether such an effect occurs is not related to the status of the receiving water. However, in the final Guidance, EPA is limiting no net addition limits to the situation where the background concentration of a pollutant in the receiving water (i.e., the quality of the water upstream of the discharger) exceeds the applicable criterion for that pollutant. This situation is also referred to as non-attainment waters. To ensure consistency, the procedure for determining whether background exceeds criteria is the same as for determining background concentration in developing a TMDL, as established in procedure 3 of appendix F of the final Guidance.

EPA's decision to limit intake credit relief to non-attainment waters is closely linked to its rationale for making intake pollutant relief available, that is, special consideration for intake pollutants is reasonable when other sources are the primary cause of the impaired water body to which the point source is discharging and the discharge itself effectively has no further adverse impact on the receiving water than that which already existed. Not providing special consideration for intake pollutants when the background water quality exceeds criteria in this situation would require the discharger to remove intake or background pollutants. Although EPA believes that requiring removal of background pollutants could be justified as furthering the restoration goals of the CWA, it believes that generally a more efficient, effective or equitable approach for attaining the desired water quality would be the fuller consideration of all sources and control strategies contemplated by the TMDL or a comparable assessment and remediation plan as provided in procedure 3.A of appendix F. In contrast, special consideration of intake pollutants is not needed to avoid requiring removal of background pollutants when the background quality of the receiving water is in attainment with water quality criteria. Indeed, in attainment waters, applying the procedures for considering intake pollutants in setting WQBELs would produce more stringent limits than would result from applying "baseline" procedures for setting limits that do not account for intake pollutants. This can be seen by comparing the wasteload allocation that would result from application of EPA's Technical Support Document for Water Quality-Based Toxics Control (TSD) to the wasteload allocation that would result from application of the no net addition approach in the final Guidance. (The TSD was used for this analysis because it formed the basis for the GLI "baseline" reasonable potential and WLA procedures.) The wasteload allocation is the discharge concentration that is necessary to meet the WQS applicable to the receiving water. EPA found that the TSD steady-state wasteload allocation procedures would always generate a less stringent wasteload allocation than background. Specifically, using the TSD resulted in limits above background (and above criteria) when waters are in attainment with WQS whereas the intake pollutant procedures would result in limits at background. Limits below criteria (but above background) are possible using the TSD procedures, but only in situations where the State or Tribe has reserved assimilative capacity for future growth or for similar reasons (e.g., used very conservative assumptions to account for significant uncertainty). EPA thinks it is appropriate to support a State's decision to reserve assimilative capacity for attained waters. Additionally, reservation of assimilative capacity usually occurs in the context of TMDL development; the assumptions used and WLAs developed as part of an approved TMDL (or comparable plan approved under procedure 3.A of appendix F) would govern over the intake credit provision in any event.

As a practical matter, using the TSD procedures in attainment waters to develop WQBELS rather than the intake water pollutant provisions is consistent with the comment that limits above background up to criteria should be allowed in attainment waters as long as compliance with such limit eliminates the discharge from causing, having the reasonable potential to cause or contribute to an excursion above the applicable State or Tribal WQS. When the source of the intake water pollutant is the same body of water as the receiving water, no net addition does not require removal of background pollutants. In response to a commenter's concern about compliance problems associated with variability, EPA notes that variability is always a potential problem in determining ambient pollutant concentration values. However, the procedures for determining background levels in procedure 3 of appendix F (the TMDL procedures) adequately account for consideration of variability for purposes of determining whether the ambient levels exceed criteria. Variability also may be considered in limit derivation, as discussed in more detail below. In addition, concerns about variability can be overcome in most cases through collection of additional data, which a discharger is free to collect and submit for consideration.

EPA does not agree with comments that WQBELs should not be required in non-attainment waters because they would effectively make technology-based limits useless and dischargers would not have workable industry standards to guide them given the varying amounts of pollutants they might be expected to control. The need for WQBELs in non-attainment waters is implicit in the requirement of section 301(b)(1)(C) of the CWA to require more stringent limits (i.e., water quality-based limits) when technology-based limits are not sufficient to attain the applicable WQS. Because the need for WQBELS is inherently site-specific, and varies over time as ambient water quality changes, it is not feasible to develop national guidelines on control strategies for particular industries.

ii. <u>Partial Credit at Discretion of Permitting Authority</u>

In the proposal, EPA solicited comments on whether options that would provide a direct adjustment to permit limits to account for intake pollutants should preclude credit for pollutants removed from the intake water prior to use at the facility. EPA explained that partial credit in this situation would be consistent with the existing approach for technology-based limits, which only allows partial credit. In a related vein, EPA requested comments on whether options 2 or 3 should be limited to situations where the discharge of intake pollutants improves receiving water quality because the discharge contains a lower mass or concentration of the pollutant than that found in the intake water. The rationale for limiting intake pollutant relief in these situations would be to advance the restoration goals of the CWA.

EPA received no comments on the option of limiting permit limit adjustments for intake pollutants to instances where the discharge produced a net improvement to the receiving water. Comments on partial credit came primarily from industry and were divided. Some commenters advocated partial credit as a way to address EPA's concerns that a no net addition approach for developing WQBELS would not necessarily advance attainment of WQS in non-attainment waters, i.e., the restoration goal. According to these commenters, partial credit could allow a facility to enjoy a "windfall" that could occur as a result of the mechanics of wastewater treatment (i.e., when dirtier water makes it easier or less costly to remove a higher percentage of a pollutant), and still produce a net discharge of pollutants that is less than the amount in its intake water. Commenters further asserted that partial credit could also be used to "level the playing field" if full credit would give a facility an undue advantage over other facilities. Several other commenters who supported partial credit urged the Agency not to focus exclusively on pollutants removed through pretreatment of intake water because if the discharger were facing new, more stringent limits to meet no net addition, it may be more cost effective or technically simpler to achieve the required removals through pre-treatment rather than post-treatment. For this reason, these commenters advocated giving the permit writer discretion to consider the overall system in determining whether full credit was appropriate.

Commenters who opposed the partial credit concept also focussed on a discharger's potential lack of flexibility in devising treatment strategies if intake pollutant relief were unavailable for pollutants removed through pre-treatment of intake water. One commenter objected that this would "result in the Agency becoming involved in minor elements of plant engineering, beyond that appropriate for a regulatory agency." Similarly, another commenter stated that allowing any removal of intake pollutants by the facility's wastewater treatment system to be replaced by an increase in the process pollutant loading to the wastewater treatment system is not unique to dischargers with pollutants in their intake water; all permittees can increase the loading to their wastewater treatment systems so long as those systems can effectively remove that additional loading. Other commenters asserted that EPA can only require removal of intake pollutants when removal is incidental through required treatment of pollutants added by a facility. Several also argued that adjusting intake credits for pollutants removed through pre-treatment of intake water effectively penalizes dischargers which pre-treat. These commenters asserted that this would be particularly inappropriate given that some dischargers which pre-treat intake water will discharge less than the mass of the pollutant removed from the intake water, thereby creating a potential for cleaner effluent as compared to the influent.

EPA has determined that allowing only partial credit for intake pollutants where a facility would remove those pollutants in any event is consistent with the CWA goal of restoring non-attainment waters. The decision to authorize limits based on a no net addition approach in the absence of a TMDL or comparable assessment and remediation plan for a period of up to 12 years from the publication date of the Guidance reflects in part a recognition that requiring dischargers to remove intake pollutants under certain conditions will not necessarily result in attainment of water quality standards in non-attainment waters. However, a policy of not compelling a discharger to remove intake pollutants is not relevant when the discharger would remove intake pollutants in any event. Similarly, EPA believes that not extending full credit when a discharger incidentally removes intake pollutants in the course of normal operation and maintenance of its treatment facility is appropriate. Other policy considerations come to the forefront when considering full credit. Here, EPA believes that extending full credit, that is, allowing the discharger to add more process pollutants to offset the amount that would be removed from its wastewater, unnecessarily impedes the goal of restoring impaired waters. Therefore, procedure 5.E.2.b of the final Guidance provides that the permitting authority may establish limits lower than background levels of the pollutant in the intake water where removal of the pollutant occurs as a result of the normal operation and maintenance of the facility's treatment system. At the same time, EPA agrees that it should avoid, where possible, interfering with plant-level determinations of whether reductions to meet new discharge limits can best be met through pre-treatment or post-treatment. Permit writers should have discretion to take facility-specific factors into account when determining whether full credit is appropriate. In addition, EPA is aware that determining whether, and to what extent, a facility would remove an intake pollutant in the course of normal operations can be technically difficult or infeasible for certain facilities with complex processes. Accordingly, the final Guidance in 5.E.2.b provides that, in determining whether to grant "partial" credit, the permitting authority has the discretion to consider factors such as removal of the pollutant achieved by proper operation and maintenance of the treatment system and the feasibility of establishing limits that reflect a "partial" credit.

iii. Developing the Limit

(A). Technology-based vs. Water Quality-based Limits. Nothing in the final Guidance changes the fundamental principle of permitting under the NPDES program that the effluent limit for any pollutant in the discharge should be the more stringent of the technology-based limit or the WQBEL. The permit writer should develop both types of the limits for the pollutant of concern to determine which is the more stringent. In developing the limits for comparison, the permit writer should consider all applicable implementation procedures for developing each type of limit independently before determining which is more stringent. For example, if the permittee has requested and qualifies for intake credits for a technology-based limit under 40 CFR 122.45(g), the permitting authority would determine the appropriate adjustment to the technology-based limit considering the partial credit provision in 122.45(g)(3). If the permitting authority further determines that the pollutant is being discharged at a level that causes, has the potential to cause, or contribute to an excursion above an applicable water quality standard and the background of the receiving water exceeds the applicable criteria, the permitting authority would determine eligibility for special consideration of intake pollutants and develop a WQBEL using the procedures in 5.E.3 of the final Guidance, including the "partial credit" provision in 5.E.2.b, and 5.E.2.c if appropriate. After this analysis is completed, the permitting authority would then determine which limit is the more stringent and include it in the permit.

(B). Expression of a Numeric Limit. The preamble to the proposed Guidance discussed different options for developing WQBELs considering the presence of intake water pollutants, but did not discuss the specifics of implementing those options. The option chosen in the final Guidance, limits based on "no net addition," essentially requires that the permittee discharge no more of the pollutant than that in the intake, or background, water supply. One commenter suggested that the geometric mean of background water quality can provide the basis for establishing daily maximum and monthly average permit limits. However, other commenters expressed concern that limits based on background water quality could create compliance problems unrelated to the discharger's actions because of variability in background water quality, especially when there is a limited data base.

The final Guidance leaves the details on actual development of permit limits to the discretion of the permitting authority. Numerical limits may be derived from data on ambient water quality or influent samples, with appropriate consideration for variability. Permitting authorities have considerable experience in judging the adequacy of data and in using available data to develop defensible limits. Seasonal limits can be developed to account for anticipated seasonal changes in background water quality. Similarly, permit limits can be modified if warranted by changed conditions. In some instances where variability and data available or quality is of particular concern, the permitting authority can develop limits to implement "no net addition" that establish the numerical limit as "zero," with required compliance monitoring based on the differences between influent and effluent samples. (EPA recognizes that developing appropriate compliance monitoring provisions in this situation may not be a simple task because of such issues as detection levels and appropriately paired samples. However, these details are more appropriately left to the permit writer's best professional judgment based on the site-specific factors at the permitted facility). The final Guidance at procedure 5.E.3.a requires the permit to contain provisions specifying how compliance with any limitations will be assessed. This language was added to the final Guidance in response to concerns that permittees would face uncertainty about their obligations with respect to potentially fluctuating levels of pollutants in the intake water. Permitting authorities may also require additional data collection to better characterize intake water quality, although the decision that more data is needed is not a reason in this case for not including a limit in the permit that implements no net addition. In sum, considerable flexibility exists in developing no net addition limits that takes into account the types of concerns raised by commenters.

F. Whole Effluent Toxicity

1. Background

As discussed in section VIII.D of this document on Additivity, a focus on individual pollutants may not provide complete protection of water quality because of the potential interactions between pollutants. See procedure 4 of appendix F to part 132. Moreover, as a practical matter, sufficient data does not exist at this time to develop chemical-specific criteria for each chemical that may be discharged in the waters of the Great Lakes System, or to categorically conclude that such chemicals are not harmful to aquatic life.

Procedure 6 of appendix F to part 132 accounts for chemical interactions and for data gaps regarding individual chemicals in an effluent by establishing procedures for limiting the toxic effect on aquatic life from an effluent as a whole (known as "whole effluent toxicity" or "WET"). The whole effluent approach to toxics control for the protection of aquatic life involves the use of acute and chronic toxicity tests to measure the toxicity of wastewaters. An acute WET test is a comparative study in which organisms that are subjected to different treatments, such as different amounts of effluent, are observed for a short period -- usually not constituting a substantial portion of their life span. Typically acute WET tests are run for a period of less than 96 hours and are evaluated using measures of mortality. A chronic WET test is a comparative study in which organisms that are subjected to different treatments are observed for a long period or a substantial portion of their life span. Typically chronic WET tests are long-term tests in which sublethal effects, such as impaired fertilization, growth, or reproduction, are measured, in addition to lethality or immobilization. Aquatic organisms used in the tests may include, but need not be limited to, invertebrates, fish, and plants.

Terms commonly used to express the toxicity of an effluent include the lethal concentration (LC) and the no observed effect concentration (NOEC). The LC50 is the concentration of an effluent at which 50 percent of test organisms die in an acute WET test (e.g., if 50 percent of the test organisms die in 20 percent effluent, the LC50 = 20). The NOEC is defined with respect to a toxicity test with aquatic organisms, as the highest concentration of toxicant to which organisms are exposed that causes no observable adverse effects. The procedures appropriate for calculating the NOEC and LC50 are described in the Technical Support Document for Water Quality Based Toxics Control, March 1991 (March 1991, TSD). Typically, the permitting authority can use a series of tests run at different dilutions of effluent to determine the NOEC, or derive the Inhibition Concentration at 25 percent effect, IC25, from a statistical analysis of the raw test data. The IC25 is defined as the toxicant concentration that would cause a 25 percent reduction in a non-quantal biological measurement for the test population. The data presented in appendix A of the March 1991 TSD demonstrate that the IC25 is comparable to the NOEC derived using the hypothesis testing of a dilution series. Other commonly used terms are acute toxic units (TU_a) and chronic toxic units (TU_c), which are defined as follows:

$$TU_a = 100/LC50$$

$$TU_c = 100/NOEC \text{ or } 100/IC25$$

For example, an acute WET test with an LC50 at 20 percent effluent translates to 5 TU_a's. A chronic WET test with an NOEC or IC25 at 10 percent effluent translates to 10 TU_c's.

Procedure 6 of appendix F to part 132 provides specific provisions for controlling the WET of discharges to the Great Lakes System. The procedure contains four sections: criteria for WET, appropriate test methods to measure WET, permit conditions, and reasonable potential procedures for determining whether or not limits for WET are necessary. The final Guidance on WET only supplements for the Great Lakes States and Tribes, and does not replace, the regulations at 40 CFR 122.44(d)(1). In addition, the March 1991 TSD contains guidance relevant to topics not addressed in procedure 6 of appendix F to part 132.

The WET provisions apply to all facilities regardless of the cause of toxicity, including toxicity caused by any "excluded pollutants" listed in Table 5 of part 132 (see 58 FR 20969) and also including pollutants other than the Table 6 of part 132 pollutants of initial focus. A contrary result would seriously limit the effectiveness of the WET procedure since the purpose of WET control is to limit the toxic effect of the combination of all pollutants in a wastestream, without the need for identifying the individual pollutants contributing to the toxicity when assessing compliance.

WET is in many ways a unique pollutant parameter that requires different implementation techniques than are used for other pollutants. Procedure 6 of appendix F to part 132 includes a complete reasonable potential section that is tailored to WET determinations. The Total Maximum Daily Load (TMDL) section, procedure 3 of appendix F to part 132, in general is not applicable to WET control because it does not account for the peculiarities of WET. For example, techniques have not yet been developed for adding the whole effluent toxicities associated with individual dischargers. Individual toxicity measurements may be based on different species, and may be independent of one another because they involve widely different classes of chemicals. Accordingly, EPA is not specifying in this rule a TMDL methodology applicable to WET. Nevertheless, procedure 6 of appendix F to part 132 incorporates by reference certain important components of the TMDL procedure, including applicable design flows for aquatic life protection and provisions for chronic mixing zones. In addition, the WET procedure addresses site-specific conditions associated with WET and, therefore the site-specific provisions in procedure 1 of appendix F to part 132 are not applicable to WET.

2. <u>Criteria for WET</u>

a. <u>Proposal:</u> The proposed Guidance prohibited any discharge from: (1) exceeding 1.0 acute toxic unit (TU_a) at the point of discharge, (2) causing or contributing to a receiving water exceeding 1.0 chronic toxic unit (TU_c) (subject to certain exceptions) and (3) causing or contributing to an excursion above any numeric WET or narrative criterion, such as the free-from toxics narrative, within State or Tribal water quality standards. The proposed Guidance did not require Great Lakes States or Tribes to adopt numeric criteria for WET. The proposed Guidance, rather, specified minimum criteria objectives, 1.0 TU_a (end-of-pipe) and 1.0 TU_c (edge of chronic mixing zone) that applied when either narrative criteria or numeric WET criteria were involved. Like the Federal regulations at 40 CFR 122.44(d)(1)(iv) or (v), which reflect the ability of States and Tribes to control WET with either numeric or narrative criteria, respectively, the proposed Guidance allowed the Great Lakes States or Tribes to choose the preferred form of criteria to implement in their State or Tribal procedures.

b. <u>Comments:</u> Several commenters expressed support for allowing a State or Tribe to adopt either numeric WET criteria or an interpretation of a narrative criterion into their water quality standards. These commenters expressed a desire to maintain the flexibility currently provided at 40 CFR 122(d)(1)(v) when implementing narrative as opposed to numeric WET criteria. These regulations provide that a permit need not contain a limitation for WET, notwithstanding a determination that a reasonable potential exists for the discharge to cause or contribute to an exceedance of a narrative criterion, if the permitting authority can demonstrate that controls on individual pollutants will ensure attainment of the narrative criterion.

Numerous commenters supported the establishment of specific minimum criteria objectives that States or Tribes would need to achieve through implementation of either numeric or narrative criteria. A few commenters supported the required adoption of numeric WET criteria to ensure consistency among States and Tribes.

c. Final Guidance: Based on existing rules and guidance and upon consideration of the comments received, EPA has decided to allow the States and Tribes to adopt into their water quality standards either numeric WET criteria or narrative criteria providing for the protection of aquatic life from toxicity. However, those States or Tribes choosing to rely on narrative criteria must also adopt into their water quality standards specific numeric interpretations of those criteria. The effect of either approach would be the same -- control of acute toxicity to 0.3 TU_a and chronic toxicity to 1.0 TU_c, either end-of-pipe or at the edge of appropriate mixing zones. This approach will ensure consistency in application of WET requirements among the Great Lakes States and Tribes, and will allow the States and Tribes to maintain the discretion they currently have under existing rules to control toxicity through implementation of either a narrative or a numeric criterion. An explanation of EPA's choice of the 0.3 TU_a and 1.0 TU_c values to protect aquatic life at the edge of mixing zones is provided in the following two sections of this document.

3. Acute Toxicity Control

a. Proposal: The proposal provided that no discharge be allowed to exceed 1.0 TU_a at the end-of-pipe to protect aquatic life in the receiving stream and ensure minimal exposure to acutely toxic conditions. This provision was based on the current EPA guidance that 0.3TU_a is necessary to protect aquatic life, and assumed a maximum 3:1 dilution by the receiving water.

b. Comments: Many commenters disagreed with the proposed lack of flexibility regarding the use of acute mixing zones, also referred to as zones of initial dilution, when developing water quality-based effluent limitations (WQBELs) for acute WET. They stated that there was no justification for imposing more stringent limitations on acute toxicity in the Great Lakes System than recommended in the March 1991, TSD because the impacts from acute toxicity would not be unique to the Great Lakes System. Also, several commenters stated that the proposed 1.0 TU_a value would be an overly protective value when applied end-of-pipe and would not be necessary to meet the 0.3 TU_a value in the receiving water. Several commenters supported the use of acute mixing zones to account for site-specific conditions and believed the 0.3 TU_a criterion applied to the edge of the acute mixing zone provides sufficient protection of the receiving water. Other commenters supported the proposed limitation on acute mixing zones for WET based, in part, on their view that the Great Lakes Water Quality Agreement (GLWQA) recommends the elimination of acute toxicological effects in all portions of the receiving water.

Based upon a review of the comments and the existing National rules and policies, EPA has determined that acute WET mixing zones are appropriate for use in the Great Lakes System. The current national policy, as articulated in the March 1991, TSD, envisions the use of mixing zones in developing WQBELs for WET, provided the acute mixing zone effectively minimizes aquatic life exposure to acutely toxic concentrations of pollutants. EPA considers acute mixing zones to be protective of water quality when the physical conditions within the acute mixing zone bar organisms from being present for sufficient time to elicit a toxic response. It is important to keep in mind that an acute mixing zone is not appropriate in all instances. Lack of flow in the receiving water for dilution or proximity of the discharge to areas of ecologic importance may preclude placement of an acute mixing zone in some cases. However, within these constraints, dilution may be considered in developing acute WET limits in NPDES permits.

EPA will review State and Tribal mixing zone policies as part of its periodic review of State and Tribal water quality standards. Moreover, EPA will review individual State and Tribal mixing zone determinations when it reviews State and Tribal NPDES permits. EPA has the authority to object to State and Tribal permits it considers inadequate to meet the requirements of the Clean Water Act (CWA).

It should also be noted that by establishing an FAV cap for individual pollutants, WET in each discharge should be substantially reduced, and fewer WET limits are likely to be required. As a result, less variability in regulation of WET discharges should ensue, notwithstanding the flexibility allowed under the final Guidance with respect to establishment of acute mixing zones.

EPA has determined that the provision to adopt a numeric or narrative criterion of 0.3 TU_a with the allowance of acute mixing zones where appropriate, and the ability to select test species appropriate for the local biological community, will provide sufficient site-specific flexibility as well as promote the consistent application of acute WET permit limits. The 0.3 TU_a criterion is based upon the evaluation of over 1200 toxicity tests with over 100 chemicals and species from several families. EPA has determined that at least 90 percent of the species subjected to an acute WET test would have survival rates of 99 percent if exposed to 0.3 TU_a. EPA believes that the level of protection associated with 0.3 TU_a is protective of aquatic life and is strongly supported by the large body of data referenced in the March 1991, TSD.

c. Final Guidance: EPA has established under procedure 6.A.1 of appendix F to part 132 a provision that a numeric acute WET criterion of 0.3 TU_a, or a numeric interpretation of a narrative at least as stringent as the acute WET numeric criterion, be adopted by States and Tribes. This criterion would apply to the receiving water and would allow for the use of acute mixing zones consistent with EPA approved State mixing zone provisions. As described in the TSD, an acute mixing zone is designed to minimize aquatic life exposure to acutely toxic conditions. This is accomplished by: (1) locating the acute mixing zone to avoid contact with immobile organisms, (2) use of high rate diffusers or other means to create a well mixed and sufficiently turbulent flow regime to discourage fish and other organisms from entering the acute mixing zone and (3) requiring that drifting organisms such as daphnia will be exposed for only a short period of time, usually less than one hour.

In cases where the available receiving stream dilution provides less than a 3:1 dilution ratio, the WQBEL for acute WET can be no greater than 1.0 TU_a -- the lowest acute toxic value that can be directly measured. In these situations, the acute WQBEL itself will not be sufficient to ensure attainment of 0.3 TU_a in the receiving water. However control of chronic toxicity in low-flow situations will generally prevent acutely toxic WET impacts.

4. Chronic Toxicity Control

a. Proposal: The proposed Guidance, required that a value of 1.0 TU_c be maintained at all points of the receiving water except (i) within a mixing zone for aquatic life as defined in section VIII.C of this document, or (ii) in any portion of the receiving water for which a permitting authority has demonstrated that due to the site-specific physical and hydrological conditions, it is unnecessary to apply any chronic WET requirements to protect aquatic life. The 1.0 TU_c value is, by definition, the point at which no effect is observed in the test species when they are exposed to undiluted effluent. The no effect determination can be performed using either hypothesis testing or the IC25 statistical procedure.

The proposed provision for site-specific modifications was similar to that included in the proposed procedure 1 of appendix F to part 132, which provided that States and Tribes could develop site-specific modifications to chronic aquatic life criteria/values for individual pollutants to reflect local physical or hydrologic conditions (see section VIII.A of this document on Site Specific Modifications to Criteria).

b. Comments: Many commenters were concerned that the chronic WET testing procedures were not sufficiently validated to be used in developing NPDES permits; however no information was presented to support this assertion. Other commenters supported the proposed flexibility for States and Tribes to adopt either numeric or narrative chronic WET criteria. Many commenters stated that if the chronic limit requirements are retained, the States and Tribes should be given flexibility as to how the NOEC is determined such as using the IC25 or other methods supported in the March 1991, TSD. Also some commenters contended that the 1.0 TU_c value could be over-protective because of the apparent lack of correlation between the chronic lab tests and the impacts observed in the receiving water. Many commenters supported the site-specific provisions for implementing the chronic WET limits.

EPA believes that the chronic WET testing procedures are suitable for supporting the inclusion of chronic WET limits in NPDES permits. EPA has documented in the TSD several studies which demonstrate that chronic toxicity tests are comparable to chemical analyses in their reliability and reproducibility. In addition, EPA has provided in the final Guidance flexibility in how the TU_c value can be determined, and supports any method consistent with the provisions discussed in the TSD including the use of the IC25. EPA agrees with the commenters that site-specific factors are appropriate to consider in matters regarding chronic WET. EPA has decided, however not to finalize the language addressing site-specific modifications in the proposal. The proposal would have allowed States and Tribes to completely eliminate chronic WET requirements as a result of site-specific physical and hydrologic conditions. Upon further consideration of this matter, EPA has determined that the general provision for documenting scientific defensibility at 132.4(g), for application of any procedure in the final Guidance, is sufficient to address those rare instances where a permitting authority can document that there are no aquatic species exposed to acute or chronic toxicity.

The final Guidance requires that States and Tribes use WET methods published in 40 CFR part 136 for all purposes in implementing chronic WET criteria. These test methods allow the use of test species representative of those capable of surviving under the physical and hydrologic conditions present in the receiving waters. Moreover, the part 136 test methods allow site-specific aquatic chemistry to be taken into account in certain situations by using site water to dilute effluent being subjected to WET tests. EPA believes that through use of the flexibility provided in the part 136 chronic WET test methods, States and Tribes can appropriately take site-specific situations into account in implementing WET controls under most conditions.

c. Final Guidance: This provision is generally consistent with the proposal, with the exception of the elimination of the site-specific modification language, as described above. The final Guidance allows the States and Tribes to adopt either a numeric chronic WET criterion of 1.0 TU_c with provisions for allowing a chronic mixing zone for aquatic life, or a numeric interpretation of a narrative criteria that establishes 1 TU_c as the necessary value to protect aquatic life from WET. The 1.0 TU_c value is defined as 100 percent effluent/NOEC or 100 percent effluent/IC25. The NOEC and the IC25, are described in the March 1991 TSD. By definition, the 1.0 TU_c criterion as it would apply to the receiving water indicates that there is no statistically significant or measurable chronic toxicity. Clearly, this criterion represents the threshold of measurable chronic toxicity and field studies documented in the March 1991, TSD indicate that this criterion is protective of natural aquatic populations.

5. Numeric and Narrative Criteria

a. Proposal: The proposed Guidance prohibited any discharge from causing or contributing to an excursion above any State or Tribe adopted numeric or narrative criteria for WET. EPA added procedure 6.A.3 of appendix F to part 132 to make it clear that the proposed Guidance on WET merely supplemented for dischargers into the Great Lakes System, rather than replaced, the requirements of 40 CFR 122.44(d)(1). EPA had determined that procedure 6.A.3 of appendix F to part 132 was necessary because there could be instances where a Federally-approved State or Tribal water quality standard had additional or more stringent requirements pertaining to toxicity than those contained in the proposal. Procedure 6.A.3 of appendix F to part 132 made it clear that these additional requirements would still need to be met.

b. Final Guidance: There were no significant comments on this provision. However, procedures 6.A.1 and 6.A.2 of appendix F to part 132, explicitly require States and Tribes to adopt (1) numeric criteria or (2) a numeric interpretation of a narrative criterion as protective of aquatic life as the numeric criteria. These modifications remove the need for the proposed provision, since States and Tribes are now explicitly required to adopt numeric or narrative criteria as the basis for WET controls. Moreover, procedure 6.C of appendix F to part 132 ensures that the limitations will be included in NPDES permits to attain and maintain these criteria.

6. WET Test Methods

a. Proposal: The proposed Guidance required that all WET tests be performed in accordance with test procedures approved under 40 CFR 136. The proposed provision was consistent with current NPDES regulations at 40 CFR 136.1, requiring that analytical methods promulgated at 40 CFR 136 are used in the NPDES permit program. In the case of WET, there were no promulgated part 136 analytical methods at the time this rule was proposed. When there is no analytical method promulgated, permitting authorities have the discretion to specify the method for use as allowed at 40 CFR 136.3. EPA's recommended test methods were referenced in the proposed Guidance.

b. Comments: Some commenters requested that approved WET test methods be adopted into 40 CFR 136 or be clearly documented and made available. In addition, some of these commenters requested that States and Tribes be allowed to exercise flexibility in selecting test species and other parameters associated with the test procedures as currently allowed in approved EPA test methods, while other commenters requested that the bounds of flexibility in method application be defined.

EPA agrees with the commenters who suggested that WET test methods be adopted in 40 CFR 136 and intends to do shortly. The methods EPA expects to adopt under part 136 are those that were referenced in the proposed Guidance. The methods provide some flexibility in conducting the tests. For example, the permitting authority can use grab or composite samples in the WET tests. Best professional judgement is needed to determine what type of sample is appropriate for a given discharge. Also, the tests can be run by using continuous flow-through of the sample and dilution water or by periodic replacement of the sample and dilution water. Costs and the variability of the effluent are key factors the permitting authority may consider when prescribing test procedures. EPA also agrees that there must be some bounds on the State and Tribal flexibility to conduct WET tests and has determined that the test procedures adopted under part 136 sufficiently define the bounds of flexibility.

As discussed in the proposal, EPA expects that WET monitoring will be performed consistent with the March 1991, TSD. At least three species representing three families should be used to assess WET toxicity, or documentation must be provided that one or two species is sufficient to adequately characterize the toxicity of an effluent. Compliance with the WET

NPDES permit limits is determined by using the test results of the most sensitive species tested.

c. Final Guidance: The final Guidance requires that part 136 methods be used when assessing compliance with WET permit limits. EPA expects to publish part 136 WET test methods shortly. In the unlikely event that such methods are not published prior to State or Tribal implementation of the final Guidance, EPA recommends that States and Tribes use the following WET test methods: "Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms," EPA/600/4-90/027; and "Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms," EPA/600/4-89/001a (except Method #1001 and #1003, marine methods, for both acute and chronic test methods). The WET test methods include provisions requiring that they be appropriate for the species selected and the approved end points for assessing the LC50 for acute, and the NOEC or IC25 for chronic, toxicity.

7. Permit Conditions

The proposed Guidance specified permit provisions for three situations: 1) when sufficient data demonstrated that the reasonable potential to exceed the provisions of proposed procedure 6.A of appendix F to part 132 existed; 2) when sufficient data are not available to determine whether the discharge had the reasonable potential to exceed the provisions of proposed procedure 6.A of appendix F to part 132; and 3) when adequate data demonstrated that reasonable potential to exceed the provisions of proposed procedure 6.A of appendix F to part 132 did not exist.

a. Data Indicates Reasonable Potential.

i. Proposal: The proposal required that permitting authorities include effluent limitations for WET when sufficient effluent-specific data demonstrate that a reasonable potential exists for an exceedance of the 1.0 TU_a and 1.0 TU_c provisions. The proposal also included three other provisions: 1) chronic WQBELs were to be calculated based upon the TMDL design flow and mixing zone requirements of procedure 3.B of appendix F to part 132; 2) a schedule of compliance consistent with proposed procedure 9 of appendix F to part 132 could be included in the NPDES permit; and 3) when regulating using a narrative criterion for water quality, a specific WQBEL for WET may not be necessary if it could be shown (and documented in a fact sheet or statement of basis for a NPDES permit) that chemical-specific WQBELs would ensure compliance with the requirements of procedure 6.A of appendix F to part 132.

ii. Final Guidance: There were few comments opposing these provisions. EPA has retained the essence of these provisions, but has modified the language somewhat to account for the changes to procedure 6.A of appendix F to part 132. In light of the requirements in the final Guidance that States and Tribes adopt criteria for WET protection, the final Guidance adheres to the reasonable potential language in 40 CFR 122.44(d) more closely than in the proposal.

The effluent limitations for acute WET will be calculated taking into account the allowable dilution for an acute mixing zone to ensure that 0.3 TU_a is met at the edge of the acute mixing zone. The effluent limitations for chronic WET will be derived using the TMDL chronic mixing zone provisions for aquatic life protection as discussed in procedure 3 of appendix F to part 132. EPA intends that the mixing zone provisions in procedure 3 of appendix F to part 132 that are applicable to non-BCCs apply to the derivation of chronic WET mixing zones. Therefore, even if there are BCCs in a discharge, there is no prohibition of chronic mixing zones for WET.

A provision has been added to the final Guidance which states that the permitting authority may specify in the NPDES permit the conditions under which a permittee would be required to perform a toxicity reduction evaluation

(TRE). This provision is consistent with existing EPA guidance and rules regarding the use of TREs in the control of WET. By including this provision in the final Guidance, EPA is encouraging the States and Tribes to address elevated levels in WET before they trigger a significant non-compliance determination.

Because some existing dischargers may not be able to meet WET limits at the time that their permits are reissued or modified to include new WET limits, EPA believes that allowing some permittees time in which to achieve compliance may be appropriate where allowed in State or Tribal water quality standards. The final Guidance requires that compliance schedules, however, be developed in accordance with procedure 9 of appendix F to part 132. The provision at procedure 6.C.1.d of appendix F to part 132 mirrors the existing regulation at 40 CFR 122.44(d)(1)(v).

EPA wishes to emphasize that there are situations when a permitting authority may determine without facility-specific effluent data that the reasonable potential to cause an excursion above a WET criterion or the narrative criterion exists. For example, effluent data from similar industrial operations can be used to evaluate a facility for which no effluent-specific data exist. This information, within the judgement of the permitting authority, can be used as a basis for evaluating whether the reasonable potential to exceed the WET criteria exists.

In addition, the factors at 40 CFR 122.44(d)(1)(ii) which apply to WET need to be evaluated in reasonable potential determinations, including: the variability of the pollutant parameter in the effluent, the sensitivity of the species to expected pollutant toxicity testing and, where appropriate, the dilution of the effluent in the receiving water.

Finally, the provision at procedure 6.C.1.e of appendix F to part 132 mirrors the existing regulations at 40 CFR 122.44(d)(1)(v). EPA is including this provision to eliminate any confusion about the applicability of 40 CFR 122.44(d)(1)(v) to facilities covered by the final Guidance.

b. Insufficient Data to Determine Reasonable Potential.

i. Proposal: As previously discussed in this document, 40 CFR 122.44(d)(1)(i) requires a permitting authority to impose effluent limitations whenever it finds that a facility has the reasonable potential to cause or contribute to an excursion above a State's or Tribe's numeric or narrative water quality criterion. Procedure 6.C.2 of the proposed Guidance recognized the potential for a permitting authority to have insufficient information prior to permit issuance to determine reliably whether a facility causes, has the reasonable potential to cause, or contributes to such an excursion. In this instance, the proposed Guidance required permitting authorities to collect sufficient information by requiring effluent monitoring in permits.

Recognizing that the approach of collecting effluent monitoring data as a permit condition could delay effluent controls necessary to achieve State or Tribal numeric and narrative water quality criteria, the proposed Guidance required that such effluent monitoring be combined with a permit requirement that the permittee initiate a toxicity reduction evaluation (TRE) if the monitoring demonstrated reasonable potential as determined by the permitting authority.

ii. Comments: Several commenters expressed confusion regarding the provisions of this section because the discussion in the proposed preamble and current national policy allows State and Tribal discretion regarding the imposition of WET monitoring and TRE requirements while the proposed Guidance used "shall require" language. Many commenters supported the use of State and Tribal discretion in making these decisions. Specifically, the commenters were generally supportive of the use of permit conditions to collect the necessary data provided States and Tribes can be flexible in establishing the appropriate monitoring frequency for a given facility. Several commenters felt that the TRE provisions as proposed did not provide adequate flexibility for the permitting authority to determine when a TRE was needed to ensure that water quality standards will be achieved.

EPA did not intend to limit State or Tribal discretion regarding WET monitoring requirements when there is insufficient information available to make a reasonable potential determination. In this respect the preamble to the proposal actually reflected EPA's intent, while the proposed regulatory language did not.

In deciding which of the facilities lacking sufficient data for reasonable potential determinations should be required to collect effluent WET monitoring data, permitting authorities should consider a number of factors including the type of facility, the potential sources of toxic contaminants, the presence of individual toxic pollutants in the effluent, and known impacts on the receiving water. These decisions are best left to a case-by-case analysis and, therefore, EPA is not requiring WET testing for all such facilities in the final Guidance. In deciding the type of monitoring that comprises a sufficient data set, EPA expects permitting authorities to require WET tests using multiple aquatic species to be consistent with the provision of 40 CFR 122.44(d)(1)(ii), requiring consideration of aquatic species sensitivity. The amount of information to be collected is left to the permitting authority to determine. However, EPA guidance in the TSD recommends that toxicity testing to characterize an effluent should require testing of three species, quarterly for one year. The means to account for the uncertainties posed by infrequent monitoring are addressed in procedure 6.D of appendix F to part 132 in this document. EPA will review State and Tribal determinations in this area when it reviews individual NPDES permits. EPA is authorized to object to NPDES permits it finds inconsistent with the requirements of the CWA, and is also authorized to take over permit issuance authority in such circumstances.

Similarly, EPA has modified the proposed requirement that a TRE be performed if effluent monitoring indicated that a reasonable potential exists to exceed State or Tribal water quality standards. EPA believes it is more appropriate to include a reopener provision to first add WET permit limits if the additional monitoring data indicate that a reasonable potential exists to exceed the State or Tribal water quality standards. This provision recognizes that it will be to the permittee's advantage to conduct a TRE as soon as possible to identify the cause of the toxicity and avoid the penalties associated with the violation of the permit limitations.

iii. Final Guidance: Procedure 6.C.2 of appendix F to part 132 has been modified to clarify that the permitting authority has discretion to decide whether to impose WET monitoring requirements in permits of facilities for which insufficient information exists to make a reasonable potential determination at the time of permit issuance. In addition, for the reasons described above, procedure 6.C.2.b. of appendix F to part 132 was modified to provide that States and Tribes should consider establishing a permit reopener clause to establish WET limits when WET monitoring data collected under a permit indicates that there is reasonable potential to cause or contribute to an exceedance of applicable criteria. The final procedure does not include a provision for requiring TREs, but EPA expects that States and Tribes will require them in NPDES permits under appropriate circumstances.

c. Data Indicates No Reasonable Potential. Commenters generally supported these provisions. EPA has decided to finalize this part of procedure 6 of appendix F to part 132 with only those modifications necessary to conform to other sections of this procedure that have been modified. Procedure 6.C.3 of appendix F to part 132 restates the current authority for a permitting authority to establish monitoring requirements for WET in an NPDES permit for dischargers for which it does not find a reasonable potential to exceed numeric or narrative water quality criteria. Where the permitting authority concludes that a continued monitoring requirement is warranted based upon the particular circumstances of a discharge, the permitting authority may require continued testing for a reasonable period of time and then evaluate the monitoring results at the conclusion of this period. For example, a permitting authority may decide to impose WET monitoring, prior to the next permit reissuance, on a discharger whose current effluent WET data indicate no reasonable potential to determine if the facility will require WET limits in the next NPDES permit. Under sections 308 and 402 of the CWA, a permitting authority can require NPDES permittees to provide WET testing data that will assist in the development of future effluent limitations.

8. Reasonable Potential Determinations

a. Proposal: The proposed Guidance at procedure 6.D of appendix F to part 132, provided that the factors described in 40 CFR 122.44(d)(1)(ii) be evaluated when making a determination whether reasonable potential to exceed the provisions of procedure 6.A of appendix F to part 132 existed. These factors need to be considered in all evaluations pursuant to 40 CFR 122.44(d)(1). In addition, the proposed Guidance included procedures and decision criteria to use in cases where facility-specific WET data existed to determine whether the discharge had the reasonable potential to cause or contribute to causing an exceedance of the proposed 1.0 TU_a or 1.0 TU_c values.

i. Characterization of the Discharge. The proposal specified that all acute toxicity values collected during the same day were to be averaged for each species. Also, the proposal specified that chronic toxicity test results from samples collected during the same month were to be averaged. When either chronic or acute toxicity values were unavailable, the States and Tribes were required to estimate the missing WET test data by using an effluent-specific acute-chronic ratio. If there was no effluent-specific acute-chronic ratio, then the missing WET test data was to be predicted using a default acute-chronic ratio of 10. For example, using an acute-chronic ratio of 10, a discharge with 5 TU_a would be equivalent to 50 TU_c.

ii. Specific Acute WET Procedure. The proposed Guidance specified that a discharge has the reasonable potential to cause, or contribute to causing an exceedance of the 1.0 TU_a value when sufficient effluent-specific information demonstrates that:

$$50\% / \%\text{effect in } 100\% \text{ effluent} < B$$

Where the effect is immobilization or mortality of the test organism in the WET test and B is the multiplying factor taken from Table F6-1 of this procedure. The B factor is derived from the number of samples and their coefficient of variation, to estimate the 95th percentile toxic unit value when multiplied by the maximum sampled toxic unit value, to determine if an effluent has the reasonable potential to exceed the 1.0 TU_a value.

iii. Specific Chronic WET Procedure. The proposed Guidance included a provision to determine if a discharge has the reasonable potential to cause, or contribute to causing an exceedance of the 1.0 TU_c value using the chronic aquatic life mixing zone provisions in the TMDL procedures in proposed procedure 3 of appendix F to part 132. The following equation was proposed for assessing reasonable potential for exceeding the 1.0 TU_c value:

$$[\text{chronic toxicity}(TU_c) \text{ of the effluent}] > 1/(B \times RWC)$$

where B is the multiplying factor and RWC is the receiving water contribution, or available dilution, as allowed under the provisions of the section VIII.C of the proposed preamble.

b. Comments: The majority of comments focussed on the frequency of WET testing and the total amount of data necessary to make a reasonable potential determination. Several commenters were concerned that the proposed requirement to average acute WET test values taken on the same day, and chronic WET test values taken in the same month, effectively required that more than one acute WET test be conducted per day and that more than one chronic WET test be conducted per month for each species tested to satisfy the reasonable potential requirements. They were concerned that such a requirement would be unnecessary and too expensive to implement. Some commenters raised concerns regarding the validity of acute-chronic ratios, but said that they could concur with a default acute-chronic ratio of 10. Some commenters recommended that only data representative of the discharge be used in reasonable potential determinations.

EPA agrees that the language in the proposal was not as clear as it should have been with respect to the data requirements for assessing reasonable potential. EPA did not intend to require that the regulated community take multiple samples in any given time period for the same species; rather the proposal simply addressed situations where multiple samples were collected and analyzed in the specified time period. Sampling from several different time periods will produce a more representative analysis of a facility's performance than several samples from the same time period. Also, the proposal specified that data from one species should not be averaged with data from other test species.

The number of WET tests to be used in the reasonable potential determinations depends on the number of test results that the permitting authority considers to be acceptable to characterize a facility's discharge. Where the permitting authority includes conditions in the permit for WET testing for purposes of assisting in future reasonable potential determinations, the permitting authority can balance cost considerations associated with an increase in set of samples against the effects of having fewer samples. One effect of decreasing the set of samples is that the multiplying factor B used in the equations for assessing reasonable potential will increase. The effect of increasing the multiplying factor B is that the projected maximum WET value for effluent will be larger than the one calculated using more data points.

EPA considers the default acute-chronic ratio of 10 suitable for reasonable potential determinations, based on an evaluation of acute-chronic ratios in the March 1991 TSD. The use of either an effluent-specific or the default acute-chronic ratio of 10 provides a cost-effective means of augmenting a reasonable potential data set. Where data exists for both acute WET and chronic WET, the permitting authority should allow the augmentation of the reasonable potential data set by: (1) allowing the use of an effluent-specific acute-chronic ratio, (2) or allowing the use of the default acute-chronic ratio of 10, (3) or allowing the facility to collect additional data before a reasonable potential determination is made.

With regard to the comment suggesting that only representative data should trigger the need for a permit limit, EPA notes that an implicit and obvious premise in the proposed and final WET procedure is that the WET data used to project maximum effluent quality are valid data that are representative of the effluent. Permittees should ensure they are reporting valid, representative data (see 40 CFR 122.41(j)(1). Where the permittee believes certain effluent measurements to not be representative of the effluent, the permittee should bring this to the permitting authority's attention. EPA's position is that valid, representative effluent data must not be ignored. To clarify this point in the final procedure 6 of appendix F to part 132, EPA has inserted the word "representative" into the first sentence of paragraph D of final procedure 6 of appendix F to part 132. It now reads, "Where representative facility-specific effluent WET data are available, apply the following requirements..."

Another commenter suggested that EPA Guidance should specify that data obtained prior to and affected by significant treatment, pretreatment, or pollution prevention modifications should not be used for making reasonable potential determinations. The commenter makes the point that effluent data used as the basis for characterizing projected effluent quality should be representative of the discharge and that data obtained prior to installation of treatment, pretreatment or pollution prevention modifications should not be used. In response to this comment, EPA agrees that effluent data used as the basis for effluent characterization should be representative of the discharge under current conditions with current treatment and management practices at the plant. The permitting authority should use judgement in determining whether available effluent data is representative of the current operating conditions at the facility. Where such data is found to be no longer representative of the current discharge, the permitting authority may choose to not use such data based on a determination that the data pre-dates current operating conditions and treatment at the facility.

c. Final Guidance: The provisions in this section of procedure 6 of appendix F to part 132 have been modified to account for the change in the acute WET criteria in procedure 6.A of appendix F to part 132, to clarify the use of average WET test results, to modify the provision regarding the use of acute-chronic ratios, and to better define the terms in the reasonable potential equations.

Procedures 6.D.1.a and 6.D.1.b of appendix F to part 132 have been modified to allow the permitting authority either to average WET test results for acute toxicity taken on the same day or use the maximum result for that day. Likewise, chronic WET test results taken in the same month may be averaged or the maximum value obtained can be used in a reasonable potential determination. The option of using the maximum value was added to allow for the possibility that a State or Tribe may choose to use a more stringent data interpretation in its reasonable potential determinations. In addition, a provision has been added to ensure that the maximum daily test result for acute WET and the maximum monthly test result for chronic WET is used in the reasonable potential determinations. This provision is consistent with the intent of the proposed Guidance and existing National policy as discussed in the March 1991, TSD.

Procedure 6.D.1.c of appendix F to part 132, specifying when acute-chronic ratios shall be used in reasonable potential determinations has been modified from the proposal. The provision states that a default acute-chronic ratio of 10 shall be used to estimate the values for the missing endpoint when data exists for either acute WET or chronic WET but not for both endpoints. This provision ensures that reasonable potential determinations will be performed for both acute WET and chronic WET when sufficient facility-specific WET effluent data is available for one of the endpoints. The requirement for use of an effluent-specific acute-chronic ratio was deleted from the final Guidance provision because its use is not essential, but only an option that can be used in augmenting a reasonable potential data set as discussed in the comments section above.

The reasonable potential equations have been reformatted so that the WET criterion is on one side of the equation to facilitate interpretation of the reasonable potential determination. These equations are consistent with the reasonable potential equations used in Chapter 7 of the March 1991 TSD. The objective of the use of these reasonable potential equations is to assess the likelihood that a facility's effluent could discharge a pollutant at a level that would violate a given water quality standard. This assessment is performed by estimating the 95th percentile concentration level, TU's for WET, from effluent sample data and determining if an allowable effluent flow into the receiving water at low flow conditions would violate the water quality standard.

The reasonable potential equations account for the effects of the available dilution, Qad, in the receiving water by taking into account:

(1) Low flow conditions used for TMDLs, wasteload allocations (WLAs) and preliminary WLAs are cross referenced or specified in procedure 6 of appendix F to part 132;

(2) Mixing zones as allowed pursuant to EPA-approved State and Tribal provisions, including provisions for chronic mixing zones consistent with provisions in the procedure 3 of appendix F to part 132;

(3) An adjustment to the low flow of the receiving water if the receiving stream is used by the facility for all or part of its process water, so that the available dilution calculated from the low flow and mixing zone procedures does not include that portion of the flow used by the facility.

The revised equations used in procedures 6.D.2 and 6.D.3 of appendix F to part 132 are presented below.

i. Reasonable Potential Equation for Acute WET

The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric acute WET criterion or numeric interpretation of a narrative criterion within a State or Tribal water quality standards, when effluent-specific information demonstrates that:

$(TU_a \text{ effluent})(B)(\text{effluent flow}/(Qad+\text{effluent flow})) > AC$

where TU_a effluent is the maximum measured acute toxicity of 100 percent effluent determined pursuant to section D.1.a. of procedure 6 of appendix F to part 132, B is the multiplying factor taken from Table F6-1 of this procedure to convert the highest measured effluent toxicity value to the estimated 95th percentile toxicity value for the discharge, effluent flow is the same effluent flow used to calculate the preliminary WLAs for individual pollutants to meet the acute criteria and values for those pollutants, AC is the numeric acute WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.1 of procedure 6 of appendix to part 132 and expressed in TU_a units, and Qad is the amount of the receiving water available for dilution calculated using: (i) the specified design flow, 1Q10, for tributaries and connecting channels, or where appropriate, procedure 3.E.1.d of appendix F to part 132 for use of dynamic modeling, and using EPA-approved State and Tribal procedures for establishing acute mixing zones in tributaries and connecting channels, or (ii) the EPA-approved State and Tribal procedures for establishing acute mixing zones in open waters of the Great Lakes System. Where there are less than ten individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a coefficient of variation (CV) of 0.6. Where there are ten or more individual WET tests, the multiplying factor taken from Table F6-1 shall be based on a CV calculated as the standard deviation of the acute toxicity values found in the WET tests divided by the arithmetic mean of those toxicity values.

ii. Reasonable Potential Equation for Chronic WET

The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric chronic WET criterion or numeric interpretation of a narrative criterion within a State or Tribal water quality standards, when effluent-specific information demonstrates that:

$(TU_c \text{ effluent})(B)(\text{effluent flow}/(Qad+\text{effluent flow})) > CC$

where TU_c effluent is the maximum measured chronic toxicity value of 100 percent effluent determined in accordance with subsection D.1.b. of procedure 6 of appendix F to part 132, B is the multiplying factor taken from Table F6-1 of this procedure, effluent flow is the same effluent flow used to calculate the preliminary WLAs for individual pollutants to meet the chronic criteria and values for those pollutants, CC is the numeric chronic WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.2 of procedure 6 of appendix F and expressed in TU_c units, and Qad is the amount of the receiving water available for dilution calculated using: (i) the design flow(s) for tributaries and connecting channels specified in procedure 3.E.1.a of appendix F, and where appropriate procedure 3.E.1.d. of appendix F, and in accordance with the provisions of procedure 3.E.5 of appendix F for chronic mixing zones, or (ii) procedures 3.D.1 and 3.D.4 of appendix F to part 132 for discharges to the open waters of the Great Lakes System. Where there are less than ten individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV of 0.6. Where there are ten or more individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV calculated as the standard deviation of the WET tests divided by the arithmetic mean of the WET tests.

Tables to Procedures 5 and 6 of Appendix F
Table F6-1
Reasonable Potential Multiplying Factors: 95% Confidence Level and 95% Probability Basis

Number of	Coefficient of Variation																			
Samples	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
1	1.4	1.9	2.6	3.6	4.7	6.2	8.0	10.1	12.6	15.5	18.7	22.3	26.4	30.8	35.6	40.7	46.2	52.1	58.4	64.9
2	1.3	1.6	2.0	2.5	3.1	3.8	4.6	5.4	6.4	7.4	8.5	9.7	10.9	12.2	13.6	15.0	16.4	17.9	19.5	21.1
3	1.2	1.5	1.8	2.1	2.5	3.0	3.5	4.0	4.6	5.2	5.8	6.5	7.2	7.9	8.6	9.3	10.0	10.8	11.5	12.3
4	1.2	1.4	1.7	1.9	2.2	2.6	2.9	3.3	3.7	4.2	4.6	5.0	5.5	6.0	6.4	6.9	7.4	7.8	8.3	8.8
5	1.2	1.4	1.6	1.8	2.1	2.3	2.6	2.9	3.2	3.6	3.9	4.2	4.5	4.9	5.2	5.6	5.9	6.2	6.6	6.9
6	1.1	1.3	1.5	1.7	1.9	2.1	2.4	2.6	2.9	3.1	3.4	3.7	3.9	4.2	4.5	4.7	5.0	5.2	5.5	5.7
7	1.1	1.3	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.1	3.3	3.5	3.7	3.9	4.1	4.3	4.5	4.7	4.9
8	1.1	1.3	1.4	1.6	1.7	1.9	2.1	2.3	2.4	2.6	2.8	3.0	3.2	3.3	3.5	3.7	3.9	4.0	4.2	4.3
9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1	3.2	3.4	3.5	3.6	3.8	3.9
10	1.1	1.2	1.3	1.5	1.6	1.7	1.9	2.0	2.2	2.3	2.4	2.6	2.7	2.8	3.0	3.1	3.2	3.3	3.4	3.6
11	1.1	1.2	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.3	2.4	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.3
12	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	3.0
13	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9
14	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.3	2.4	2.5	2.6	2.6	2.7
15	1.1	1.2	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	1.9	2.0	2.1	2.2	2.2	2.3	2.4	2.4	2.5	2.5
16	1.1	1.1	1.2	1.3	1.4	1.5	1.6	1.6	1.7	1.8	1.9	1.9	2.0	2.1	2.1	2.2	2.3	2.3	2.4	2.4
17	1.1	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3
18	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.1	2.2	2.2
19	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.5	1.6	1.6	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.1	2.1
20	1.1	1.1	1.2	1.2	1.3	1.4	1.4	1.5	1.5	1.6	1.6	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0
30	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5
40	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3
50	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
60	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
70	1.0	1.0	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
80	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8
90	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
100	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7	0.7

G. Loading Limits

1. Proposal

The proposed Guidance provided that water quality-based effluent limits (WQBEL) be expressed in terms of both concentration and mass loading rates, except for those pollutants that cannot appropriately be expressed in terms of mass. These provisions clarify the application of existing Federal regulations at 40 CFR 122.45(f) to the Great Lakes System in order to most effectively implement the objectives of the Clean Water Act. The proposed Guidance accounted for the following three factors in establishing procedure 7.

First, the proposed Guidance provided one exception from the requirement to express WQBELs in both concentration values and mass loading rates. Consistent with the existing Federal regulations at 40 CFR 122.45(f)(1)(i), the proposed Guidance would not have required Great Lakes States and Tribes adopting this procedure to express WQBELs as mass loading rates for pollutants that cannot be appropriately expressed in terms of mass, such as pH, color, temperature, or radiation.

Second, the proposed Guidance did not apply to technology-based limits, and therefore did not propose to affect the application of this provision to limits established using 40 CFR 125.3.

Third, the proposed Guidance emphasized the need to express WQBELs as both concentration values and mass loading rates in order to implement the antidegradation policy for the Great Lakes System. The use of mass limits in the Great Lakes antidegradation analysis is discussed in appendix E of the final Guidance.

The proposed Guidance was consistent with the EPA March 1991, Technical Support Document for Establishing Water Quality-Based Effluent Limits, TSD.

2. Comments

Many of the comments on the Loading Limit procedure addressed the need for loading limits and concerns regarding the applicability of loading limits to POTW discharges under wet weather conditions. A summary of the key points raised by commenters for these two topics is presented below.

a. Need for Loading Limits

Many commenters expressed concern that the inclusion of mass loading limits is not necessary if concentration limits are also required. They did not see any environmental benefit to requiring both types of limits. Other commenters expressed support for the use of loading limits, especially as a means to limit bioaccumulative contaminants and to aid in the implementation of the antidegradation procedures.

EPA has determined that mass-based limits are necessary to prevent the use of dilution as a means of treatment. Where water quality is impaired, mass-based limits are used to implement TMDL mass load reduction targets and other procedures to establish WQBELs to control total loadings to the receiving water body. EPA determined from past experience that mass loading limits are a valuable regulatory tool in many discharge scenarios and therefore continues to support the requirement for including mass loading limits in all NPDES permits. For example, such mass-based limits enable POTWs to more effectively control toxics and bioaccumulative contaminants originating from indirect dischargers by limiting the mass of contaminants that these facilities are allowed to discharge into the sewer system. Such mass-based limits prevent the facilities from using the domestic waste at the POTW to dilute their toxic discharges.

b. Wet Weather Discharges

Many commenters expressed concern that requiring mass loading limits for POTWs with CSOs, especially if those loading limits are based on daily maximum design flows and weekly average flows, would not adequately account for the intermittent wet weather flow conditions. Commenters were concerned that such loading limits would place POTWs with CSOs in non-compliance status several times per year. Also several commenters recognized the need to account for wet weather conditions in compliance determinations while maintaining the use of loading limits to protect the receiving water body. Few commenters supported the use of annual mass limits to account for WET weather flow impacts on POTWs.

EPA does not envision that dischargers will be unnecessarily restricted in allowing elevated flows and loads under wet weather conditions using procedure 7. Existing Federal, State and Tribal regulations and policies allow flexibility in addressing wet weather conditions and intermittent increases in flows due to wet weather events. It is not the intent, or design, of the final Guidance to limit existing regulatory flexibility regarding wet weather flows. Rather, it is in EPA's interest to promote consistent policy objectives among programs impacting NPDES permit requirements. The EPA CSO Strategy encourages POTWs to treat as much wet weather flow as possible, recognizing that treatment efficiencies will likely decrease due to higher flows during wet weather events, EPA supports the continued use of State and Tribal discretion in determining special NPDES permit conditions and other appropriate mechanisms to address wet weather flows. Therefore, EPA sees no need to establish any additional provisions, such as annual mass-based WQBELs, regarding wet weather discharges in the final Guidance.

3. Final Guidance

After fully considering the comments and evaluating the use of mass-based WQBELs to date, EPA has retained, virtually unchanged, the provision for including mass-based WQBELs as outlined in procedure 7 of appendix F, of the proposal. In the final Guidance procedure 7 of appendix F, EPA establishes requirements to calculate mass-based WQBELs to restrict the loadings of pollutants to the Great Lakes System. As discussed above, procedure 7 specifies that when a WQBEL is developed using procedures for Total Maximum Daily Loads, 3, and Reasonable Potential, 5, of appendix F , or other State and Tribal procedures, the limitation must be expressed in terms of both concentration and mass loading rate, except for the specific exclusions identified in §132.

Procedure 7.A specifies that the concentration and mass WQBELs must be consistent in terms of daily, weekly, and monthly averages, or in other appropriate averaging periods. For example, where a concentration-based WQBEL is expressed in terms of maximum daily and average monthly limitations, the corresponding mass loading rate limitations must likewise be expressed as maximum daily and average monthly limitations. Existing Federal regulations at 40 CFR 122.45(d). require that limitations for continuous discharges be expressed, unless impracticable, as average weekly and average monthly limitations for POTWs and maximum daily and average monthly limitations for all other continuous discharges. The final Guidance does not change these existing requirements, but instead ensures consistency between mass-based and concentration-based WQBELs in individual NPDES permits.

Procedure 7.B of appendix F directs the permit writer to use effluent flow rates when developing the mass loading rate WQBELs that are consistent with those used in procedures 3 and 5 of appendix F, or other State and Tribal procedures, to develop the concentration-based WQBELs. The existing Federal regulations at 40 CFR 122.44(d)(1)(vii)(B) and 123.25(a)(15) require that water quality-based effluent limits in State, Tribal and Federal NPDES permits be ". . . consistent with the assumptions and requirements of any available wasteload allocation for the discharge. . ." By specifying this requirement in the final Guidance, EPA believes that it clarifies any confusion that might arise regarding the proper effluent flow rate to use in developing mass loading rate permit limitations. In addition, this approach ensures greater consistency in WQBELs among the Great Lakes States and Tribes.

EPA recognizes that POTWs with CSOs are subject to intermittent increases in effluent flow above the dry weather flows used to develop the WQBELs. EPA defers to the States and Tribes to use existing permit procedures to address these intermittent flow increases in evaluating compliance with the concentration-based and mass-based limits.

H. WQBELs Below the Level of Quantification

Several pollutants of initial focus in Table 6 and many of the BCCs are known to cause unacceptable toxic effects at water column concentrations lower than what the most sensitive analytical techniques can currently quantify. Accordingly, for these pollutants, water quality criteria necessary to protect the designated uses have been established at levels below quantification. Therefore, WQBELs calculated for these pollutants can also be below current minimum quantification levels. The final Guidance contains procedure 8 of appendix F, which establishes procedures for expressing WQBELs in these circumstances, assessing compliance with such limits, and requiring pollutant minimization programs. Procedure 8 is intended, in part, to increase consistency among the Great Lakes States and Tribes in addressing these types of permit limits. As required by the Critical Programs Act, the provisions of procedure 8 reflect existing national policy and guidance.

1. Expressing a WQBEL Below the Minimum Quantification Level

a. Proposal: The Great Lakes Guidance proposal provided that all WQBELs included in an NPDES permit be expressed exactly as calculated and that a compliance evaluation level (CEL) be specified in the permit, which signified the level of the pollutant in the effluent that was not to be exceeded. The proposal further provided that the CEL was the level at which compliance with the effluent limit would be assessed. The preamble to the proposal also recognized the difficulty of making a definitive statement as to whether or not the concentration of a pollutant is above or below the WQBEL, and therefore, characterized the pollutant minimization plan as one means of increasing the likelihood that the concentration of the pollutant is as close to the WQBEL as possible.

b. Comments: Several commenters opposed EPA's proposal to require WQBELs to be expressed in NPDES permits exactly as calculated and the implication that the permittee comply with such limits even if they are below quantification levels. Some commenters asserted that the provision in the proposed guidance would require substances to be removed below the levels that exist in nature. Others contended that EPA lacks the legal authority under the Clean Water Act (CWA) to regulate substances that are discharged below levels that can be accurately quantified and asserted that issuance of permit limits in such circumstances violates due process. They asserted that an effluent limitation below the level of quantification is constitutionally defective insofar as it subjects the permittee to criminal sanctions while failing, in the commenters' view, to specify clear and ascertainable standards of conduct. These commenters contended that permittees subject to such limits will have no idea whether they are complying with their limits and thus will be unable to take action to avoid noncompliance. They further asserted that they have no way to determine exactly what conduct is prohibited and hence concluded that such limitations are void for vagueness.

Other commenters supported using the WQBELs as calculated as the permit limit irrespective of the minimum quantification level and emphasized the need to hold facilities accountable for meeting those limits. Some commenters felt that those limits are especially important in controlling the discharge of BCCs.

c. Final Guidance: EPA has retained the requirement that the WQBELs be included as calculated as the permit limit in NPDES permits, even if the WQBEL is below the minimum quantification level. However, EPA wants to clarify here that it is the Agency's policy that any effluent sample analyzed in accordance with the analytical method specified in the permit and other applicable procedures that is found to be below the quantification level shall be deemed in compliance with the WQBEL.

EPA's national guidance in the 1991 Technical Support Document for Water Quality-based Toxics Control (TSD) recommends expressing WQBELs in permits exactly as calculated, even if they are below the minimum quantification level, in order to comply with the CWA and implementing regulations at 40 CFR 122.44(d)(1)(vii), which require that NPDES permits ensure water quality standards be met. Specific examples, such as the development of dioxin WQBELs for paper mills, were discussed in the preamble to the proposed Guidance.

EPA believes that such WQBELs are required by the CWA. Under the CWA, States and Tribes are required to adopt water quality standards to protect the public health and welfare, enhance the quality of water and serve the purposes of the Act. See CWA section 303(c)(2)(A). Such standards shall consider, among other things, the waters' use and value for the propagation of fish and wildlife. As part of their standards, States and Tribes are required to adopt water quality criteria for particular pollutants that reflect concentration levels deemed protective of the waters' designated uses. In addition, the CWA further requires that, once these standards are adopted by a State or Tribe, point source dischargers must achieve effluent limitations as necessary to implement such standards, including any numeric water quality criteria therein. See CWA section 301(b)(1)(C). These principles are reiterated in section 118 of the CWA, under which authority this Guidance is issued. In that section, Congress directed EPA in its Guidance to specify numerical limits to protect human health, aquatic life, and wildlife and to provide guidance to the Great Lakes States on water quality standards and other aspects of their water quality programs. None of these sections provides an exception for pollutants that are known to be present in the effluent or wastewater but not in reliably quantifiable amounts.

EPA disagrees with the comments that EPA is regulating pollutants that are not present in the effluent. It is important to keep in mind that a WQBEL is derived only when the permitting authority has determined there is reasonable potential for a discharge to cause or contribute to an exceedance of a water quality standard for that pollutant. The procedures for determining reasonable potential are presented in procedure 5 of appendix F of this final Guidance. Even though a pollutant may not be present at quantifiable concentrations in the effluent, the permitting authority may have information, such as fish tissue data, samples with detectable concentrations or process information, that documents the presence of the pollutant in sufficient quantity to warrant a finding that the pollutant has the reasonable potential to cause or contribute to an exceedance of the applicable water quality standard. If a reasonable potential determination is made, a WQBEL must be calculated in order to assure the water quality standard will be attained and maintained. The CWA provides no exception to this principal when the pollutant of concern is present at concentrations below quantifiable levels.

EPA acknowledges that, in some cases, the water quality criterion calculated to protect a particular designated use may require establishment of a WQBEL that authorizes discharges at levels lower than those that exist in nature. In these cases, the State or Tribe could adopt a site-specific modification of the criteria consistent procedure 1 of appendix F; or alternatively, the State or Tribe could grant a variance to the standard under procedures 2 of appendix F, which allows for consideration of naturally occurring pollutant concentrations which prevent the attainment of standards.

For the reasons set forth above, EPA has concluded that it has the legal authority and obligation under the CWA to require the establishment of WQBELs below the level of quantification. EPA disagrees with those commenters that argued that imposing permit limits in such circumstances violates due process. Contrary to the commenters' assertions, the WQBEL expressed in the permit establishes a clear and certain numeric standard of conduct. In addition, a discharger will be deemed to be in compliance with the permit, as discussed below, if samples analyzed in accordance with the analytical method specified in the permit, and other applicable procedures, are found to be below the quantification level. Furthermore, it is EPA's current policy that analytical methods other than those specified in the permit cannot be used to establish a violation of the WQBEL. Instead, it is EPA's position that special conditions in the permit such as fish tissue sampling, WET tests, limits and/or monitoring requirements on internal waste streams, and monitoring for surrogate parameter can be used to reopen the permit to establish more stringent effluent limits.

EPA acknowledges commenters' concerns that it may be difficult to demonstrate that it is achieving these limits. However, EPA disagrees that this prevents permittees from assessing their compliance status or from selecting control strategies to avoid non-compliance. As discussed above, it is EPA's current policy that a permittee shall determine whether it will be deemed in compliance with the permit by monitoring its effluent using authorized methods, the same methods that would be used by an enforcement authority in an enforcement action.

2. Compliance Issues

a. Proposal: Under the proposed Guidance, the permitting authority would specify in the permit an analytical method, a monitoring frequency, and a corresponding compliance evaluation level (CEL) for each pollutant with a WQBEL below the minimum quantification level. A CEL was defined as the concentration at which compliance with the WQBEL is assessed. The preamble discussion provided guidance that the permitting authority should specify the most sensitive analytical method and define the CEL as the Minimum Level (ML) specified in or approved under 40 CFR 136, if available. The guidance also proposed that, when MLs are not available, the permitting authority must still specify a CEL in the permit. Section 132.2 of the proposal defines the ML as the lowest level at which the analytical system gives recognizable spectra and acceptable calibration points. This is the lowest level at which the concentration of the pollutant can be reliably measured. The proposed guidance also allowed adjustments for matrix interference in establishing the ML. In addition, the preamble to the proposal discussed several approaches for selecting an analytical method and CEL for chemicals not addressed by 40 CFR 136, but the proposed guidance itself was silent on this matter.

b. Comments: EPA received a variety of comments pertaining to this portion of procedure 8. Many commenters expressed confusion regarding the relationship between the WQBEL, CEL and ML. This was due in part to the several options presented in the preamble for establishing the CEL, including the use of the WQBEL as the CEL.

Many commenters advocated the use of the practical minimum quantification level (PQL) as the CEL. The PQL is typically defined as a concentration 5 to 10 times the method detection level (MDL). The MDL is defined according to a procedure specified in 40 CFR 136 appendix B. Measurements at or above the MDL value are highly unlikely to be associated with a true concentration of zero. Their contention was that the PQL could be derived in a straightforward manner and would be less onerous to use in comparison to the ML, especially for facilities that experience matrix interference in analytical testing procedures. Many commenters agreed with the provision to allow for matrix interference when setting minimum quantification levels in a permit.

In addition, for the majority of chemicals that do not have MLs in 40 CFR 136, several commenters advocated using the PQL in lieu of determining the ML for these chemicals. Other commenters supported the use of the MDL as a CEL in cases where the WQBEL is much lower than the ML, since any detection of the chemical could, in their opinion, indicate an exceedance of the WQBEL.

Commenters also expressed concern that the level at which compliance would be measured would change as analytical methods improve, thus exposing them to enforcement actions and to successively more stringent permit limits for which immediate compliance would be required. Some commenters contended that this potential for change in analytical methods would prevent them from determining whether they were in compliance with their limits or from selecting controls necessary to achieve compliance. Others contended that, by specifying procedures for determining compliance when WQBELs are below the level of quantification, the Guidance will eliminate the discretion traditionally vested in the States for determining such compliance. Other commenters argued that laboratory detection capabilities vary greatly throughout the Great Lakes region, which would lead to widely disparate treatment requirements and enforcement activities. Some commenters expressed concern that the long lag time between sampling and analysis could mean that the permittee could unknowingly be out of compliance for a lengthy period. A few commenters stated that laboratory analyses should be done under the Superfund Contract Laboratory Program protocol to ensure uniformity. These commenters also expressed concern that there will be a greater likelihood of false readings from using equipment at the frontiers of detection capability.

A number of commenters expressed a related concern that, if a permit does not specifically provide that compliance with the minimum quantification level constitutes compliance with the permit, permittees will be vulnerable to law suits for violations of effluent limitations in situations where a more sensitive analytical technique is developed that shows that pollutants are being discharged above the WQBEL but below the permit-specified minimum quantification level. These commenters also suggest that permittees may be subject to frivolous law suits based upon wholly unreliable data.

c. Final Guidance: In developing the final Great Lakes Guidance, EPA acknowledges the need to develop regulatory procedures that provide the public with a clear and unambiguous means of evaluating compliance with WQBELs below the minimum quantification level. EPA modified the Guidance based upon the comments received and has revised the compliance requirements associated with this procedure. The principal change eliminates the use of the CEL term. This clarifies that the WQBEL as actually calculated is the enforceable permit limit even if it is below the minimum quantification level. Under procedure 8.B.1, once adopted by a State or Tribe or promulgated by EPA, the regulatory authority must specify in the NPDES permit for each WQBEL that is calculated to be less than the quantification level, the applicable method to be used for monitoring the presence and amount of the pollutant in an effluent. The permit shall also specify the quantification level pursuant to procedure 8.B.2.

Like the proposal, the final Guidance provides that the analytical method and minimum quantification level is to be specified in the permit. In EPA's view, requiring States and Tribes to specify approved analytical methods or if none are available, the most sensitive analytical method practicable, and a corresponding analytically determined minimum quantification level for reporting monitoring information, will ensure a sufficient level of consistency between States and Tribes in evaluating compliance with WQBELs below the minimum quantification level.

A new provision has been added as procedure 8.B.2 in the final Guidance, which specifies that, for analytical methods under 40 CFR 136, for those approved under the Alternate Test Procedures at 40 CFR 136.3(d), or other methods specified in the permit that do not have an ML specified under 40 CFR 136 or 136.3(d), the permitting authority is required to specify a minimum quantification level in the permit that is as close to the WQBEL as practicable. The preamble to the proposed guidance discussed several options for addressing the above condition, but the proposed Guidance was silent as to how to establish the appropriate minimum quantification level in NPDES permits in such cases. Procedure 8.B.2 is included in the final Guidance to increase consistency in application of procedure 8 among States and Tribes for cases where the ML has not been specified in 40 CFR 136 or pursuant to 136.3(d). This provision addresses the concerns of several commenters that felt that too much flexibility was being granted to the permitting authorities in selecting the minimum quantification level in these cases.

The discharger has the opportunity to document a higher minimum quantification level if repeated attempts to overcome matrix interferences are unsuccessful. EPA has provided Guidance Associated with Compliance Monitoring (EPA 821-B-93-001; the "Monitoring Guidance"), for dischargers attempting to overcome matrix interference problems. Recent evaluations of effluent data from well-designed, well-operated waste treatment facilities indicate that in all instances in which a good-faith attempt was made to overcome matrix interferences using the strategies set forth in the Monitoring Guidance, or similar strategies, matrix interferences have not been an impediment to achieving the minimum quantification level in EPA's analytical methods.

Procedure 8.B.2 allows flexibility in developing a minimum quantification level in these instances and should not place an undue burden on the States, Tribes, or permittees. EPA's MLs do not get promulgated in 40 CFR 136 until after public notice and comment. Consequently, these MLs are the most appropriate minimum quantification levels to use, if available, for NPDES monitoring data requirements because they represent the most stringent, scientifically reliable minimum quantification level available. EPA has used the ML in Clean Water Act programs since the mid 1980's. EPA rejected the use of the MDL and other non-quantifiable concentration levels because these concentrations, by definition, do not represent concentrations that are both reproducible and quantifiable indicators of the actual concentration of a given sample, and hence are not reliable measures for permit compliance purposes.

However in the absence of an ML specified in, or approved under, 40 CFR 136, the permitting authority is required to specify a minimum level of quantification at the lowest practicable quantifiable level above the level of detection. As with any permit condition, such level is subject to public notice and comment and may be contested on appeal, thereby insuring its validity. EPA has no national guidance or policy on how to develop the lowest quantifiable level that can be used as a tool to assess compliance with WQBELs. Currently States and Tribes develop their own lowest practicable quantifiable level above the level of detection and they range from the use of practicable quantitation levels (PQLs), minimum quantitation levels (MQLs), quantitation levels (QLs), reliable quantitation levels (RQLs), plus many more.

EPA's Engineering and Analysis Division (EAD) has developed a procedure for calculating the Minimum Level (ML) of quantification for those pollutants that do not have MLs specified in or approved under in 40 CFR 136. The MLs are the lowest levels used in establishing the calibration required by the analytical methods in the NPDES program. The procedure, based on the "ML concept," calculates the minimum quantification level by multiplying the MDL by a factor of 3.18. This factor produces an ML approximately equal to values obtained by methods for developing the Limit of Quantitation endorsed by the American Chemical Society. The MDL has been established for more than 130 analytical methods and several hundred chemicals. Another approach for developing a quantification level in the absence of an ML specified in, or approved under 40 CFR 136, would be to determine an MDL as specified in 40 CFR 136, appendix B, and multiply the result by 3.18.

These approaches are designed to produce values which approximate specified or approved MLs, thereby providing consistency with the monitoring requirements imposed for those chemicals with specified or approved MLs. The above examples for calculating a required minimum level of quantification, are some of many approaches currently being used and are intended as guidance, not requirements. The permitting authorities have the flexibility under this provision to develop other credible procedures for calculating a minimum quantification level for use in a NPDES permit in the absence of an EPA promulgated ML. The only requirement is that the permitting authorities must demonstrate that any minimum quantification level specified is as close to the WQBEL as practicable.

Some commenters urged that the PQL be used to establish the quantification level. The PQL, which has been used by EPA's drinking water and solid waste programs, is defined as the level at which reliable measurements can be made under routine operating conditions (50 FR 46908; 52 FR 25699). The PQL is typically established by multiplying the MDL by a factor ranging from 5 to 10. One criticism of the PQL procedure is the ambiguous nature of the multiplier and the resulting levels being perceived as too high for regulatory or compliance purposes for wastewaters. EPA does not endorse the use of the PQL for the NPDES program. EPA acknowledges that the PQL has been used by EPA's drinking water and solid waste programs; however, during the past few years, EPA's drinking water program has been investigating alternatives to the PQL. Since the EPA is actively reevaluating its use of the traditional PQL values, EPA does not endorse them for evaluating compliance with WQBELs below the minimum quantification level.

Commenters also expressed concern that the level at which compliance would be measured would change as analytical methods improve, thus exposing them to enforcement actions and to successively more stringent permit limits for which immediate compliance would be required. It is EPA's intent, however, to promote the development of more sensitive analytical techniques, to adopt these techniques into 40 CFR 136, and to require the States and Tribes to specify the most sensitive tests, specified in or approved under 40 CFR 136, in the NPDES permit. In addition, the Guidance has been modified to require that a permit subject to procedure 8 shall contain a reopener clause authorizing modification or revocation and reissuance of the permit if new information generated as a result of special conditions included in the permit indicates the presence of the pollutant in the discharge at levels above the WQBEL. If a new analytical procedure is authorized by 40 CFR 136, either directly or through the alternate testing procedure at 40 CFR 136.3(d), States and Tribes have the discretion of reopening the permit to include a new analytical method or to wait until the permit is reissued to include a new, more sensitive analytical method. However, because there are several factors to consider, such as the degree of improvement in the minimum quantification level, time remaining on the existing permit, current compliance status, and administrative costs of modifying a permit, EPA has determined that it would be inappropriate to dictate the timing and implementation of more sensitive analytical techniques. Therefore, neither this Guidance nor EPAs' existing regulations require permits to be reopened under such circumstances.

EPA also acknowledges commenters' concerns that, because analytical methods can change, a discharger deemed to be in compliance with its WQBEL today (as indicated by current analytical methods) has no assurance that it will be complying with its limit in the future. However, EPA disagrees that this raises a due process question. It is EPA's current policy that new analytical methods will not be a basis for determining compliance with the WQBEL unless they are specifically included in the permit. Permits can be reopened to include more stringent limits or conditions, for example when data generated from the special conditions of the permit support it. Permittees will have the opportunity to comment on the new requirements before they become effective in their permits. While EPA expects the sensitivity of several analytical methods to improve, the Agency would expect that permitting authorities, when requiring the use of new methods in NPDES permits, would consider establishing compliance schedules, if authorized by law, to allow the facility time to achieve full compliance. While the approach described above is consistent with existing EPA guidance, EPA is currently reevaluating its National policy regarding the implementation of WQBELs that are below the level of quantification; any changes to the National policy would apply to the Great Lakes States and Tribes.

EPA also notes that the commenters' concerns about a lack of certainty regarding future compliance status or changing permit terms are not unique to this procedure. For example, all permittees, even those not affected by this procedure, may be subject to increasingly stringent WQBELs in successive permits as circumstances change (e.g., lower water quality or improved analytical methods), because CWA section 301(b)(1)(C) requires in each permit the establishment of effluent limits as necessary to achieve water quality standards. In such cases, a permittee must comply immediately with more stringent limits unless a State's or Tribe's water quality standards or implementing regulations authorize a compliance schedule. Opportunities for notice and comment as well as administrative and judicial review however, avoid due process concerns.

EPA notes that procedure 8 is consistent with EPA's guidance in the 1991 TSD. In section 5.7.3 of the TSD, EPA recommends that special conditions be included in certain permits, such as those subject to procedure 8 here, to help ensure that the limits are being met and that excursions above water quality standards are not occurring. EPA has incorporated several of these conditions into the pollutant minimization program. Information derived from these conditions, including fish tissue data and analyses and in-plant monitoring data, can be used to help support reopening the permit to establish more stringent limits and controls, if necessary to ensure that the WQBEL is attained. Procedure 8 of appendix F simply codifies existing EPA guidance.

EPA also acknowledges commenters' concerns regarding the lack of uniformity among laboratories performing analyses under the analytical methods and related issues. The ML procedure used under 40 CFR 136 relies on the use of a well-defined MDL. Before a particular laboratory can be employed by a permittee to analyze its effluent for compliance with the WQBEL, an individual laboratory would need to demonstrate that its procedures can reliably quantify the MDL, which has been established for more than 130 analytical methods and several hundred chemicals. In this way, EPA hopes to minimize any disparity among laboratory performance and hence to minimize any differences across the Great Lakes basin in treatment requirements and enforcement activities. An ML, defined as the lowest calibration point, can then be determined at an approved laboratory for use in evaluating compliance data. Since all laboratories seeking to use the same analytical procedures would need to demonstrate that they can reliably achieve the published MDL and use approved calibration techniques, the MDL establishes a uniform standard that must be met.

Moreover, the enforcement authority has the burden of proving non-compliance, which can be difficult if all of the samples analyzed in accordance with the specified analytical methods are below quantification and hence do not support allegations that a violation has occurred. In addition, even though the WQBEL is below the level of quantification, a permittee seeking greater certainty regarding its compliance status may be able, in some instances, to monitor its wastestreams within the plant, prior to dilution, at points where the presence of the pollutant may be detected directly. Thus, a permittee possesses the tools necessary to avoid noncompliance, and can develop and implement appropriate pollution control or prevention strategies as necessary to keep the presence of the pollutant below the ML. See below for a discussion of in-plant monitoring in connection with the pollution minimization program. Furthermore, in no case can civil or criminal penalties be imposed against a permittee without a hearing to ensure that the permittee is accorded due process. For these reasons, EPA concludes that requiring a permitting authority to impose in the permit the WQBEL as calculated does not violate due process.

3. <u>Compliance with the CEL</u>

a. <u>Proposal:</u> The proposed Guidance included a provision that a CEL be established for each daily, weekly, and monthly NPDES permit limit. The proposed Guidance did not specify how to define the CEL for the above permit limits. The proposed procedure 8.C of appendix F, deferred to existing State and Tribal procedures for determining how to average compliance data that includes non-quantifiable data.

b. Comments: Many commenters expressed confusion concerning the relationship between the WQBEL, ML and CEL, as previously discussed in Compliance Issues section of this document. Many commenters supported the provision to defer to existing permitting authority procedures for averaging compliance data. A few commenters supported a consistent approach for assessing non-quantifiable data by using surrogate values. These values ranged from zero to the ML value.

c. Final Guidance: EPA modified the provisions in procedure 8.B.4 to clearly state that permitting authorities can use their existing compliance data averaging procedures, in evaluating compliance with WQBELs below the minimum quantification level. Thus the permitting authority may specify that effluent samples that are below the minimum quantification level should be deemed equal to zero, equal to one-half the minimum quantification level, etc. However, regardless of the averaging procedures used, the resulting value must be compared to the WQBEL in assessing compliance.

EPA addressed the confusion regarding the relationship between the WQBEL, ML, and CEL by eliminating the CEL term and establishing the WQBEL exactly as calculated as the appropriate compliance level. The ML and other established minimum quantification levels are specified in the NPDES permit to clearly establish the compliance monitoring requirements. EPA agrees with the commenters that supported deferring to permitting authorities' existing compliance data averaging procedures. EPA believes that existing State and Tribal procedures, in conjunction with the other permit requirements for addressing WQBELs below the minimum quantification level, will result in adequate consistency among States and Tribes.

4. Pollution Minimization Program

a. Proposal: In order to increase the likelihood that the concentration of the pollutant in the effluent is as close to meeting the WQBEL as possible, EPA included procedure 8.D in the proposed Guidance, which provided that a pollutant minimization program (PMP) be specified and implemented as a permit condition for each pollutant with a WQBEL below the minimum quantification level. This proposal reflected EPA's recognition that effluent monitoring data alone is not sufficient to ensure that the WQBELs below a minimum quantification level are being attained. Under the proposed PMP provision, a permittee was to develop a PMP to reduce all potential sources of the pollutant in all internal, or indirect, wastewater streams contributing to the permittee's wastewater collection system with the goal of maintaining the effluent at or below the WQBEL.

Under the proposal, the PMP included, but was not limited to, the following components: annual review and semi-annual monitoring of sources of the pollutant; quarterly monitoring of the pollutant in the influent to the treatment system; submittal of a control strategy for reducing loadings of the pollutants of concern to the treatment system; implementation of appropriate control measures which are consistent with the control strategy, as the sources of the pollutants are discovered; and submittal of an annual status report of activities.

EPA expected the PMP to reflect that there are practical constraints on treatment capabilities. EPA did not view the PMP as a zero discharge requirement. Instead, EPA viewed it as a means to ensure that WQBELs were achieved. The effects of a PMP may be to reduce all pollutant(s) of concern in the internal streams to non-detectable levels, but this is not equivalent to a zero discharge requirement. A PMP-type requirement is consistent with the guidance found in section 5.7.3 of the March 1991, TSD and in the May 21, 1990 "Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the United States." The proposal preamble indicated that a permittee may be allowed to consider cost-effectiveness in developing a pollutant minimization program. In considering alternative elements of a PMP, the permittee was also allowed to consider the cost-effectiveness of each element.

b. Comments: EPA received many comments in opposition to or in support of the PMP provision in procedure 8. Several commenters opposed the PMP requirement on legal grounds. One commenter questioned the need to eliminate a pollutant merely because the WQBEL for that pollutant is below detection. Some characterized the PMP as an attempt to regulate pollutants that are not being discharged by the permittee and asserted that EPA lacks the legal authority under the CWA to regulate pollutants under such circumstances. Others asserted that the PMP represents an unlawful attempt by EPA to dictate pollutant reduction strategies to the permittee. They contend that the PMP essentially specifies discharge levels for internal waste streams that exactly equal the permit limits imposed on the effluent. They assert that as long as the aggregated effluent discharged to the receiving water meets the WQBEL, there is no justification for imposing a PMP on internal wastestreams. These commenters asserted that EPA's proposal to require PMPs conflicted with EPA's decision in the OCPSF rule to reject in-plant limitations in favor of traditional end-of-pipe limitations.

Some commenters also asserted that the PMP contravenes EPA's guidance, particularly its May 1990 guidance pertaining to the pulp and paper industry, by ignoring the role of wastewater treatment systems in reducing pollutant discharge levels, especially when treatment is more efficient and cost-effective. Some commenters criticize as arbitrary the assumption that wastewater treatment facilities are only capable of treating to a level between the WQBEL and the ML. Other commenters objected that permittees would be unable to determine what to include in their control strategies to ensure compliance because the guidance fails to prescribe criteria for assessing minimum technology requirements. Several commenters stated that the guidance does not address how a municipality would implement a pollutant minimization program, especially with respect to households. Other commenters stated in that context, that minimization programs would be equivalent to product bans and zero discharge from indirect sources. Other commenters stated that PMPs should be required only when statistically quantifiable concentrations of the pollutant are present in the discharge, based on a significant number of analyses demonstrating concentrations above the PQL.

c. Final Guidance: Procedure 8.D of the final Guidance includes the PMP components, largely as proposed, with certain additions. In response to comments and to prevent undue burden on permitees, the final Guidance authorizes States and Tribes to consider cost-effectiveness when establishing the requirements of a PMP. The final Guidance also specifies that cost-effective control measures consistent with the PMP's control strategy shall be implemented when sources of the pollutant of concern are discovered. The final Guidance also clarifies that fish tissue and other bio-uptake studies can be used to monitor potential sources of the pollutant of concern. Finally, it provides that any information generated as a result of this provision can be used to support a request for subsequent permit modifications, including revisions to or removal of the requirements of procedure 8.D of appendix F (once adopted by a State or Tribe), consistent with 40 CFR 122.44 and 122.62.

In EPA's view, the PMP provisions will not result in any undue burden on permittees since the States and Tribes will be allowed to consider a permittee's costs and benefits analysis of any requirement that they impose through the PMP. Cost-effectiveness may also be considered. EPA recognizes that each industry type, size of facility, and type of industrial user for a POTW will have unique considerations as to what is considered practicable. In addition, EPA recognizes that the household contribution of pollutants with WQBELs below the quantification level would best be controlled by public education, product bans, and establishing hazardous waste depositories. EPA's experience is that permittees, using these guidelines, can develop effective PMPs that include clear measures for compliance with the PMP requirements. It is not EPA's intent to require an open-ended PMP that cannot be objectively evaluated; rather EPA is promoting State and facility flexibility in addressing facility-specific and pollutant-specific issues.

The final Guidance also includes a provision in the TMDL section to use the PMP in evaluating an application for an exception to the mixing zone ban for certain BCC discharges pursuant to procedure 3.C.6 of appendix F, once the ban on mixing zones for BCCs is implemented. The purpose of this language is to clarify that the need for a mixing zone should be evaluated, in part, based on the extent to which a PMP can achieve a WQBEL calculated without a mixing zone.

In addition, all PMPs are subject to revision as analytical methods improve, new technologies become available, economic conditions change, and other factors are modified that affect the PMP. EPA envisions that the implementation of PMPs will be iterative where the annual results of the PMP are used to modify subsequent updates of the PMP as appropriate, including requiring more or less frequent monitoring or the removal of some or all of the PMP requirements.

EPA disagrees with the comments asserting that EPA, through the pollutant minimization program, is unlawfully attempting to regulate pollutants that are not present in a discharger's effluent. The pollutant minimization provision of procedure 8 clearly applies only when a WQBEL for that discharger is calculated below the level of detection. Because no WQBEL can be imposed with respect to a pollutant unless the permitting authority determines that it has the reasonable potential to cause or contribute to an exceedance of water quality standards (see procedure 5 of appendix F), application of the PMP provision necessarily assumes that the pollutant is present in the effluent, albeit in non-quantifiable amounts. If the permitting authority can demonstrate reasonable potential without the use of data indicating detectable levels of the pollutant in the effluent as some commenters wanted as a prerequisite for implementing a PMP, such as by the use of bio-uptake studies or documentation that the pollutant is present in the wastestream at a concentration above the WQBEL, a PMP would be required. If a discharger can demonstrate that the pollutant does not have the reasonable potential to cause or contribute to an exceedance of water quality standards, especially if the facility meets the provisions to obtain an intake credit to address discharges at or below the intake water concentration as discussed in procedure 5 (simple pass through), then no WQBEL and, therefore, no PMP would be necessary. Such demonstrations could include treatability studies to document that the treatment process can remove the pollutant of concern to the WQBEL concentrations.

Contrary to some commenters' assertions, the goal of the pollutant minimization program is not to eliminate the pollutant from a discharger's effluent merely because it is present in nondetectable amounts. (EPA notes, however, that section 101 of the Clean Water Act establishes as a goal of the Act the elimination of the discharge of pollutants into the Nation's waters.) Rather, the purpose of the program is to ensure that a discharger's WQBELs are achieved at the end of the pipe, a purpose that is compatible, as noted by some commenters in apparent opposition to the pollutant minimization provision, within EPA's overall authority to ensure that the ultimate levels discharged after treatment are acceptable. The applicable water quality criteria dictate to the permitting authority what level of pollution is acceptable in a discharger's effluent because of its effect on the surface water.

In order to ensure that acceptable level is reached, EPA is authorized to require dischargers to monitor for the presence of the pollutant in-plant if monitoring after treatment is not a practical or feasible way to evaluate whether acceptable levels of the pollutant in fact are present in the effluent. See 40 CFR 122.45(h). Quarterly monitoring for the pollutant in the influent to the wastewater treatment system pursuant to the pollutant minimization program, ideally prior to commingling with and dilution by wastestreams not bearing that pollutant, provides information for both the permittee and the permitting authority regarding the potential detectable quantity of the pollutant in the wastestream. Among other things, this information, in conjunction with bio-uptake studies of the effluent, allows the permittee to evaluate the effectiveness of its treatment system (which is infeasible to evaluate when the pollutant is undetectable in the wastewater reaching the treatment system) and allows the permitting authority to estimate the quantity of the pollutant that may be present in the effluent discharged to the receiving water in order to determine whether it exceeds levels necessary to protect the receiving waters designated and existing uses.

Moreover, procedure 8 sets forth as a goal, not a requirement, of the PMP that permittees reduce all potential sources of the pollutant as necessary to achieve the WQBEL. If the discharger can demonstrate, by means of an analytical method specified in or approved under 40 CFR 136, that the effluent is at or below the WQBEL, then procedure 8 does not apply and no PMP is necessary. However, if the discharger cannot feasibly or practically demonstrate compliance at the end of the pipe, then in-plant compliance monitoring is necessary and authorized by EPA's regulations and the CWA.

The goal that a permittee's wastestreams meet the WQBEL prior to treatment at the wastewater collection system is simply intended as a goal to mitigate the effects of dilution, not as an explicit compliance requirement. As noted above, however, if in-plant monitoring indicates, in conjunction with flow and treatment data, that the pollutant is being discharged at levels above the WQBEL but below the quantification level, then that data may be evidence of noncompliance with the WQBEL. The internal monitoring provision also is intended to increase the likelihood of demonstrating that the concentration of the pollutant in the effluent is at or below the WQBEL.

Monitoring influent prior to treatment, as provided in the PMP, is consistent with the longstanding principle that dilution as an alternative to treatment is impermissible. EPA expects that, in order to monitor for the presence of a pollutant instream, a permittee will select a monitoring point prior to dilution of that wastestream by other wastestreams. This will not only help the permittee to identify and control the amount of that pollutant in the effluent, but it will also help the permittee ascertain the effectiveness of the treatment technology and to promote the development of even more sophisticated technologies that may remove greater quantities of the pollutant. Several courts have upheld EPA's authority to set effluent limitations for a plant's wastewater stream before it is diluted internally by other wastestreams, such as cooling waters. See Texas Municipal Power Agency v. EPA, 836 F.2d 1482 (5th Cir. 1988); Hercules, Inc. v. EPA, 598 F.2d 91 (D.C. Cir. 1978).

In procedure 8, EPA does not go so far as to set in-plant effluent limitations, but rather simply provides for internal monitoring and adoption of control strategies with a goal of maintaining all sources of the pollutant to the wastewater collection system below the WQBEL. The WQBEL itself continues to apply only at the end of the pipe, after treatment.

Some commenters asserted that procedure 8's PMP provision conflicted with EPA's decision in a 1987 effluent guideline regulation to reject in-plant limitations in favor of traditional end-of-pipe limitations. In that regulation, which established effluent limitations and standards for the organic chemicals, plastics and synthetic fibers (OCPSF) category of point sources, EPA based it limits and standards on an in-plant treatment technology but imposed monitoring requirements at the end of the pipe. 52 FR 42522 (Nov. 5, 1987). EPA acknowledged in that regulation, as it does here today, that the Clean Water Act provides no explicit authority for specifying technology. See 52 FR 42560. EPA further acknowledged, as it does here today, that dischargers are allowed to select the means by which they would comply with effluent limitations. Id. Finally, EPA also acknowledged that in-plant limitations would be inconsistent with the Agency's general approach up to that time, which was to determine compliance with effluent limitations at the end of the pipe. Id.

Nevertheless, even at that time, EPA had already promulgated its regulation authorizing, in certain circumstances, the imposition of effluent limitations on internal waste streams. See 40 CFR 122.45(h). Moreover, prior to that time, EPA had invoked that regulation to impose effluent limitations in-plant. While it is true, as EPA noted in the preamble to the OCPSF rule, that EPA's general approach was to focus on end-of-pipe compliance, nowhere did EPA say that approach was the only approach authorized by the Clean Water Act. Therefore, while EPA's decision to impose end-of-pipe limitations made sense in the specific context of the OCPSF effluent guideline, it does not prevent EPA from making a different policy decision in different circumstances, such as these, where the WQBEL for the pollutant in question is calculated below the level of quantification. EPA also notes that the OCPSF effluent guidelines were established at a level equal to or above the ML; therefore, these effluent guidelines did not raise a quantification level question.

Some commenters objected that the PMP represents an unlawful attempt by EPA to dictate pollutant reduction strategies to the permittee. EPA disagrees with this comment. The PMP nowhere specifies what control measures, if any, a discharger will need to implement in order to ensure that the effluent discharged to the receiving water actually achieves the WQBEL. Indeed, the PMP provision affords the permittee considerable flexibility in meeting its WQBEL; appropriate control strategies to reduce the particular pollutant could include not only new treatment approaches but also source reduction and substitution. In short, a permittee implementing a PMP can devise any control strategies it determines will minimize the presence of the pollutant in its wastestreams. EPA also recognizes that there are practical constraints on treatment capabilities. The PMP makes no attempt to dictate the treatment or source reduction strategies that a permittee could or should implement. Rather, EPA recognizes that the permittee is in a far better position to devise innovative approaches to meeting its WQBEL. The PMP is intended to emphasize the opportunities afforded by source reduction up front, rather than by traditional reliance on end-of-pipe treatment. In this way, the pollutant minimization program in procedure 8 is consistent with the national goals articulated in the Pollution Prevention Act of 1990, 42 USC 13101, et seq., which criticizes the traditional regulatory emphasis on treatment and disposal at the expense of source reduction. See 42 USC 13101(a)(3). Congress therefore declared as part of a national policy on pollution prevention that pollution should be prevented or reduced at the source whenever feasible and that disposal or other release into the environment should be employed only as a last resort. See 42 USC 13101(b). By promoting the identification and control of sources of pollution, the pollutant minimization program is consistent with that national policy.

As set forth in the preamble to the proposed guidance, EPA expects the PMP specified in the final Guidance to reflect that there are practical constraints on treatment capabilities. EPA does not view the PMP as a zero discharge requirement. Instead, EPA views it as a means to ensure that WQBELs were achieved. The effects of a PMP may be to reduce all pollutant(s) of concern in the internal streams to non-detectable levels, but this is not equivalent to a zero discharge requirement. A PMP-type requirement is consistent with the May 21, 1990 "Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the United States." In addition, in the final Guidance a permittee is allowed to consider cost-effectiveness in developing a pollutant minimization program, including alternative elements of a PMP. For this reason, EPA is not prescribing specific technology requirements for PMPs, rather EPA will defer to the permitting authority to determine the appropriate level of evaluation and controls to impose with the PMP.

EPA has determined that it is justified in requiring a permittee to document that all practicable steps are being taken to comply with a WQBEL that cannot be directly measured. EPA and State experience with such requirements, especially in the paper industry for 2,3,7,8 TCDD and large POTWs for PCBs, is that these PMPs lead to reductions in the pollutant of concern and compliance with the PMP requirements can be evaluated objectively. Another way to look at the PMP requirement is as a public statement of intent that the facility is undertaking a rigorous program to reduce the pollutant(s) of concern to levels which will not adversely impact the environment.

5. BCC Requirements

a. Proposal: In the proposal, fish tissue monitoring or other bio-uptake studies were required to assess PMP performance and trigger additional PMP actions if elevated levels of BCCs were detected.

b. Comments: Many commenters questioned the broad application of caged fish samples, the use of resident fish studies, and other bio-uptake studies in assessing a permittee's compliance with their PMP and, by inference, the WQBEL. Specific concerns included that caged fish may not receive a natural diet due to being physically restricted to cages, the resident fish may be subjected to contaminated food sources not attributed to the facility, and costs associated with these and other bio-uptake studies would be burdensome to small facilities.

c. Final Guidance: Based upon the comments received from the States and other commenters, EPA believes that fish tissue and other bio-uptake monitoring programs can be properly designed to provide quality data to use as an assessment tool for reasonable potential determinations and as an indication of ambient pollutant concentrations. However, the cost of performing such tests may not be justified for all facilities, especially if they can identify all the sources of the contaminant and demonstrate that they are already doing everything practicable to eliminate them. Since the original intent of this procedure was to use the fish monitoring and other bio-uptake studies to evaluate PMP performance, EPA does not believe it is necessary to require such monitoring methods universally for all cases. Therefore, proposed procedure 8.F has not been included in the final Guidance.

Nevertheless, the final Guidance encourages the States and Tribes to include fish tissue sampling or any other test procedures they deem necessary to properly evaluate the performance of a PMP. Fish tissue monitoring can be an effective means for some facilities to document that the PMP actions accomplish the desired load reductions to achieve WQBELs and, therefore, can provide a factual basis to allow a facility to reduce the PMP requirements or even remove such permit conditions. Where facilities are expected to discharge levels of BCCs, above the WQBEL but below the minimum quantification level, fish monitoring data can be valuable in assessing PMP performance and determining the need for additional pollution reduction efforts.

6. Other Conditions

a. Proposal: The proposed Guidance included a provision to allow States and Tribes to require a permittee, on a case-by-case basis, to develop or use analytical techniques more sensitive than the ones specified in the permit, internal waste stream monitoring and other methods capable of adequately determining the compliance status of the effluent.

b. Comments: EPA considers these optional measures suitable for inclusion in a PMP and, therefore, addressed them under the PMP comment discussion and the analytical methods comment discussion.

c. Final Guidance: Since these measures are intended to be optional and they are suitable for PMP purposes or special permit conditions, EPA decided that a separate provision for including these measures is not necessary.

I. Compliance Schedules

For purposes of the final Guidance, a compliance schedule refers to an enforceable sequence of interim requirements in a permit leading to ultimate compliance with water quality-based effluent limitations (WQBELs) in accordance with the Clean Water Act (CWA). This procedure allows, but does not require, States or Tribes to include such compliance schedules in permits under appropriate circumstances. A State or Tribe authorized to administer the National Pollutant Discharge System (NPDES) may exercise discretion when deciding if a compliance schedule is justified because of the technical or financial infeasibility of immediate compliance.

1. Proposal

Procedure 9 of the proposed Guidance allowed compliance schedules only for "existing dischargers," not "new" or "increasing" dischargers. For existing dischargers whose permits were reissued or modified to contain more stringent limitations based upon certain water quality requirements, the permit could allow up to three years or the length of the permit, whichever was less, to comply with such limitations. The provision applied to effluent limitations based on a Tier I criterion, Tier II value, whole effluent toxicity (WET) criterion, or narrative criterion, provided the criterion or value was adopted (or, in the case of a narrative criterion, newly interpreted) after July 1, 1977.

Under the proposal, where such a schedule of compliance exceeded one year, interim requirements were to be specified and interim progress reports submitted at least annually.

For existing dischargers with more stringent effluent limitations based on Tier II values, the proposal allowed a reasonable period of up to two years for the permittee to conduct studies necessary to develop a Tier I criterion or modify the Tier II value. After completion of such studies, and upon an appropriate showing, the permit could be modified or the compliance schedule could be extended to the end of the permit. The proposal stated that such permit modifications would not be affected by the anti-backsliding provisions of section 402(o) of the CWA. For further discussion on anti-backsliding provisions, see section II.C of this document.

These compliance schedule provisions were included in the proposal because of the potential for existing dischargers to have more stringent effluent limitations, under the final Guidance, for which immediate compliance would be impossible or impracticable. Schedules of compliance to accommodate such situations may be included in permits only if the State water quality standards or implementing regulations authorize them.

2. Final Guidance

As explained below, the final Guidance follows the general approach of the proposal; however, several modifications were made to address issues raised by commenters. These modifications include expanding the definition of existing discharger, extending the possible length of compliance schedules from a maximum of three years to a maximum of five years, allowing schedules of compliance to extend beyond the term of the permit in limited situations, and clarifying some of the language.

a. Eligibility

The proposal did not allow schedules of compliance for dischargers who commenced discharging or increased flow, concentration or loading after the effective date of the final rule. States and the regulated community objected to excluding from eligibility those permittees with an increased discharge or those who commenced discharging after the Guidance becomes effective. They specifically argued that the availability and duration of compliance schedules should be within the permitting authority's discretion, the new requirements may be difficult for new, existing or increasing dischargers to meet, and exclusions of some dischargers may result in competitive disadvantages. For example, a new permittee may have already invested a lot of resources (including time) in the planning and construction of a facility only to be immediately out of compliance with the final Guidance's requirements.

As a result of considering the comments, EPA made some changes to increase eligibility for compliance schedules. Specifically, EPA revised the Guidance to eliminate the definition of "increasing discharger" and redefined the term "existing discharger" to include any discharger which is not a "new Great Lakes discharger." The definition of a "new Great Lakes discharger" (in § 132.2 of the final Guidance) includes "any building, structure, facility, or installation from which there is, or may be, a 'discharge of pollutants', the construction of which commenced after March 23, 1997." The final Guidance's revised definitions were modeled after the existing 40 CFR 122.2 definitions for parallel terms, but with the cut-off date modified to reflect the date by which States or Tribes must adopt provisions consistent with the final Guidance. Only "new Great Lakes dischargers" are required to comply immediately upon commencement of discharge with effluent limitations derived from a Tier I criterion, Tier II value, whole effluent toxicity criterion, or narrative criterion. Therefore, existing dischargers, including those previously defined as increasing dischargers, are eligible for schedules of compliance to meet more stringent limitations derived from specified criteria and values.

EPA has included increasing dischargers within the category of existing dischargers since they are factually closer to existing dischargers than to new dischargers. Increasing dischargers may be existing facilities which have a change (an increase) in their discharge. Such facilities may include those with seasonal variations. Increasing dischargers will already have treatment systems in place for their current discharge. Thus, they have less opportunity than a new discharger does to design and build a new treatment system which will meet new water quality-based requirements for their changed discharge. Allowing existing facilities with a changed discharge (increasing discharger) a compliance schedule will avoid placing them at a competitive disadvantage vis-a-vis other existing dischargers, who are eligible for compliance schedules.

The final Guidance retains the prohibition against compliance schedules for new Great Lakes dischargers because, as defined in § 132.2, these permittees are the facilities whose construction commences more than two years after the final Guidance is published in the Federal Register. Therefore, these permittees will have had ample notice of the Guidance's new requirements and should have included the requirements in the planning of the new facility. Continuing this prohibition is also consistent with the national regulations.

The final Guidance does not prohibit the use of a short-term "shake-down period" for new Great Lakes dischargers as is provided for new sources or new dischargers in 40 CFR 122.29(d)(4). These regulations require that the owner or operator of a (1) new source; (2) a new discharger (as defined in 40 CFR 122.2) which commenced discharge after August 13, 1979; or (3) a recommencing discharger shall install and implement all pollution control equipment to meet the conditions of the permit before discharging. The facility must also meet all permit conditions in the shortest feasible time (not to exceed 90 days). This shake-down period is not a compliance schedule. This approach may be used to address violations which may occur during a new facility's start-up, especially where permit limits are water quality-based and biological treatment is involved.

Another approach is to use prosecutorial discretion as an unofficial shake-down period. That is, the permitting authority may elect not to take enforcement action against a new source which has installed the necessary treatment prior to discharging and is making a good faith effort to come into compliance as soon as possible. Alternatively, the permitting authority may issue a compliance order (under section 309(a) or equivalent State authority) requiring compliance by a specified date, where circumstances warrant.

b. Duration of Compliance Schedules

Paragraphs 9.B and C of the final Guidance set forth the basic requirements for compliance schedules for existing dischargers with new or more restrictive limitations. As a result of the changed definitions discussed above, these paragraphs now also apply to those dischargers formerly considered increasing dischargers. There are two principle changes from the proposal: the maximum length of compliance schedules is changed from three to five years in limited circumstances, and the proposed requirement that schedules of compliance not extend beyond the term of the permit is eliminated.

EPA received comments from States, the regulated community and environmental groups on the issue of duration of compliance schedules. States and the regulated community commented that the proposed three-year maximum duration for compliance schedules was too short.

With regard to the time to meet post 1977 Tier I criterion/Tier II values, whole effluent toxicity criteria, or narrative criteria, the final Guidance provides for compliance schedules for up to a maximum of five years. EPA continues to believe that compliance schedules of three years or less will be sufficient to allow facilities to make the changes necessary to meet new or revised discharge requirements in most cases. Such compliance periods are consistent with analogous provisions of the CWA including sections 301(b)(2) and 304(l). For example, section 301(b)(2) (C) - (F) of the Act provided that various technology-based effluent limitations shall be complied with as expeditiously as possible but no later than three years after effluent limitation guidelines are promulgated. Similarly, section 304(l) provides that sources shall comply with individual control strategies (water-quality based requirements) within three years.

However, the Agency also recognizes the concerns raised by commenters regarding the amount of time and resources in some cases that may be needed for implementing certain new treatment technologies. Commenters have asserted that installing state-of-the-art treatment to meet the final Guidance's new requirements would include the following efforts: identifying the appropriate technology, evaluating budgetary constraints, installing the technology, and effectively implementing the new treatment system. The regulated community commented that these efforts are resource and time intensive and, therefore, would not be feasible to accomplish within the proposed three year time period.

EPA acknowledges that in limited situations it may be difficult to accomplish the objectives listed above in three years to identify, design, and implement complex state-of-the-art treatment technology. The Agency also recognizes that evaluation, design, and implementation of facility-wide comprehensive pollution prevention control strategies involving product substitution, process line changes, new piping, new raw materials and revised waste handling, recycling, and disposal procedures may require more than three years at large facilities. In addition, EPA is aware that the technical and administrative process of modifying and implementing revised requirements for numerous industrial users at POTWs, as well as planning, budgeting, and undertaking significant new construction to change treatment processes at a municipal treatment works, may require more than three years.

Therefore, the final Guidance has been revised to provide that compliance schedules may provide for up to five years to meet new or more stringent effluent limitations in those limited circumstances where the permittee can demonstrate to the permit authority that such an extended schedule is warranted. The Agency emphasizes its belief that in most situations less than three years will be required. EPA believes that permit authorities should consider shorter compliance schedules wherever possible or, alternatively, not allow compliance schedules where unnecessary.

Comments from an environmental group recommended immediate compliance or that only one additional year be allowed for facilities to comply with the new requirements. Environmental groups were concerned that the three-year maximum would become a default compliance schedule duration for facilities. As discussed above, the final Guidance has been revised to provide for a maximum five-year compliance schedule. EPA emphasizes that the five-year is a "maximum" and that permitting authorities, based on their discretion, should consider shorter periods of time, or alternatively, not allow compliance schedules. If a permit grants a schedule of compliance where the need for a schedule has not been substantiated, the permit would be objectionable. EPA has review authority to ensure that the additional time period is "reasonable" and not based upon a standard practice of granting additional time without appropriate technical justification. The burden is on the permit applicant to justify a compliance schedule.

The regulated community also commented that toxicological studies are difficult to conduct and that facilities may not be able to complete the research within the three-year maximum. The regulated community also argued that once studies are completed (which justify modifying a permit to incorporate the results) permittees may need additional time to modify the operation of their facility to reflect the studies' findings.

If permits are modified to reflect the results of studies conducted by a permittee and/or to allow for a changed operation, the public would have an opportunity to comment upon the appropriateness of any extension of the compliance schedule as well as the modified WQBEL.

Some commenters were concerned that conducting toxicity tests to justify new or revised criteria was not a "routine exercise" and warranted a longer compliance schedule. However, both the proposal and the final Guidance address this concern for permits based on Tier II values by providing up to two years for completion of studies and calculation of a revised limit where appropriate, and then up to five years additional time to come into compliance with the applicable limit. With respect to commenters' concerns over the length of time needed to perform toxicity tests, EPA's experience indicates that the necessary toxicity studies can likely be accomplished in one year.

Some States felt that limiting compliance schedules to the term of, or expiration date of, a five-year permit was not realistic and did not provide adequate time for permittees to implement new technologies or complete additional research studies. These States claimed that this scenario would be especially true for those permittees in the third or fourth year of their permit who would not be allowed the maximum schedule of three years for compliance due to their permit's expiration date. The regulated community commented that limiting the duration of compliance schedules to the term of the permit could create unfair competitive disadvantages and that three years was an unrealistic amount of time for permittees to change their operations or install new technologies to comply with the new requirements and to complete the additional toxicological studies for developing a Tier I criterion or modifying a Tier II value.

EPA recognizes that permittees in the third or fourth year of a permit may receive modified or revised permits reflecting the final Guidance's new requirements. If the permitting authority has no discretion to extend the compliance schedule beyond the permit's expiration date, but immediate compliance is infeasible, these permittees may be out of compliance and potentially subject to enforcement actions. Such violations may be avoided with the discovery and implementation of new technologies or revised limits due to completed additional studies by industry. EPA has addressed this comment by further clarifying the maximum five-year compliance schedule approach in the next paragraph.

While the final Guidance has been changed to all compliance schedules to extend to a maximum duration of five years (see discussion above), EPA recognizes that where a permit is modified near the end of the permit term, the permittee may still need a full five years to comply. The Agency finds no persuasive reason for distinguishing between these permittees and permittees who are in the earlier part of a permit cycle. Therefore, the final Guidance provides that the compliance schedule can go beyond the term of the permit. When this occurs, an interim permit limit effective upon the permit expiration date shall be included in the permit, in effect giving the permittee up to the same five years. The fact sheet and administrative record shall address the final limit and its compliance date.

States and the regulated community also raised issues concerning EPA's interpretation of its anti-backsliding provisions. States and the regulated community commented that EPA's policies were unclear as to whether compliance schedules would be affected by anti-backsliding provisions. They also questioned whether revised permit limits based on new information resulting from the completion of additional studies by a permittee would present an anti-backsliding issue. The anti-backsliding requirements of section 402(o) of the CWA do not apply to revisions to effluent limitations made before the scheduled date of compliance for those limitations. Anti-backsliding requirements are discussed in section II.C.3 of this document.

IX. EXECUTIVE ORDER 12866

A. Introduction and Rationale for Estimating Costs and Benefits for the Great Lakes Water Quality Guidance

Under Executive Order 12866, [58 FR 51735 (October 4, 1993)] the Agency must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive Order defines a "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The final Guidance establishes minimum water quality criteria, antidegradation provisions, and implementation procedures for the Great Lakes System. Implementation of these provisions is dependent upon future promulgation of provisions consistent with the final Guidance by State or Tribal agencies or, if necessary, EPA. Until actions are taken to promulgate and implement these provisions (or equally protective provisions consistent with the final Guidance), there will be no economic effect of this rule on any entities.

EPA anticipates that States or Tribal agencies will promulgate provisions consistent with the final Guidance. Therefore, pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it may impose an annual cost or benefit to the economy of $100 million. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

Executive Order 12866 requires EPA to submit an assessment and description of potential costs and benefits anticipated from the regulatory action and reasonable alternatives considered for "significant" regulations meeting the definition described above. Under the Clean Water Act (CWA), costs and benefits are not directly relevant in establishing water quality criteria. However, if a range of scientifically defensible criteria that are protective of the designated use in question is identified, costs may be considered in selecting a particular criterion within that range. In addition, under EPA's regulations, certain costs can be considered in the context of use attainability analyses, variances, and antidegradation. Moreover, as a matter of good government, EPA considers costs and benefits in making its decisions. Accordingly, consideration of costs and benefits has been an integral part of the deliberations involving the States, environmental interests, the regulated community, and EPA in the development of the Great Lakes Water Quality Guidance.

In addition to the requirements set forth in Executive Order 12866, the States of Ohio, Michigan, and Wisconsin had specifically requested that EPA examine the costs and benefits of the Guidance. Some members of the Public Participation Group also expressed a concern during the Steering Committee meetings that the costs to point sources could be sizeable. Other public comments expressed concern about the need for specifically identifying the benefits. During the Steering Committee deliberations in November and December 1991, EPA expressly committed to estimate various costs and benefits that could accrue from the proposed Guidance and to include that analysis in the public comment process associated with the proposed regulation.

As noted above, Executive Order 12866 requires EPA to prepare an assessment of the potential costs and benefits for proposed and final major rules. The studies described below (collectively referred to as the Regulatory Impact Analysis) have been submitted to OMB to fulfill this requirement. These cost and benefit studies are summarized below. The documents underlying this summary are available in the administrative record for this rulemaking.

B. Summary of Proposal

The following discussion briefly describes how EPA prepared the original estimate of both costs and benefits associated with the proposed Guidance. More detailed information regarding the procedures used by EPA to estimate compliance costs for the proposed Guidance is included in the EPA *Assessment of Compliance Costs Resulting from Implementation of the Proposed Great Lakes Water Quality Guidance* (April 16, 1993). In general, aggregate costs were estimated for all direct (i.e., point source) and indirect dischargers in the Great Lakes System. Benefits and costs were also assessed for direct industrial and municipal point source dischargers at three case study sites in the Great Lakes System, the results of which were not appropriate to use in evaluating the aggregate benefits and costs of the proposed Guidance. Section IX.C.1 of this document discusses modifications to the approach for the proposed Guidance that were made to estimate costs for the final Guidance.

1. Costs

EPA focused its initial assessment on categories of industries and municipalities that would be likely to be affected by the proposed Guidance. EPA conducted a detailed review of a random stratified sample of direct dischargers to serve as the basis for reasonable extrapolation to the universe of Great Lakes System dischargers. These sample facilities were considered representative of all types and sizes of facilities in the Great Lakes Basin.

a. Method

EPA selected 50 sample facilities to represent the estimated 588 major dischargers and 9 facilities to represent the 3,207 minor dischargers in the Great Lakes Basin. For major dischargers, sample facilities were selected from each of the major categories of facilities, which included nine primary industrial groups and a category for municipalities, also known as Publicly Owned Treatment Works or POTWs. The nine industrial categories were Mining, Food and Food Products, Pulp and Paper, Inorganic Chemical Manufacturing, Organic Chemical Manufacturing/Petroleum Refining, Metals Manufacturing, Electroplating/Metal Fabrication, Steam Electric Power Plants, and Miscellaneous facilities (e.g., remedial clean-up discharges, tire manufacturers). Sample major facilities were also selected to ensure representation across facility size (as measured by discharge flow volume), through stratification by flow within each category.

Because minimal compliance costs were anticipated by minor dischargers, EPA analyzed a limited number of randomly selected minors to verify that assumption. Furthermore, because EPA had limited discharge flow data for minor dischargers, it was not possible to adopt a flow-stratified analytical plan similar to that used for majors.

For each sample facility under review, the most current NPDES permit data and background information were collected to calculate the limits that would be anticipated from current regulatory requirements (if not incorporated into the current permit) and to develop additional (hypothetical) permit requirements based on the proposed Guidance. EPA gathered information from State and Regional files that included permit applications, permit fact sheets or rationales, inspection reports, discharge monitoring reports, pretreatment reports, short-term waste characterization studies, receiving stream low-flow scenarios and total maximum daily loads/waste load allocation reports. In addition, EPA used any other readily available information including industry-wide studies of various industrial categories used in developing effluent guidelines.

For each sample facility, new hypothetical permit limits and permit conditions were developed based on the implementation procedures in the proposed Guidance. The proposed criteria would require some permitted facilities to meet new limits and adopt other permit conditions such as whole effluent toxicity testing and additional monitoring. New limits were calculated for those 32 pollutants for which numeric Tier I criteria were proposed. For a given facility, only those pollutants that were detected in the discharge, or expected to be present in the discharge but reported as not detected because of use of less sensitive EPA approved analytical methods, were evaluated. The need for whole effluent toxicity limits and monitoring was also evaluated in accordance with the proposal. For each facility, limits were calculated for the outfalls that contained or might contain observed or anticipated loadings for the pollutants of concern.

If the existing effluent limits for some of the permitted facilities selected did not reflect current State water quality standards and implementation policies, EPA calculated hypothetical, alternative permit limits to reflect the newly-revised State standards and requirements, which are based on the adoption of toxic water quality standards under section 303(c)(2)(B) of the CWA (referred to here as baseline requirements). This approach more accurately reflected differences between existing effluent limits based on newly revised State requirements and procedures required in the proposed Guidance.

In determining specific requirements imposed by the proposed Guidance, site-specific wasteload allocations (WLAs) were calculated for discharges to both the open waters of the Great Lakes and their tributaries using equations set forth in the proposed implementation procedures. Because of the general lack of readily available background concentration data for receiving waters, two different WLAs were calculated for each sample facility. The first WLA assumed zero background in the absence of background data (WLA #1). The second WLA assumed a value for background concentrations where no background data existed (WLA #2). The assumed background values were approximately 50 percent of the proposed Guidance water quality criteria.

The resulting WLAs were then used to establish water quality-based effluent limits (WQBELs) for the sample facilities; the daily maximum WQBEL for a pollutant was set equal to the Final Acute Value, which represents the WLA to achieve the acute aquatic life criterion; monthly average WQBELs were set equal to the most stringent WLA calculated to protect chronic aquatic life, wildlife, or human health criteria. When negative WLAs were calculated for a pollutant (because of high background concentrations of pollutants reported for a receiving water), two different sets of WQBELs were calculated for each facility, which resulted in different compliance cost scenarios. In cases where negative WLAs were calculated using WLA #1, the WQBEL was set equal to the background concentration (WQBEL #1); when negative WLAs were calculated using WLA #2, then the WQBEL was set equal to the most stringent water quality criteria (WQBEL #2).

If either WQBEL #1 or WQBEL #2 was more stringent than the existing effluent limits--either in current permits or calculated against current regulatory requirements--then EPA developed costs based on options that would likely be available to the facility to comply with the more stringent effluent limits.

To estimate costs to the particular facilities reviewed and to develop potential compliance options, an engineering analysis for each facility in the sample was conducted. This included a review of existing treatment systems at the facility and an assessment of the need to add new or supplement existing treatment capabilities. Having defined the control options, EPA estimated the compliance costs to facilities implementing each option. Compliance costs generally included treatment costs, monitoring, and operations and maintenance costs, and a variety of one-time costs of limited durations (e.g., waste minimization audits of production processes). Residual management costs were also estimated for industrial and municipal facilities that were projected to install end-of-pipe treatment and generate additional sludge (e.g., sludge produced from chemical precipitation).

If the analysis showed that additional treatment was the most likely control method to be used to comply with either WQBEL #1 or #2, then EPA generally assumed that this treatment would be added as an end-of-pipe unit process (i.e., the treatment unit process would be added at a point just prior to discharge to the receiving water). While additional treatment at end-of-pipe may be neither technically nor economically efficient in a variety of circumstances, EPA did not have the necessary facility- or process-specific information such as contributing wastewater flows, in-plant treatment capabilities or opportunities, process waste characteristics, or recycling capabilities that would allow an assessment of other potentially less expensive alternatives. However, in the majority of instances, additional end-of-pipe treatment was not projected for a facility. This was the case where existing treatment facilities could accomplish the required treatment, current permit requirements or construction plans were already in place to provide the additional treatment, the incremental amounts of pollutants to be removed were insignificant, or waste minimization/pollution prevention control techniques were believed to be adequate to comply with the Guidance. In each of these instances, appreciable treatment capital costs directly attributable to the proposed Guidance were not anticipated.

In the case of municipalities, or POTWs, consideration was given to the number and types of industrial users discharging to the collection system, as well as the size of the POTW. If additional pretreatment controls or modifications seemed unlikely to achieve the pollutant reductions, then additional treatment at the POTW was considered the next most likely option.

Monitoring costs for permitted facilities were also estimated. In those cases where additional parameters and limitations were deemed necessary because of the Guidance, the monitoring regimes (i.e., sampling frequency) were established consistent with the existing monitoring requirements for other parameters. Monitoring costs were then estimated based upon average costs per analytical method for the more common techniques.

Because the discharge of bioaccumulative chemicals of concern (BCCs) are of special concern under the proposed Guidance, EPA included monitoring-only costs for Tier I BCCs for all affected facilities, regardless of whether Tier I BCCs were detected or expected to be present in a discharge.

A number of other costs were also considered depending on the specific circumstances surrounding a particular type of facility. These were generally one time costs related to pollutant minimization studies, bioconcentration studies, whole effluent toxicity testing, pretreatment program revisions, waste minimization audits, and implementing pollution prevention techniques. Generally, these costs were included with the capital costs for purposes of calculating annualized costs of compliance.

Four different cost estimates were developed to account for differences between limits based on WLA #1 (zero background absent actual data) and WLA #2 (assumed 50 percent of the most stringent Guidance criteria as background absent actual data), as well as the potential range of costs associated with implementation of waste and pollutant minimization studies and controls. These scenarios are described below:

<u>Scenario 1</u>: Limits based on WLA #1 and the low end of the estimated range of waste minimization costs for all facilities.

<u>Scenario 2</u>: Limits based on WLA #2, the middle of the estimated range of waste minimization costs for industrial facilities, and high end of the estimated range costs for the POTWs aggressively implementing the pretreatment program to promote source control.

<u>Scenario 3</u>: Limits based on WLA #2, the middle of the estimated range of waste minimization costs for industrial facilities, and end-of-pipe treatment installation by POTWs.

<u>Scenario 4</u>: Limits based on WLA #2, high end of an estimated range of waste minimization costs, and end-of-pipe treatment installation by POTWs.

The major difference between Scenario 2 and Scenario 3 was the emphasis on pollution prevention versus end-of-pipe treatment. Assumptions underlying Scenario 2 emphasized pollution prevention through source control. Scenario 3 focused on end-of-pipe treatment, especially at POTWs.

To develop a single cost estimate for each facility for each scenario described above, the three cost categories mentioned above (treatment, monitoring, and one-time costs) were combined into a single annualized cost, which reflects the annual economic costs associated with recurring activities (e.g., compliance monitoring, and operation and maintenance), repaying capital expenses, and special studies. Annualized costs were calculated by assuming that all capital costs and special study costs would be paid by borrowing money at an interest rate of seven percent and paying it back over a 10-year period. Annual costs of monitoring, operation, and maintenance were added directly.

Given a single estimate of the annualized cost for each facility, the procedure for extrapolating costs from the sample to the entire population was pre-determined by the stratified random sampling procedure used to select the subset of facilities examined in detail. Using the single annualized cost figure for each plant, an estimate of the cost for each category was calculated by averaging the values for applicable (sample) plants and then multiplying by the total (population) number of plants in that stratum. The cost estimate for the category was calculated by summing the strata in the category. The cost estimate for the entire universe of facilities was the sum across categories. This procedure was followed to estimate costs for each scenario.

EPA identified an estimated 3,500 indirect industrial dischargers that discharge to POTWs in the Great Lakes System and developed preliminary estimates of compliance costs for them. These preliminary cost estimates were based on the assumption that indirect dischargers affected by the proposed Guidance would incur costs comparable to those incurred by direct industrial dischargers. In addition, EPA assumed that costs to industrial users subject to categorical pretreatment standards would be higher than the costs to non-categorical significant industrial users. The following four scenarios for indirect dischargers are consistent with the four cost scenarios developed for direct dischargers.

<u>Scenario 1</u>: Assumes that 10 percent of all indirect dischargers in the Great Lakes Basin would install additional controls.

Scenario 2: Assumes that 30 percent of all indirect dischargers in the Great Lakes Basin would install additional controls.

Scenario 3: Assumes that 20 percent of all indirect dischargers would install additional controls.

Scenario 4: Assumes that 20 percent of all indirect dischargers would install additional controls (same as Scenario 3).

The estimated percent of indirect dischargers affected by the proposed Guidance was based on an assessment of conditions involving industrial users and their toxic discharges to a moderately large POTW in the Great Lakes Basin.

b. Results

The total annualized compliance costs of implementing the proposed Guidance to direct and indirect dischargers were estimated to be between $80 million under Scenario 1 and $505 million under Scenario 4. EPA considered Scenario 2 to be the most likely scenario of the four scenarios evaluated because it was assumed that dischargers would pursue more cost effective approaches to comply with the Guidance (as opposed to always installing treatment), and estimated the annualized compliance cost to be about $192 million. Under Cost Scenario 2, direct dischargers accounted for 59 percent of the total estimated compliance cost of the proposed Guidance; indirect dischargers accounted for 41 percent of the total estimated cost. Direct major industrial dischargers accounted for 32 percent of the total estimated cost under Scenario 2; direct major POTWs accounted for 21 percent of the total cost. Major POTWs accounted for the largest proportion of total annualized costs borne by any of the categories of dischargers; the mining category was estimated to incur the lowest proportion of costs for the universe of industrial categories.

Annualized capital costs accounted for about 7 percent of the total annual cost for majors, but none of the costs for minors, which did not require investment in treatment technology. Waste/pollutant minimization studies and implementation of appropriate controls/techniques were a very significant portion of the total expected cost of the proposed Guidance. The total annualized costs of such pollutant controls made up about 54 percent of the costs for direct dischargers under Scenario 2. The annual cost of monitoring, operating and maintaining equipment, etc., made up about 36 percent of the estimated annual costs for direct dischargers. Special monitoring studies accounted for about 4 percent.

EPA identified several limitations in the scope of the cost study for the proposal and performed several sensitivity analyses in an effort to evaluate the impacts of these study limitations on the total estimated compliance cost. The analyses performed included:

-- evaluating the cost impact assuming that Tier I BCCs are found bioaccumulating as a result of Guidance monitoring requirements when Guidance-based WQBELs were below analytical detection levels;

-- estimating the impact of the proposed antidegradation requirements;

-- analyzing the potential effect should BCCs be detected in the future;

-- evaluating the impact of eliminating mixing zones for BCCs;

-- evaluating the prevalence of Tier II BCCs and potential BCCs; and

-- evaluating the potential costs associated with the proposed options to control pollutants in intake waters.

Based on these sensitivity analyses, EPA estimated that an additional $40 million annually in costs may also be attributable to the proposed Guidance. This incremental cost represented about a 21 percent increase above the cost study estimate. When added to the most likely cost study estimate (i.e., Cost Scenario 2), the total compliance costs were estimated to reach as high as $232 million annually.

2. Cost-Effectiveness

Based on the cost estimates described above, EPA evaluated the cost-effectiveness of the proposal. Cost-effectiveness is defined as the incremental annualized costs of a pollution control option per incremental pollutant removal. Cost-effectiveness is measured using pounds of pollutant removed weighted by an estimate of the relative toxicity of the pollutant (referred to as pounds-equivalent). As also described in section IX.C.1.g of this document, EPA derives toxic weights through standardizing pollutant criteria by using the original EPA criterion for copper.

a. Method

EPA estimated pollutant loadings reductions to indicate the decrease in pollutants discharged due to more stringent proposed Guidance-based limits. Baseline loadings were determined in pounds per day by multiplying the existing permit limit or effluent concentration by the facility's average flow rate and a unit conversion factor. If either the permit limit or effluent concentration for a pollutant was reported as less than a detectable level, the reported detection level was divided in half. Using extrapolation procedures similar to those used for compliance costs, EPA averaged sample facility baseline loadings across all facilities in each stratum, multiplied by the total number of facilities in each stratum, and summed.

EPA calculated Scenario 1 (reflecting WQBEL #1) and Scenario 2 (reflecting WQBEL #2) loading reductions by finding the difference between the existing permit limits (or highest reported concentration in the absence of an existing permit limit) and the proposed Guidance-based limit for each pollutant. The resulting difference was converted to pounds per day by multiplying the difference by the facility's flow rate and a unit conversion factor. Several assumptions were made to calculate the loading reduction for a pollutant:

i. In the absence of an existing permit limit, if the difference between the Guidance-based WQBEL and the highest reported concentration was negative, zero reduction was assumed. This situation occurred because there were instances where the reported concentration was below the Guidance-based WQBEL.

ii. When the highest reported concentration was reported as below a detection level, one-half of the reported detection level was used as the baseline concentration. When the Guidance-based WQBEL was below analytical detection levels, one-half of the detection level was used for purposes of calculating a difference.

iii. It was assumed that facilities are discharging at the level of the existing permit limitation.

Loading reductions were calculated for each direct discharging facility in the sample and then extrapolated to all direct discharging facilities in the Great Lakes System.

The pollutant loading reductions from direct dischargers were weighted using EPA toxic weights (EPA/OST 1988 Cost Effectiveness Criteria and Weights), which result in reductions expressed in toxic pounds-equivalent per day. Annual pollutant reduction values were then calculated by multiplying the pounds-equivalent per day by 365 days under each scenario. Total annualized costs for direct dischargers in each scenario were then divided by total annual pounds-equivalent for each scenario to estimate the cost per pounds-equivalent per year for each scenario.

b. <u>Results</u>

EPA estimated that the proposed Guidance would reduce the baseline toxic-weighted pollutant loadings (126 million pounds-equivalent per year) by about 30 percent. The cost-effectiveness of all four cost scenarios ranged from $1.30 per pounds-equivalent to $10.40 per pounds-equivalent over the baseline; the cost-effectiveness of the most likely scenario was $2.60 per pounds-equivalent (the estimated costs for indirect dischargers are not included in these calculations). When compared with the cost-effectiveness of various effluent guidelines, these values were at the low end of the range of $1 to $500 per pounds-equivalent. However, as discussed below, the cost estimates for the proposed Guidance were reevaluated using the revised approach for estimating costs and load reductions for the final Guidance. For consistency, costs and load reductions based on the revised approach will be used when comparing the proposal to the final Guidance.

C. <u>Revisions to Projected Costs</u>

This section discusses EPA's approach to revising its original cost estimates to comply with the final Guidance. The revisions to the approach are based primarily upon the changes to the proposal discussed throughout this document, the preamble and rule for the final Guidance, and the public comments received on the Regulatory Impact Analysis methodology used for the proposal. In addition, in making final decisions related to the Guidance, EPA performed numerous analyses of different regulatory options for the following issues identified at the time of the proposal: intake credits, use of Tier II values, impact of analytical detection levels, elimination of mixing zones for BCCs, and additivity.

1. <u>Summary of Revised Approach to Estimate Costs and Pollutant Load Reductions</u>

In general, EPA employed the basic methodology used to estimate compliance costs and pollutant load reductions attributable to the proposal (as described in IX.B.1 of this document). However, EPA revised the approach based on comments it received to more accurately project the costs to the regulated community and to better account for the pollutant load reductions. Several of the significant revisions are described briefly below. All of the revisions made by EPA are documented in the "Revised Assessment of Compliance Costs Resulting From Implementation of the Final Great Lakes Water Quality Guidance," which is available for review in the public docket for the rulemaking.

EPA has also revised its assessment of compliance costs to reflect modifications made to the final Guidance to provide increased flexibility for State and Tribal implementation. For example:

-- Site-Specific Modifications: Great Lakes States and Tribes may adopt either more or less stringent modifications to human health, wildlife, and aquatic life criteria based on site-specific circumstances. All criteria, however, must be sufficient not to cause jeopardy to threatened or endangered species listed or proposed to be listed under the Federal Endangered Species Act.

-- Intake Credits: Great Lakes States and Tribes may consider the presence of intake water pollutants in establishing water quality-based effluent limits.

-- Mixing Zones: Great Lakes States and Tribes may authorize mixing zones for existing discharges of BCCs after a 12-year phase-out period, if the permitting authority determines, among other things, that the discharger has reduced its discharge of the BCC for which a mixing zone is sought to the maximum extent possible. Water conservation efforts that result in overall reductions of BCCs are also allowed even if they result in higher effluent concentrations.

For purposes of estimating compliance costs, EPA assumed that permitting authorities would use the more stringent provisions specified in the final Guidance even when the Guidance provides for less stringent alternatives. For example, this document and the preamble to the final Guidance suggests that the permitting authority require bio-uptake studies for BCCs when WQBELs are below analytical detection levels; however, the regulation to the final Guidance contains no such requirement. For purposes of estimating compliance costs, EPA conservatively assumed that bio-uptake studies would be required for BCCs. Table IX-1 describes several other conservative assumptions that were made in estimating compliance costs for the final Guidance.

TABLE IX-1
COST STUDY ASSUMPTIONS THAT ARE MORE STRINGENT THAN REQUIRED BY FINAL GUIDANCE

Final Guidance Requirement	Description of Cost Estimate Assumptions
WATER QUALITY CRITERIA	
Appendix B - Bioaccumulation Factors Human heath and wildlife criteria to be derived using measured or predicted BAFs	BAFs used to develop criteria for the costing analysis were calculated using conservative assumptions. BAFs were therefore more stringent than those that would be calculated by States and should result in more stringent criteria than would be developed by States. Projected costs, therefore, will likely overestimate actual costs.
Appendix C - Human Health Requires use of drinking water factors where discharge is to open waters, connecting channels, or designated drinking water sources. Uses 15 grams/day fish consumption rate	Assumed all receiving waters were drinking water sources. This resulted in more stringent criteria. Therefore, projected costs will likely overestimate actual costs. Assumed a fish consumption rate of 45 grams/day. States will most likely use 15 grams/day; thus, the cost projections will likely overestimate actual costs.
IMPLEMENTATION PROCEDURES	
Procedure 1: Site Specific Modifications Allows States to use more or less stringent aquatic life criteria and BAFs	Cost analyses are based on Guidance recommendations. It is most likely that, States will use the provision to relax criteria and BAFs, thus, projected costs will likely overestimate actual costs.
Procedure 3: TMDL/WLA All mixing zones for BCCs eliminated within 12 years of rule publication. Extensions may be granted for technical and economic considerations.	Assumed immediate elimination of all mixing zones for BCCs. Costs were developed assuming BCC criteria were applied at end-of-pipe. Since States will likely allow mixing zones for many existing sources up to 12 years. This would allow permittees to defer some costs over the 12 year period. Projected costs, therefore, will likely overestimate actual costs.
Procedure 4: Additivity Requires States to adopt an additivity provision. States must address additivity by assuming an additive risk of $1x10^{-4}$, an individual risk of $1x10^{-6}$, or other defensible approach.	WQBELs were calculated assuming that all carcinogens were additive. Assumed an additive risk of $1x10^{-5}$. This assumption is likely to be at the stringent end of the options selected by States. The projected costs, therefore, should slightly overestimate actual costs.
Procedure 6: Whole Effluent Toxicity (WET) WET limits must be determined where reasonable potential is determined. States must develop and apply WET limits, but may defer limit application until sufficient data have been generated.	Costed WET testing requirements for all facilities where WET data were unavailable, and where toxic pollutants were present in discharge. Rigorous WET testing requirements will likely exceed State requirements; thus, projected costs will likely overestimate actual costs.
Procedure 8: WQBELs Below Detection Permits will specify the most sensitive analytical technology and will establish the "Minimum Level of Quantification" (MLOQ).	Cost analyses used the method detection level (MDL) as the target concentration. Since the MDL will be equal to, or more stringent than the MLOQ, the projected costs will likely overestimate the actual costs.
Procedure 9: Compliance Schedules Final Guidance allows States to provide a three year compliance period upon permit reissuance. This could allow costs to be deferred for up to eight years (i.e., 5-yr permit cycle + 3-yr schedule).	Cost analyses did not consider compliance schedules. Costs were assumed to be incurred immediately. Since States will likely provide compliance periods for many existing sources, projected costs will likely overestimate actual costs.

a. Revised Criteria and Implementation Procedures

The costs to comply with the final Guidance were estimated based on the revised implementation procedures and criteria. Following are brief descriptions of the specific procedures that were changed from the original cost analysis.

i. Dissolved Metals Water Quality Criteria

As described in sections III, V, and VI of this document, EPA revised many of the criteria originally proposed under the Guidance. These revised criteria were used as the basis for calculating WQBELs for the sample facilities and then estimating compliance costs.

In order to apply metals criteria in the dissolved form, EPA used conversion factors, based on toxicity testing results, to revise criteria from the total form to the dissolved form. The conversion factors were based on the ratio of dissolved to total metals present in the laboratory toxicity tests performed to establish the criteria for toxic metals. Conversion factors ranged from 0.333 for trivalent chromium, to 1.0 for trivalent arsenic. Where conversion factors were not available, EPA assumed the most protective conversion factor of 1.0. The criteria for the dissolved form of the metals were then adjusted back to the total form using the theoretical partitioning relationship between the total/dissolved phases described in the EPA policy memo from Martha G. Prothro, dated October 1, 1993, to EPA's Water Management and Environmental Services Division Directors in Regions I-X.

The memo reiterates EPA's position that permit limits for metals must be established for total metals and describes three methodologies for translating dissolved metals criteria to the total form. Two of the three methods rely on site-specific studies performed to determine actual in-stream partitioning relationships. However, since actual metals partitioning data were not available for any of the 59 study facilities, the third alternative, based on the theoretical partitioning relationship, was utilized to calculate Guidance-based WQBELs. The theoretical partitioning relationship is based on a partitioning coefficient, determined empirically for each metal, and the concentration of total suspended solids (TSS) in the receiving water. Using this relationship, EPA determined partitioning factors from dissolved to total metals in the range of 2.0, for nickel, to 20.55, for trivalent chromium. Where empirically determined partitioning coefficients were not available, a partitioning factor of 2.0 was assumed. Therefore, partitioning factors assumed to be 2.0 would produce the most stringent possible permit limit.

ii. Intake Credits

In estimating the compliance costs for the sample facilities, EPA applied the intake credit provisions to applicable facilities. Consistent with the proposal, intake credits were provided in one of two general ways.

First, EPA evaluated whether there would be a reasonable potential for the discharge to cause or contribute to an excursion above a narrative or numeric water quality criterion. For purposes of estimating compliance cost estimates, EPA determined no reasonable potential and did not establish WQBELs for outfalls that met the following criteria:

-- The facility withdrew 100 percent of the intake water containing the pollutant from the same body of water into which the discharge was made.

-- The facility did not contribute any additional mass of the identified intake water pollutant to its wastewater.

-- The facility did not alter the identified intake water pollutant chemically or physically in a manner that would cause adverse water quality impacts that would not occur if the pollutants were left in-stream.

-- The facility did not increase the identified intake water pollutant concentration compared to the pollutant concentration in the intake water.

-- The timing and location of the discharge would not cause adverse water quality impacts to occur that would not occur if the identified intake pollutants were left in-stream.

It should be noted that when EPA did not possess intake pollutant data for a sample facility, then EPA assumed that there would be a reasonable potential to exceed WQBELs, and appropriate compliance costs were estimated for the sample facility. This assumption tends to overstate the costs, since some of the facilities for which no data was available could qualify for an intake credit. There were also instances when some intake pollutant data was available, but not all the data needed to determine whether all five of the criteria described above would be met. In general, for purposes of estimating compliance costs, EPA assumed there would be no reasonable potential to exceed water quality standards if at least the first two criteria described above (i.e., withdrawing 100 percent from the same body of water, and no additional pollutant was added to the discharge) were met. This assumption could potentially underestimate the cost impact of the intake credit provisions contained in the final Guidance.

Second, EPA granted intake credits for sample facilities when the level of the pollutant upstream of the discharge exceeded the most stringent applicable water quality criterion for that pollutant. When this situation occurred, relief was provided by making the WQBEL for the pollutant(s) equal to the most stringent Guidance criterion, instead of prohibiting the discharge or making another more stringent assumption. EPA did this for both discharges to different and same bodies of water. The final Guidance allows "no net increase" (i.e., discharge at background concentrations) for up to 10 years following promulgation of procedures by the State or Tribal agency, or until a total maximum daily load (TMDL) is established, for discharges to the same body of water. EPA conservatively assumed in its cost estimates that TMDLs justifying loads greater than criteria would not be developed and dischargers to the same body of water would need to comply with the most stringent criteria at end-of-pipe.

iii. Additivity/TEFs

EPA's estimate of costs for the sample facilities accounted for additivity of human carcinogenic effects of pollutants contained in a discharge. To estimate costs for the final Guidance, EPA assumed that the total carcinogenic risk of the mixture of two or more carcinogens in a discharge would not exceed a lifetime incremental cancer risk equal to one in 100,000 (10^{-5}). The final Guidance allows States to use a less stringent incremental cancer risk equal to one in 10,000 (10^{-4}) for additivity, but EPA decided to use a 10^{-5} risk level for the mixture for estimating costs because some States may choose to use a 10^{-5} risk level. In addition, the final Guidance allows a State and Tribe to account for additivity by establishing individual human carcinogen doses at levels corresponding to an incremental cancer risk of one in 1,000,000 (10^{-6}), or applying a scientifically defensible method to account for the additive effects of carcinogens.

The first step in estimating the cost attributable to additivity was to determine the number of potential carcinogens discharged by a study facility, the concentration of those pollutants in the discharge, and the background concentrations in the ambient water for those pollutants. The second step was to determine the human cancer value (HCV) associated with a lifetime incremental cancer risk equal to one in 100,000 for those individual pollutants identified in the discharge. The third step was to divide each of the HCVs for those carcinogens identified in the discharge by the total number of carcinogens in the discharge to determine the allowable concentration for each carcinogen that could be discharged. This concentration was then compared to the actual concentration in the discharge for that pollutant to determine whether the facility needed to reduce that pollutant. This approach results in an equivalent (proportional) reduction for each HCV at a sample facility. This approach was selected to provide a consistent method for addressing additivity to all sample facilities.

EPA also considered use of toxicity equivalent factors (TEFs) when establishing wasteload allocations for both human health non-cancer and cancer criteria for compounds similar to 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) in accordance with procedure 4 of appendix F of the final rule. It should be noted, however, that for those sample facilities for which 2,3,7,8-TCDD WQBELs were established, no concentration data existed for the chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs) in an effluent. Thus equivalent concentrations for 2,3,7,8-TCDD-type chemicals were not developed.

iv. Acute Mixing Zones for WET

As discussed in section VIII.F of the document, the proposed implementation procedures originally required that facilities comply with an acute WET criterion of 1.0 acute toxic unit (TU_a) at the end-of-pipe (i.e., no mixing zone allowed). The final Guidance requires that no discharges exceed 0.3 TU_a at the edge of an approved acute mixing zone. As a result, for purposes of estimating costs, EPA allowed mixing zones to comply with acute WET criteria. EPA used the WLA equations provided in procedure 3 of appendix F of the proposed Guidance and the 1-year, 10-day (1Q10) critical receiving water flow as recommended in procedure 3 of the final Guidance to calculate acute WET limits.

b. Criteria for Tier I and Tier II Pollutants

The proposed Guidance, while generally applying to all pollutants, was structured to provide an initial focus on 138 pollutants. The 138 pollutants were identified as those being known or suspected of being of primary concern in the Great Lakes Basin. The proposed Guidance included numeric criteria to protect aquatic life, human health, and/or wildlife for 32 of the 138 pollutants. The cost study for the proposed Guidance was based on these 32 pollutants. Because of concern that the 32 pollutants did not represent all the possible pollutants that may contribute to potential costs, EPA evaluated whether additional pollutants should be included in the cost analysis. The evaluation used three criteria to determining whether additional pollutants should be included in the final analysis: loadings, frequency of occurrence, and toxicity.

To determine which pollutants exhibited significant loadings to the Great Lakes Basin, the loadings for all 138 pollutants of initial focus listed in the proposed Guidance at the 59 study facilities were calculated. The loadings were based on facility permit limits or measured effluent concentrations. The loadings were then multiplied by EPA toxic weights to normalize the toxicity of each pollutant to that of copper. Using the statistical extrapolation factors developed for the costing analysis, the total toxic weighted loadings for the 138 pollutants were extrapolated to the universe of major dischargers in the Great Lakes Basin. Based on the results of this evaluation, EPA determined that pollutants that exhibited "de minimis" loadings would be omitted from the final costing analysis. The "de minimis" value selected was 10 pounds-copper toxicity equivalents per day. This value corresponds to a total pollutant load from all major point source dischargers to the Great Lakes Basin of 10 pounds of copper per day.

In addition to the loadings analysis, EPA wanted to ensure that other pollutants that were frequently limited or required to be monitored at facilities, but that might have been undetected or that exhibited low toxicity and thus were not captured in the loadings analysis, were also included in the final costing analyses. Since the loadings analyses should have captured the most significant pollutants of concern, this evaluation was considered a "safety net." This analysis captured any pollutant that was limited, detected, or required to be monitored at three or more of the 59 sample facilities.

As a final "safety net" EPA ensured that any pollutant limited, detected, or required to be monitored at any facility that exhibited a high toxicity (high toxic weight) was included in the final costing. This evaluation was performed by multiplying the "frequency of occurrence" for a given pollutant by its toxic weight. The resulting value was designated the "Occurrence Toxic Equivalent" (OTE). The OTE analysis captured those pollutants that might have not been detected, and so escaped the loadings evaluation, but that had monitoring requirements at one or more facilities. A target value of 0.1 OTE was selected to ensure that any pollutant with a toxic weight of 50 or greater, and even a single monitoring requirement at one sample facility, would be included in the final costing analysis.

The additional pollutant evaluation identified 76 pollutants that were limited, detected in the effluent, or required to be monitored at one or more of the 59 sample facilities. From this list of 76 pollutants, 37 were determined to be of consequence to the loadings and costing analyses using the rationale described above. This increased the total number of pollutants evaluated for loadings and costs in the final analysis to 69. The list of pollutants included in the final analysis and those found, but not included in the costing analyses, are provided in the following table.

PARAMETERS IDENTIFIED FOR FINAL COSTING ANALYSIS

PARAMETERS IN PROPOSED ANALYSIS	PARAMETERS ADDED FOR FINAL ANALYSIS	PARAMETERS FOUND BUT NOT ANALYZED
2,3,7,8-TCDD	1,1-Dichloroethane	2-Nitrophenol
2,4-Dimethylphenol	1,1-Dichloroethylene	4-Nitrophenol
2,4-Dinitrophenol	1,1,1-Trichloroethane	1,2-Dichlorobenzene
Arsenic(III)	1,2-Dichloroethane	1,3-Dichlorobenzene
Benzene	1,2-Dichloropropane	1,4-Dichlorobenzene
Cadmium	1,2-trans-Dichloroethylene	3,4-Benzofluoranthene
Chlordane	1,2,4,5-Tetrachlorobenzene	11,12-Benzofluoranthene
Chlorobenzene	2,4,6-Trichlorophenol	1,1,2-Trichloroethane
Chromium(III)	3,3-Dichlorobenzidine	1,2,4-Trichlorobenzene
Chromium(VI)	4,4-DDD	1,1,2,2-Tetrachloroethane
Copper	4,4-DDE	1,2,3,4-Tetrachlorobenzene
Cyanide, free	Acrylonitrile	2-Chlorophenol
Cyanide, total	Aldrin	2,4-Dichlorophenol
DDT	alpha-Endosulfan	2,4-Dichlorophenoxyacetic acid
Dieldrin	alpha-Hexachlorocyclohexane	Acenaphthene
Endrin	Aluminum	Acenaphthalene
Heptachlor	Antimony	Acrolein
Hexachlorobenzene	Benzidine	Anthracene
Hexachloroethane	Benzo[a]pyrene	Bis(2-chloroethyl)ether
Lindane	Beryllium	Bis(2-chloroisopropyl)ether
Mercury	beta-Endosulfan	Bromoform
Methylene Chloride	beta-Hexachlorocyclohexane	Butylbenzylphthalate
Nickel	Carbon tetrachloride	Chlorodibromomethane
Parathion	Chloroform	Chloroethane
PCBs	Chlorpyrifos	Dichlorobromomethane
Pentachlorophenol	Chrysene	Diethyl phthalate
Phenol	Endosulfan	Di-n-butylphthalate
Toluene	Fluoranthene	Dimethylphthalate
Total Selenium	Fluoride	Ethylbenzene
Toxaphene	Hexachlorocyclohexane	Fluorine
Trichloroethylene	Iron	Hexachlorobutadiene
Zinc	Lead	Indeno[1,2,3 cd]pyrene
	Pentachlorobenzene	Isophorone
	Phenanthrene	Methyl bromide
	Silver	Methylchloride
	Tetrachloroethylene	Naphthalene
	Thallium	Octachlorostyrene
		Pyrene
		Vinyl Chloride

An example of a pollutant found at study facilities, but excluded from the final analyses, is vinyl chloride. Vinyl chloride was limited in the permit for one facility and was detected in the effluent at a second facility. Based on the permit limit and the monitoring data, a total load for vinyl chloride of 0.04 pounds per day was determined. Using the vinyl chloride toxic weight of 0.0013 and extrapolating the load to the 588 major discharges in the Great Lakes Basin, a total toxic weighted load of 0.0018 pounds-equivalent per day was estimated, which is below the "de minimis" criteria of 10 pounds-equivalent per day. The occurrence frequency for vinyl chloride (2 of 50 facilities or 4 percent), did not exceed the trigger of 5 percent. The OTE was then calculated by multiplying the occurrence frequency of 4 percent by the toxic weight (0.0013). This resulted in an OTE of 0.00005, which is less than the 0.1 OTE trigger. As a result of this analysis, vinyl chloride was not considered in the final costing analyses.

Having established the list of pollutants for the final costing analyses, EPA developed criteria for these pollutants utilizing the Tier I and Tier II procedures outlined in Appendices A, B, C, and D of the final Guidance and readily available data.

c. Data for the Sample Facilities

The original analysis was performed based on data collected from EPA Region 5, State permitting authorities, EPA development documents, and special studies. Discharge data were based on 1990 Permit Compliance System (PCS) data, and facility-specific permit file information were generally from 1992. For this final rule, EPA ensured that the current information and data (including permits, fact sheets, permit applications, and other relevant discharge information) were used as the basis for comparison to Guidance requirements. In addition, State permitting authorities were requested to review each sample facility evaluated in the original cost estimate, and to provide comments and additional information as necessary to ensure accurate reflection of current permit requirements and discharge conditions.

For the cost estimate for the final Guidance, EPA specifically used 1993 PCS discharge data, as well as permit file information and data provided by the State permitting authorities (generally representing permits issued as late as through mid-1994). As a result of use of more recent data, EPA noted a shift in the baseline of permit requirements for the sample facilities; the baseline was lowered based on more stringent NPDES permit requirements being applied by permitting authorities. As will be discussed further in section IX.C.2 of this document, the overall effect of lowering the baseline is that estimated compliance costs and pollutant load reductions will not be as substantial as was originally projected for the proposed Guidance.

One of the limitations of the original compliance cost study was a general lack of site-specific receiving water data (i.e., background data) for the sample facilities. To fully evaluate EPA's provisions in the final Guidance for intake credits (i.e., determining whether discharges are to same or different bodies of water and for identifying non-attainment waters), as well as to ensure that all available data were used for the cost analysis, EPA gathered additional background concentration data for each of the sample facilities. EPA also reviewed and considered data submitted as a part of the public comments, as well as examined the water quality files contained in the STORET data base. In addition, EPA worked closely with the State permitting authorities to collect all applicable data.

Consistent with procedure 3 of appendix F to the final Guidance, EPA also collected fish tissue data (either caged or resident fish tissue data) to represent ambient water column background concentrations. When fish tissue data were available for the pollutants being evaluated at a sample facility, EPA used a simplified approach for converting the tissue data to ambient water column concentrations. This method entailed dividing fish tissue data (in mg/kg wet weight) by the pollutant-specific bioaccumulation factor (BAF) used to derive Tier I criteria (in l/kg) and multiplying the result by 1,000 to give the result as concentration of pollutant (μg/l). When data for more than one species was available, the geometric mean for all species was calculated and used.

d. Compliance Cost Decision Matrix

In deriving the cost estimate for the proposed Guidance, EPA assumed that when treatment costs became excessive in light of the amount of pollutant to be removed, or if information regarding the existing treatment system was lacking, that waste minimization/pollution prevention techniques would be the preferred control approach selected by the regulated community. In addition, for the proposed Guidance, EPA also did not consider the alternatives available to facilities through regulatory relief mechanisms such as variances, mixing zone studies, phased-TMDLs, site-specific criteria, etc.

The Guidance, consistent with the CWA and NPDES program, does not direct facilities on how to comply with permit requirements. Therefore, each regulated facility can consider a variety of options to comply with permit requirements. In estimating compliance costs, EPA selected control options for the sample facilities. However, in an effort to ensure consistency in estimating the general types of controls that would be necessary for a sample facility to comply with the final Guidance (assuming that the Guidance resulted in more stringent requirements), as well as to integrate into the cost analysis the other alternatives available through the final Guidance, EPA developed a costing decision matrix that was used for each sample facility. The underlying assumption of the decision matrix is that a facility will examine least-cost alternatives prior to incurring the expense and potential liabilities associated with constructing end-of-pipe treatment.

Under the decision matrix, costs for minor treatment plant operation and facility changes were considered first. Where it was not technically feasible to simply adjust existing operations, waste minimization/pollution prevention controls were considered; however, these controls were costed only where they were considered feasible based on EPA's understanding of the process(es) at a facility. In general, detailed treatment and manufacturing process information is not available in NPDES permit files; therefore EPA's assessment of feasibility was primarily based upon best professional judgement using general knowledge of industrial and municipal operations.

If waste minimization was deemed not feasible to reduce pollutant levels to those needed to comply with the final Guidance criteria, a combination of waste minimization/pollution prevention and simple treatment was considered. If these relatively low-cost controls could not achieve the Guidance-based WQBELs, then finally end-of-pipe treatment was considered.

However, before assuming that treatment would be installed by the facility, EPA first considered the relationship between the cost of adding the treatment and other types of remedies or controls. If EPA concluded that other remedies or controls would be more feasible than installing end-of-pipe treatment, EPA assumed that a facility would alternatively pursue some type of regulatory relief from the WQBEL. If the estimated annualized cost for removal of a pollutant exceeded $200 per toxic pounds-equivalent then EPA assumed that dischargers would explore the use of other remedies or controls. This cost trigger was based on the upper end of the range of the costs to comply with promulgated effluent guideline limitations and standards for direct discharger industrial categories. When EPA assumed that facilities would pursue alternative relief, no treatment cost was estimated for a facility; however, a nominal cost for some efforts to reduce the pollutant until the relief is granted was included. In addition, EPA did not take credit for any load reduction for any pollutant for which alternative relief was assumed. Finally, based upon discussions with EPA Regional and State permitting agencies and outside experts, EPA estimated the typical cost to facilities pursuing relief from Guidance-based WQBELs. These costs will be in the form of additional monitoring, performing special studies, etc., to support facilities' requests for relief from the Guidance-based WQBEL. The costs estimated by the Regions and States for the relief mechanisms ranged from a high of $1,000,000 per pollutant for phased-TMDLs to a low of $20,000 for criteria modifications. For purposes of estimating compliance costs, EPA used a mid-range cost value of $200,000 per pollutant for each time a relief mechanism was assumed necessary.

In developing and using the cost decision matrix, EPA acknowledges that granting relief from WQBELs is dependent upon the specific circumstances at a facility, as well as the judgement and implementing procedures of State and Tribal permitting authorities. EPA also acknowledges that opportunities for waste minimization are dependent upon the specific circumstances at a facility. The use of a $200 per toxic pounds-equivalent trigger for a "facility" assumes that the regulatory flexibility in the Guidance would be available and granted to all facilities that exceed the cost trigger. Section IX.D.1 of this document provides further discussion regarding the use of regulatory relief for purposes of estimating compliance costs for the final Guidance.

Acknowledging that the use of regulatory relief may be limited depending upon the particular circumstances for a "facility," EPA also estimated costs under a higher cost scenario that assumes regulatory relief would be granted only when the cost for the particular "category of dischargers" exceeds a cost trigger. Particularly, if the estimated annualized cost for a "category of dischargers" exceeded $500 per toxic pounds-equivalent then EPA assumed that dischargers within the "category" would be granted regulatory relief. This cost trigger was based on the highest costs to comply with promulgated effluent guideline limitations and standards for direct discharger industrial categories, which ranged from just over $1 to over $500 per toxic pounds-equivalent per industrial category.

e. Pollution Prevention/Waste Minimization Costs

As discussed briefly in the section above, EPA used waste minimization/pollution prevention techniques as controls for a number of sample facilities. The costs associated with the implementation of these techniques were originally based upon a limited evaluation of information available through the EPA Pollution Prevention Clearinghouse. In the absence of information for a particular category of dischargers, EPA used best professional judgement to estimate the cost to implement pollution prevention.

Since the time of proposal, EPA has attempted to collect additional information to verify or replace its original estimates of pollution prevention/waste minimization costs. EPA particularly solicited input from the EPA Pollution Prevention Office and the American Institute of Pollution Prevention. Both of these organizations acknowledged the difficulty in developing generic costs because of the site-specific nature of manufacturing processes and pollutants being removed. In fact, the implementation of waste minimization/pollution prevention techniques may actually result in a cost saving for a facility. Because of the general lack of information related to the cost of pollution prevention techniques, EPA retained its original estimates for waste minimization/pollution prevention.

f. Indirect Dischargers

As discussed in section IX.B.1.a of this document, EPA's basic approach to estimating indirect discharger costs was based on an analysis of one major, highly industrialized, sample POTW. Based on this evaluation, it was assumed that the number of indirect dischargers that could be affected ranged from 10 to 30 percent. To further verify this range, EPA analyzed information for an additional eight POTWs based on data collected from the Michigan DNR and Wisconsin DNR, as well as reevaluated the original sample POTW based on changes to the final Guidance (as reflected in estimated WQBELs for the POTW).

Since not all of the eight POTWs were selected as a sample facility and analyzed under the study, EPA assumed for the purpose of this analysis, that the pollutants limited by each POTW's existing NPDES permit would be the same as those that would require regulation under the Guidance (i.e., the Guidance would not result in additional pollutants being regulated, but would result in more stringent permit limits). Based on the results provided in the EPA *Draft Analytical Survey of Nine POTWs from the Great Lakes Basin* (December 15, 1994), this assumption was considered reasonable in light of the limited detection of pollutants, particularly BCCs. It should also be noted that information for three of the additional POTWs was not sufficient for EPA to determine the number of industries potentially affected.

For each POTW, the potential indirect dischargers of each regulated pollutant were identified from among the POTW's list of indirect dischargers, as well as the number of industrial users found to be violating the POTW's permit limits for any of the pollutants of concern over a 1-year period. Based on these data, the range of potentially affected indirect users is estimated to be 8 to 44 percent of the total number of the indirect dischargers to a POTW. The results show that EPA's assumed range of indirect dischargers affected (10 to 30 percent) had a reasonable basis.

For purposes of developing costs for the final Guidance, EPA assumed that 10 to 30 percent of all indirect dischargers in the Great Lakes Basin would be impacted by source control efforts by POTWs as a result of more restrictive Guidance-based WQBELs. EPA also updated the average compliance cost per direct discharger facility, based on the revisions made to the sample facilities as a result of the final Guidance, and used this updated compliance cost to estimate costs for indirect dischargers.

g. Revised Toxic Weights

EPA used toxic weights to derive cost-effectiveness estimates for the proposed Guidance, as well as to compare the relative loadings of the 138 pollutants of concern analyzed for the cost study (as discussed in section IX.B.2.a). Toxic weights are used by EPA as normalizing factors that relate the toxicity of any pollutant to the toxicity of copper. The factor considers the aquatic toxicity and the human health effects of a pollutant and is calculated using the following formula:

Toxic Weight = 5.6/[fresh water chronic criteria (μg/l)] + 5.6/[human health criteria (μg/l)]

The value of 5.6 μg/l was the original national chronic water quality criterion for copper; thus, the toxic weight for copper was equal to one. A pollutant with a toxic weight of 10, therefore, would be considered 10 times as toxic as copper.

The national chronic water quality criterion for copper has since been revised to 12 μg/l; however, the 5.6 value is retained by EPA for consistency. This results in copper currently having a toxic weight of 5.6/12, or 0.47.

EPA used toxic weights from 1988 in calculating baseline pollutant loads and load reductions for the proposed Guidance. These loads and load reductions are expressed in toxic pounds-equivalent. In analyzing the impact of the final Guidance, toxic weights were developed or recalculated for all 69 pollutants included in the cost study, using the most recent criteria and toxicity information available to EPA. These updates resulted in both raising and lowering of the 1988 toxic weights, depending on the toxicity data available for a specific pollutant.

2. Results

Based upon the adjustments made to the cost study approach as described in section IX.C.1 above, EPA revised its estimate for the compliance cost of the Guidance, as well as its estimate of pollutant reductions attributable to the final Guidance. This section presents these results and discusses them in relation to EPA's estimates for the proposed Guidance.

a. Estimated Compliance Costs

As shown in Table IX-2, the total annualized costs of implementing the final Guidance to direct and indirect dischargers is estimated to range from $61 million dollars to $376 million dollars. As shown in Table IX-2, under the low-end estimate, direct dischargers account for 67 percent of the total estimated compliance cost and indirect dischargers are estimated to incur 33 percent of the total cost. Under the high-end estimate, direct dischargers account for 98 percent of the total estimated cost, and indirect dischargers account for 2 percent. This shift in proportion of costs between direct and indirect dischargers between the high and the low estimates is due to the increased use of end-of-pipe treatment for direct dischargers under the high-end estimates. In addition, it was assumed that a smaller proportion of indirect dischargers (10 percent) would be impacted under the high-end estimate, since municipalities are adding end-of-pipe treatment which should reduce the need for source controls (i.e., reduce the need for increased pretreatment program efforts).

i. EPA's Low-End Estimate

Under the low-end estimate for the direct dischargers, municipal majors are expected to incur 39 percent of total costs and industrial majors account for 26 percent of total costs. Minor direct dischargers are estimated to incur just under 3 percent of the total costs. The two major industrial categories with the largest total annualized cost are the pulp and paper (14 percent of total) and miscellaneous (8 percent) categories. The food and food products and metal finishing categories are estimated to incur less than 1 percent of the total annualized cost.

Although the municipal major category accounts for almost 40 percent of the total estimated cost, the average annual cost is just over $75,000 per facility. Average annualized costs for industrial majors vary widely across categories, with the highest average cost estimated for the miscellaneous ($168,000 per plant) and pulp and paper ($151,000 per plant) categories. For minor facilities, average costs are negligible at an estimated $500 per facility.

Costs to direct dischargers for developing and implementing pollutant minimization plans (required when WQBELs are below detection levels) account for most of the costs (39 percent of total annual costs). Annualized capital and operation and maintenance costs make up just over 14 percent of total annual costs; waste minimization costs account for almost 8 percent.

Common to both the reevaluated proposal and the final Guidance, the lowering of the permit baseline (discussed previously in section IX.C.1.c of this document) also accounts for an overall decrease in compliance costs and load reduction. The lowering of the permit baseline was expected due to State implementation of the requirements of section 303(c) of the CWA, which required all States to promulgate water quality criteria for certain toxic pollutants. To ensure that the requirements of section 303(c) are met, EPA promulgated the National Toxics Rule (57 FR 6084; 12/22/92) to provide water quality criteria for pollutants for which States did not promulgate criteria. More important, each of the Great Lake States has been actively involved in the Great Lakes Water Quality Initiative since 1989, acting as co-partners and major participants in developing the Guidance.

By pollutant, controls for mercury account for over 20 percent of annual costs (attributable primarily to pollutant minimization plan-related costs). Other pollutants that account for significant costs include methylene chloride, aluminum, benzene, and copper.

TABLE IX-2
SUMMARY OF ANNUALIZED COSTS

COST CATEGORIES	NUMBER OF FACILITIES	LOW-END ESTIMATED COSTS (First quarter 1994 $, Millions)	HIGH-END ESTIMATED COSTS (First quarter 1994 $, Millions)
Major Direct Dischargers–Industrial	272	15.7	108.2
Major Direct Dischargers--Municipal	316	23.8	259.8
Minor Direct Dischargers	3,207	1.6	1.6
Indirect Dischargers	3,528	19.9	6.6
TOTAL	7,323	61.0	376.2

Source: Revised Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance.

ii. EPA's High-End Estimate

Under the high-end estimate for the direct dischargers, municipal majors are expected to incur just under 70 percent of total costs and industrial majors account for 29 percent of total costs. Minor direct dischargers are estimated to incur less than 1 percent of the total costs. The two major industrial categories with the largest total annualized cost are the pulp and paper (23 percent of total) and miscellaneous (3 percent) categories. Even under the high-end, the food and food products and metal finishing categories are estimated to incur less than 1 percent of the total annualized cost.

The municipal major category accounts for almost 70 percent of the total estimated cost, the average annual cost is just over $822,000 per facility. Average annualized costs for industrial majors vary widely across categories, with the highest average cost estimated for pulp and paper ($1,583,000 per plant) and miscellaneous ($433,700 per plant) categories. For minor facilities, average costs are negligible at an estimated $500 per facility.

For the high-end scenario, costs to direct dischargers shifted away from developing and implementing pollutant minimization plans and waste minimization to capital, operating and maintenance costs (over 52 percent of total annual costs) associated with construction and application of end-of-pipe treatment. Annualized costs for developing and implementing pollutant minimization plans make up just over 6 percent of total annual costs; waste minimization costs account for less than 1 percent.

By pollutant, controls for lead account for over 60 percent of annual costs (attributable primarily to end-of-pipe treatment related costs). Other pollutants that account for significant costs include heptachlor, pentachlorophenol, lindane, and mercury.

iii. Comparison of Estimated Costs for the Final Guidance to Costs of Proposed Guidance

Table IX-3 provides a comparison of EPA's cost estimate for the final Guidance to costs of the original proposal. The original proposal estimates were revised to reflect changes made in the approach to estimating costs for the final Guidance. As shown in Table IX-3, reevaluation of the original proposal resulted in an increase in costs of about $240 million under the low-end scenario and $265 million for the high-end when compared to the final Guidance.

As shown, EPA's annual cost estimate for the final Guidance is significantly lower than the revised estimates for the proposed Guidance. EPA attributes some of this reduction to the final Guidance intake credit provisions, which provide relief to several significant dischargers that discharge to non-attained waters, and to the use of dissolved metals criteria, which also tends to lower the costs for the final Guidance.

Consequently, most of the Guidance and current State water quality standards have a wide number of similarities. In fact, some States have already elected to promulgate more stringent requirements for a variety of Guidance-related provisions in anticipation of the Guidance. For example, New York, Minnesota, Illinois, and Wisconsin all use a higher fish consumption rate than required by the final Guidance for deriving human health criteria. Many of the Great Lakes States also currently have provisions in their water quality programs to account for additivity of risk from carcinogens. As a result of these and many other efforts by States, the stringency of NPDES permit requirements continues to increase, which decreases the incremental difference between the current State permit limits and Guidance-based WQBELs.

TABLE IX-3

COMPARISON OF PROPOSED AND FINAL COMPLIANCE COST ESTIMATES

COST CATEGORY	ANNUAL COMPLIANCE COST ESTIMATE ($ Millions)			
	ORIGINAL PROPOSAL (LOW ESTIMATE)[1] (1st Quarter 1994)	ORIGINAL PROPOSAL (HIGH ESTIMATE)[2] (1st Quarter 1994)	FINAL GUIDANCE (LOW ESTIMATE)[3] (1st Quarter 1994)	FINAL GUIDANCE (HIGH ESTIMATE)[4] (1st Quarter 1994)
Major Direct Dischargers--Industrial	20.7	376.5	15.7	108.2
Major Direct Dischargers--Municipal	259.9	259.9	23.8	259.8
Minor Direct Dischargers	1.6	1.6	1.6	1.6
Indirect Dischargers	19.9	6.6	19.9	6.6
TOTAL COST	302.1	644.6	61.0	376.2

[1] The proposed Guidance cost estimate revised to reflect the low-end cost assumptions made for the Regulatory Impact Analysis for the final Guidance.
[2] The proposed Guidance cost estimate revised to reflect the high-end cost assumptions made for the Regulatory Impact Analysis for the final Guidance.
[3] Estimated costs to comply with the final Guidance using low-end assumptions.
[4] Estimated costs to comply with the final Guidance, but assuming limited regulatory relief is available.

b. Estimated Pollutant Reductions

Table IX-4 presents the toxicity-weighted pollutant baseline and reductions estimated for the final Guidance. As shown in Table IX-4, the baseline pollutant loadings are projected to be approximately 36 million toxic pounds-equivalent per year (lbs-eq/year). This baseline pollutant loading represents a 71 percent reduction in the baseline projected by EPA for its original analysis of the proposed Guidance (126 million lbs-eq/year, April 16, 1993).

This downward shift in the baseline pollutant loadings is particularly significant in light of the fact that over 35 more pollutants were added for the analysis of the final Guidance. As discussed above, EPA attributes the shift to the fact that the existing permit baseline also moved downward (i.e., existing permit limits for the sample facilities were found to be more stringent). This downward shift in the permit baseline is due, in part, to increased efforts by States to protect water quality. EPA also attributes the difference to the use of dissolved criteria for metals for the final Guidance, which tended to eliminate metals from the cost and loading analyses. As discussed in section IX.C.1.d of this document, EPA did not take load reduction credit for pollutants for which regulatory relief was assumed necessary to comply with Guidance-based WQBELs.

Upon implementation of the final Guidance, EPA estimates that pollutant loadings under the low-end estimate would be reduced by 5.8 million lbs-eq/year, which represents a 16 percent reduction of the baseline pollutant loadings. Under the high-end cost estimate, pollutant loading reductions would increase by 1.8 million lbs-eq/year to a total of 7.6 million lbs-eq/year, which represents a 22 percent reduction of the baseline pollutant loadings.

The percent reductions estimated for the final Guidance are also lower than projected for the proposed Guidance reevaluated using the revised approach for estimating costs and load reductions. Pollutant loadings under the proposed Guidance would be 8.4 million lbs-eq/year (24 percent reduction) and 10.1 million lbs-eq/year (29 percent reduction) for the low- and high-end scenarios, respectively. The drop in estimated pollutant loadings can also be credited to the changes made by EPA to the criteria for the final Guidance (e.g., adjusting bioaccumulation factors, use of dissolved criteria for metals) and the toxic weights. The combined result of these changes was essentially less stringent criteria, which would tend to reduce the difference between existing permit limits and the Guidance-based WQBELs.

Under the low-end estimate for the final Guidance, the largest pollutant load reductions occur for dieldrin and lead, which account for over 50 percent of the toxic weighted load reduction. Chlordane, heptachlor, and pentachlorobenzene were also reduced by significant amounts from the baseline. Under the high-end estimate, the largest pollutant load reductions occur for heptachlor, dieldrin, and lead which account for about 70 percent of the toxic weighted load reduction.

TABLE IX-4

POUNDS-EQUIVALENT POLLUTANT LOADING REDUCTIONS

POLLUTANT	POLLUTANT LOADING (lbs-eq/year)		
	BASELINE	REDUCTION (LOW ESTIMATE)	REDUCTION (HIGH ESTIMATE)
Acrylonitrile	—*	—	-
Aldrin	—	—	-
Aluminum	2,379,890	25,419	25,419
Antimony	—	—	-
Arsenic(III)	21,975	21,556	21,556
Benzene	164	1	1
Benzidine	—	—	-
Benzo[a]pyrene	—	—	-
Beryllium	—	—	-
Cadmium	344,827	0	0
Carbon tetrachloride	648	527	562
Chlordane	975,523	664,604	664,604
Chlorobenzene	—	—	-
Chloroform	129	7	7
Chlorpyrifos	—	—	-
Chromium(III)	—	—	-
Chromium(VI)	—	—	-
Chrysene	—	—	-
Copper	2,402	744	744
Cyanide, free	95,940	10,623	10,623
Cyanide, total	—	—	-
4,4-DDD	45	23	23
4,4-DDE	21	10	10
DDT	88,152	212	212
3,3-Dichlorobenzidine	110,466	68,619	90,465
1,1-Dichloroethane	—	—	-
1,2-Dichloroethane	29	19	19
1,1-Dichloroethylene	62	0	0
1,2-trans-Dichloroethylene	—	—	-
1,2-Dichloropropane	5	5	5

POLLUTANT	POLLUTANT LOADING (lbs-eq/year)		
	BASELINE	REDUCTION (LOW ESTIMATE)	REDUCTION (HIGH ESTIMATE)
Dieldrin	3,190,719	2,092,368	2,092,368
2,4-Dimethylphenol	—	—	-
2,4-Dinitrophenol	—	—	-
alpha-Endosulfan	—	—	-
beta-Endosulfan	—	—	-
Endosulfan	—	—	-
Endrin	189,557	183,778	183,778
Fluoranthene	—	—	-
Fluoride	73,584	0	0
Heptachlor	2,324,390	434,659	2,201,441
Hexachlorobenzene	542,816	195,908	195,908
alpha-Hexachlorocyclohexane	82,945	81,721	81,788
beta-Hexachlorocyclohexane	23,117	22,423	22,423
Hexachlorocyclohexane	34,675	33,172	33,172
Hexachloroethane	—	—	-
Iron	17,732	0	0
Lead	1,794,813	1,080,141	1,080,141
Lindane	5,366	0	5,289
Mercury	519,286	66,304	67,878
Methylene Chloride	5	2	2
Nickel	88	76	76
Parathion	—	—	-
PCBs	454,908	0	0
Pentachlorobenzene	443,840	441,528	441,528
Pentachlorophenol	6,742	0	5,891
Phenanthrene	—	—	-
Phenol	—	—	-
Selenium, total	—	—	-
Silver	426,685	0	0
1,2,4,5-Tetrachlorobenzene	388,895	376,802	386,536
2,3,7,8-TCDD	3,989,245	0	0
Tetrachloroethylene	—	—	-

POLLUTANT	POLLUTANT LOADING (lbs-eq/year)		
	BASELINE	REDUCTION (LOW ESTIMATE)	REDUCTION (HIGH ESTIMATE)
Thallium	—	—	-
Toluene	12	0	2
Toxaphene	16,833,496	36,956	36,956
1,1,1-Trichloroethane	—	—	-
Trichloroethylene	8	6	6
2,4,6-Trichlorophenol	—	—	-
Zinc	1,735	76	76
TOTALS	35,364,934	5,838,289	7,649,510

*—indicates that there was no reasonable potential for the pollutant to exceed Guidance-based WQBELs for any of the sample facilities.

Approximately 80 percent of the pollutant load reduction for the final Guidance, regardless of the scenario, is attributable to reducing bioaccumulative pollutants of concern (BCCs) as a result of pollution minimization plans and end-of-pipe treatment. However, it should be noted that for several BCCs (e.g., PCBs, 2,3,7,8-TCDD, mercury, toxaphene), little or no reduction from the baseline is estimated. This phenomenon occurs because of the method used by EPA to derive load reductions. As described in section IX.B.2.a, when an existing permit limit or a Guidance-based WQBEL is below the analytical detection level, one-half of the method detection level is used for each. The result of this approach is that no pollutant reduction would be estimated, regardless of whether the Guidance-based WQBEL was further below detection levels than the existing permit limit. Therefore, in effect, for several of the toxic pollutants of concern, the lack of estimated reduction is due to the downward shift in the permit baseline (i.e., more stringent existing permit limits). As discussed below in the benefits section (section IX.E), this results in fewer benefits than originally anticipated for the April 16, 1993, proposal.

c. Estimated Cost-Effectiveness

EPA estimates that the cost-effectiveness of the final Guidance under the low-end estimate is just under $7.00/lbs-eq for the direct dischargers only; with the cost for indirect dischargers, the cost-effectiveness rises to $10.30/lbs-eq. Under the high-end estimate, the cost-effectiveness increases to just over $49.00/lbs-eq.

The estimates for the final Guidance are considerably more cost-effective than those estimated for the proposed Guidance using the revised approach ($35.96/lbs-eq and $63.82/lbs-eq; low-end and high-end scenarios, respectively). For comparative purposes, cost-effectiveness values for effluent limitations guidelines and standards range from just over $1.00/lbs-eq/year to over $500/lbs-eq/year.

D. Major Issues/Comments and Responses Related to Estimated Costs

EPA's cost estimate for the proposed Guidance generated extensive comments related to the potential costs of numerous aspects of the Guidance. In terms of the total estimated cost for the proposed Guidance, most of the regulated community, driven by the uncertainty of future impacts of the Guidance, claimed the costs were orders of magnitude higher than those estimated by EPA. Alternatively, there were concerns from several States that the estimated impact of the proposed Guidance, in relation to their current program to regulate point source dischargers, was too high.

The remainder of this section discusses the major issues raised by commenters and EPA's approach to evaluate and address these issues. In evaluating the impact of these issues on the cost to comply with the final Guidance, EPA used both the low- and high-end compliance cost estimates as the basis for comparison.

1. Use of Pollution Prevention/Waste Minimization to Achieve Guidance-Based Limits

a. Comments

Many comments from the regulated community stated that EPA's compliance costs relied too much upon pollution prevention techniques. Commenters maintained that pollution prevention techniques may not always be feasible for some industries and processes. This was particularly noted for mercury and PCBs that are apparently present in intake waters (deposited to surface waters through atmospheric deposition and precipitation, or release from historically contaminated sediments) for which pollution prevention would be infeasible. In the absence of process-specific information, many commenters felt that it is impossible for EPA to determine whether pollution prevention would reduce pollutants in process wastewaters.

b. Response

As discussed in section IX.C.1.e, EPA attempted to collect some data related to the cost and effectiveness of pollution prevention techniques for the pollutants being regulated under the final Guidance. The result of these efforts, which generally constituted an extensive review of the EPA Pollution Prevention Information Clearinghouse (PPIC), was that very little is documented regarding the effectiveness of pollution prevention to remove many of the pollutants subject to the Guidance. The limited data did, however, suggest that there are facilities that have reduced toxic pollutants to below analytical detection levels using pollution prevention techniques.

As also discussed in section IX.C.1.d., EPA developed and used a decision matrix for purposes of estimating the types of controls and costs associated with these controls to avoid unjustified use of waste minimization/pollution prevention techniques to achieve Guidance-based WQBELs. Under the decision matrix, waste minimization/pollution prevention was considered only after consideration of modifying existing treatment systems to achieve Guidance-based WQBELs. Further, waste minimization/pollution prevention controls were only considered when a relatively insignificant amount of pollutant needed to be removed (i.e., less than 10 to 25 percent of current discharge levels) and when EPA considered the production process or source generating the pollutant to be amenable to pollution prevention techniques.

As an alternative to the use of waste minimization/pollution prevention, EPA also considered the use of the flexibility provided through the Guidance (i.e., regulatory relief) as a control alternative in estimating costs for the final Guidance. However, the use of regulatory relief was limited to only those facilities (under the low-end scenario) and categories (under the high-end scenario) where the estimated cost was disproportionately high as compared to the resulting estimated pollutant reduction. The primary difference between the low-end and high-end cost estimates is that under the high-end scenario, EPA's decision matrix relied on end-of-pipe treatment to achieve Guidance-based WQBELs by limiting compliance costs based upon the use of waste minimization/pollution prevention techniques and the costs associated with pursuing a relief mechanism (e.g., standard variance, phased-TMDL, etc.).

In summary, in estimating costs to comply with the final Guidance, EPA has taken steps to ensure that the use of waste minimization/pollution prevention as a method to comply with Guidance-based WQBELs was limited to only those facilities where its use was considered technically feasible. This is particularly true under the high-end scenario where end-of-pipe treatment formed the basis of compliance cost estimates.

2. Future Impact of Detection Levels

a. Comments

Many commenters disagreed with the cost study approach for the proposed Guidance to only use current analytical detection levels as the basis for estimating costs. Further, many commenters stated that regular improvements in analytical detection levels should be expected over time, resulting in a dramatic impact on the costs to comply with the final Guidance in the future. Commenters felt that they would need to design and operate treatment systems and incur the costs now to achieve the WQBELs, in order to reduce the chance that the technology will have to be replaced when analytical detection levels improve in the future. Several commenters also stated that EPA underestimated the cost associated with implementing pollution prevention and waste minimization (through the required pollutant minimization plan) to consistently keep discharge levels below detection levels.

b. Response

In recent years, several States in the Great Lakes System have promulgated water quality criteria for various toxic pollutants that are more restrictive than the level of analytical detection. Implementation of these existing water quality criteria by these States do take into account the ability to detect the pollutant in the wastestream. Likewise, procedure 8, appendix F, of part 132 clearly provides that the water quality-based effluent limit must be derived from the water quality criterion; compliance with that limit, however, will be based on the Minimum Level (ML) where available. When a promulgated ML is not available, compliance with that limit may be based on the lowest level of quantification (at the State's discretion) defined in procedure 8 of part 132.

In estimating the compliance cost for the final Guidance, EPA conservatively used the method detection level (MDL) as the compliance level. In actuality, the State permitting authority is only required to use the ML (as defined under 40 CFR part 136), which is generally higher than the MDL, as the basis for reporting compliance with the Guidance-based WQBEL. Although EPA used the pollutant MDL for costing purposes, the Agency acknowledges that estimating treatment costs for WQBELs below the MDL, and most likely below the ML, would be speculative, particularly as such estimation relates to expected performance of treatment processes.

However, EPA does believe that an aggressive pollutant minimization plan can successfully result in compliance with WQBELs below detection levels. In fact, several of the sample facilities examined as part of the cost study have successfully performed studies, required as part of their current NPDES permit, to effectively reduce all detectable amounts of particular pollutants of concern from their discharge. For example, the State of Wisconsin required the Fort Howard Paper Company, as part of an NPDES permit special condition, to perform a PCB reduction study "to reduce PCBs to the maximum extent possible with a goal of zero discharge." Resulting effluent concentrations of PCBs allowed the State of Wisconsin to recommend reduced permit requirements for PCBs in the subsequent draft reissued permit.

EPA agrees that some facilities will want to ensure compliance with WQBELs below detection levels through the use of additional or enhanced end-of-pipe treatment. But as shown by the above examples, pollution minimization plans can be effective in achieving WQBELs below detection levels.

As discussed in section IX.C.2 of this document, EPA estimates that pollutant minimization plans account for a significant proportion of the total compliance cost under the low-end scenario. EPA evaluated the impact of these requirements by deriving cost estimates assuming that permitting authorities would only require increased monitoring for any pollutant for which a Guidance-based WQBEL was below analytical detection levels. Under this scenario, EPA estimates that annual compliance costs for direct dischargers will decrease by over 60 percent to $16.6 million. EPA did not take pollutant reduction credit when Guidance-based WQBELs were below detection levels, and as a result the estimated pollutant load reductions decrease to 1.3 million lbs-eq/day, which is almost 80 percent less then the reduction estimated for the final Guidance. Under the high-end, compliance costs do not drop as dramatically as the low-end costs due to the shift towards end-of-pipe treatment, however, the pollutant load reductions decrease by over 50 percent. Because of the impact on pollutant load reductions, EPA concludes that retaining the pollutant minimization plan requirements is justified for the final Guidance.

EPA also evaluated the potential impact improvements to analytical detection levels would have on compliance cost estimates. EPA particularly estimated costs and pollutant load reductions under two scenarios, one that assumes MDLs improve 10-fold over time and another that assumes MDLs improve 100-fold over time. The results of the analysis show conceivable increases in estimated compliance costs. When MDLs become 10 times more stringent, annual costs increase by over $500 million dollars. Pollutant load reductions also increase when MDLs decrease 10-fold by over 12 million toxic pounds-equivalent per year. When MDLs become 100 times more stringent, the annual compliance costs are estimated to increase by just over $880 million and pollutant load reductions would increase by approximately 19 million toxic pounds-equivalent per year above the final Guidance estimates. These results indicate that as analytical detection levels improve, the costs to implement the final Guidance increase. However, the projected increase in compliance costs are offset by comparable pollutant load reductions, which in the future could significantly improve water quality in the Great Lakes Basin.

3. Intake Credits

a. Comments

As described in section VIII.E.3 of this document, there were many comments related to whether EPA can and should regulate pollutants in a discharge that originate in the discharger's water supply. Many commenters particularly believed that the compliance costs would be very high if intake credits would not be provided for once-through, non-contact cooling water. In fact, most of the regulated community studies assumed that the proposed Guidance would not exempt once-through, non-contact cooling water, and these wastestreams were treated as process wastestreams for purposes of estimating compliance costs.

b. Response

In generating cost estimates for the proposed Guidance, EPA accounted for the provision that intake pollutants would not present reasonable potential at facilities that merely passed through the pollutants unchanged. As discussed in section IX.B.1.a, EPA also developed two different cost scenarios to account for the lack of ambient background concentration data and for negative wasteload allocations. As also discussed in section IX.C.1.a.ii, EPA revised its approach to developing cost estimates to reflect the intake pollutant provisions of the final Guidance.

In an effort to evaluate the impact of intake pollutants on estimated compliance costs, EPA developed compliance costs under a number of different intake pollutant scenarios. For discharges to different bodies of water, EPA estimates no significant impact (less than 0.5 percent) to either the compliance costs or pollutant load reduction estimates under both the low- and high-end scenarios, regardless of whether intake credits are relaxed (no net increase) or made more stringent (no intake credit allowed). This result occurred because discharges occurred infrequently to different bodies of water that were not attaining water quality standards for the pollutant or pollutants requiring intake credits.

Alternatively, the form of intake credits does impact discharges to the same body of water. When intake credits were not allowed for discharges to the same body of water, the annual compliance costs for direct dischargers increased by $245 million, representing over a 600 percent increase from the final Guidance low-end estimate. In addition, pollutant load reductions increased to 6.4 million lbs-eq/year, which represents a 9 percent increase from the final Guidance low-end estimate. The cost-effectiveness of the low-end scenario increases to almost $45/lbs-eq. EPA projects the same trend using high-end scenario costs where the costs increase by over 60 percent, but pollutant reductions increase by only 7 percent.

As a result of this analysis, EPA agrees that the absence of intake credit provisions, particularly for discharges to the same body of water, will have an impact on the cost to comply with the final Guidance. EPA, however, has included intake credits as part of the final Guidance.

4. Tier II Criteria

a. Comments

EPA stated in its cost estimate for the proposal that evaluating the costs to comply with only numeric Tier I criteria was a limitation of its cost study. Many commenters agreed with EPA and stated there would be a significant cost to comply with Tier II values. This cost would first include monitoring to generate the data for the Tier II value itself, and then the cost to comply once the values were used as the basis for a Guidance-based WQBEL.

b. Response

EPA agrees that compliance costs should have been estimated for pollutants for which Tier I criteria or Tier II values could be developed and that were present in effluent at levels of concern. As a result, EPA's cost estimate for the final Guidance is based upon evaluation of compliance for 69 pollutants (see discussion in section IX.C.1.a above). To determine the potential impact of the use of Tier I criteria versus Tier II values, EPA developed compliance costs under a variety of scenarios.

If only Tier I criteria are used, the annual compliance costs for direct dischargers would drop by $5 million, which is just under 12 percent of the final Guidance low-end estimate. The pollutant load reductions would also decrease by about 8 percent of the estimate for the final Guidance. Under the high-end scenario, both costs and pollutant load reductions decrease similarly (2 percent drop in costs and 6 percent drop in pollutant load reduction).

If Tier I criteria and Tier II values are used for all pollutants, the annual compliance costs increase insignificantly at both the low- and high-end. This result was expected since the scenario only added Tier II wildlife values. Although many of these additional Tier II wildlife values are more stringent than other Guidance criteria, the impact is insignificant since both the Tier II wildlife values and the other Guidance criteria are below analytical detection levels.

5. Wildlife Criteria/Mercury Criteria

a. Comments

A significant number of comments were received stating that the wildlife criteria, and particularly the criteria for mercury, would result in significant compliance costs for the regulated community. Of particular concern to commenters was the ubiquitous nature of mercury in the Great Lakes System, and, as a BCC, the potential for high costs associated with installing treatment to achieve the mercury criteria after mixing zones are eliminated.

b. Response

EPA agrees that the wildlife criteria proposed under the Guidance could impact the costs to comply with the Guidance. As discussed in section V.I of this document, the final wildlife criteria for mercury has increased from 180 picograms per liter (pg/l) to 1,300 pg/l. Further, the final Guidance limits the use of the wildlife criteria methodology to the Tier I procedure for the 22 BCCs for which sufficient data exist.

The final Guidance cost estimate includes Tier I wildlife criteria for mercury, 2,3,7,8-TCDD, PCBs, and DDTs. In addition, hypothetical Tier I criteria were developed for three additional BCCs and hypothetical Tier II values for 21 other pollutants which were used to assist in estimating costs for the final Guidance. Six of the 21 pollutants are not BCCs, which tends to further overstate the impact of the wildlife criteria, as the final Guidance limits development of Tier I wildlife criteria for only BCCs. Further, these values were estimated using many simplifying and conservative assumptions that are expected to be generally more stringent than the values that would be derived by permitting authorities using the wildlife methodology in the final Guidance.

However, using the additional wildlife criteria results in an insignificant increase in annual compliance costs. Alternatively, excluding all wildlife criteria also results in essentially no difference in compliance cost estimates at both the low- and high-end. These results indicate that factors other than the wildlife criteria tend to drive the costs of the final Guidance. In the absence of wildlife criteria, the Guidance human health criteria would form the basis for Guidance-based WQBELs. The Guidance human health criteria for most pollutants are below analytical detection levels and, as such, the costs for treatment and pollutant minimization plans would be incurred by a facility. Although the wildlife criteria in general are more stringent than the Guidance human health criteria, they would also result in Guidance-based WQBELs below analytical detection levels and, therefore, the same treatment and pollutant minimization plan requirements and costs.

6. Elimination of Mixing Zones for BCCs

a. Comments

EPA received numerous comments that the study neglected the costs related to the eventual elimination of mixing zones provision for BCCs. Further, most commenters stated that the elimination of mixing zones for BCCs in 12 years will impose enormous costs without commensurate benefits.

b. Response

As discussed in section VIII.C of this document, and as promulgated in procedure 3 of appendix F to part 132, the final Guidance retained the requirement for elimination of mixing zones within 12 years, but does provide some flexibility to allow limited mixing zones for BCCs if the facility can show that all prudent and feasible treatment technologies are being implemented to reduce the discharge of BCCs to the maximum extent possible.

EPA began to address this issue in the sensitivity analyses performed for the proposal. In general, if analytical detection limits remain the same, it was concluded that a cost would be incurred infrequently for a BCC after mixing zones have been taken away. This conclusion was based on the fact that many of the WQBELs and associated criteria for BCCs were already below analytical detection levels.

In estimating costs for the final Guidance, EPA conservatively assumed that no mixing zones were allowed for BCCs. The cost for the final Guidance was presented previously in section IX.C.2. To determine the impact of this requirement on facilities (in terms of cost) and the environment (in terms of pollutant load reductions), EPA revaluated the sample facilities allowing the same mixing zones for BCCs as are allowed for non-BCCs.

EPA estimates that the addition of mixing zones for BCCs results in an incremental annual cost savings to direct dischargers of just over $200,000, which is less than a 0.5 percent increase above the final Guidance low-end estimate. In terms of pollutant load reductions, the addition of mixing zones results in lowering reductions by 15,700 lbs-eq/year (which is less than 1 percent of the total estimated pollutant reductions for the final Guidance). Slight reductions in cost and pollutant load reductions were also found under the high-end scenario.

The relatively small impact associated with the elimination of mixing zones for BCCs is primarily because the criteria for most BCCs are relatively stringent, and usually well below analytical detection levels. Even with the dilution afforded by the mixing zones allowed under the final Guidance, the resulting WQBELs are still below analytical detection levels and, as a result, do not drastically impact the costs and load reductions (i.e., the pollutant controls would not change if both WQBELs were below analytical detection levels). As a result of this analysis, EPA disagrees that the elimination of mixing zones for BCCs will have an adverse impact on the regulated community.

7. Antidegradation

a. Comments

EPA received numerous comments that the regulatory impact analysis for the proposed Guidance neglected the costs related to the antidegradation provisions. Although EPA performed a sensitivity analysis for the antidegradation issue at the time of proposal, many comments stated that the analysis only estimated the cost of the demonstration process. Many commenters felt that although the demonstration process can assist in compliance, it does not ensure compliance or necessarily make it cheaper. Finally, many commenters stated that the antidegradation provisions will inhibit economic growth in the region, because facilities would be prohibited from returning to full production or increasing current production capacities.

b. Response

EPA agrees with the commenters that the antidegradation provision of the final Guidance, as promulgated under appendix E to part 132, may impact the regulated community. However, EPA disagrees that the impact will be significant. EPA also agrees that costs other than demonstration cost may be incurred by a facility in the form of lost opportunities for business.

In an effort to estimate what the lost opportunity cost could be related to implementation of the antidegradation provision of the Guidance, EPA performed a separate cost analysis. This analysis was based on the antidegradation requirements for BCCs contained in the final Guidance, that requires an antidegradation review if there is a deliberate action on the part of a facility that results in a significant lowering of water quality (i.e., the activity results in an increase in BCC loadings). The general premise behind EPA's analysis was that the economic growth in the region (as indicated by total value of shipments for six major categories of direct dischargers in the basin) would continue at a pace equal to the average growth over the last 8 years (1987-1994). The resulting estimated incremental annual growth ($864 million) served as the baseline from which impacts were estimated.

Under the worst case, it was assumed that all facilities with BCCs in their discharge (approximately 5 percent of all facilities) requested an antidegradation review and were denied; thus, 5 percent, or $43.2 million, of the incremental annual growth would be lost due to the Guidance. More realistically, if it was assumed that half of the facilities requesting antidegradation reviews for BCCs were allowed to increase discharges, only $21.6 million of opportunity would be lost each year. Finally, assuming that only 10 percent of the facilities discharging BCCs request an antidegradation review, and only half are denied, then the opportunity lost for growth would be approximately $2.2 million.

EPA does not expect to see an increase in baseline loadings for BCCs because for many, their use is already banned or severely restricted by the Agency. A study performed for EPA shows that 14 of the 28 BCCs are banned or severely restricted, and another four of the 28 are by-products of banned or severely restricted BCCs. The remaining 10 BCCs have some limited restrictions for use or are not restricted at all, or no data were found for them. EPA therefore believes that the mid- and high-estimates of lost opportunity are unlikely because the increase of banned or restricted BCCs should not occur due to releases from the manufacture or use of the BCC. In fact, EPA assumes that the levels of these BCCs will decrease over time in point source discharges and in the environment. Several other BCCs are present as contaminants or by-products of banned or restricted BCCs (e.g., heptachlor epoxide is a metabolic breakdown product of heptachlor), and for the same reason, the levels of these BCCs should also decrease over time. Therefore, EPA does not anticipate antidegradation reviews as a result of an increase in loading levels for BCCs that result in a significant lowering of water quality.

If the low-end estimate is used, then EPA would expect a modest 3 percent increase in the low-end annual compliance cost. The potential benefits, although not quantified by EPA, could be relatively significant for some receiving waters because additional discharges of BCCs would be denied.

8. Additivity

a. Comments

EPA received several comments related to the potential impact of the additivity provision discussed in the preamble to the proposed Guidance. Most of these commenters felt that the additivity provision will increase the estimated compliance costs of the Guidance.

b. Response

In an effort to evaluate the impact of the additivity provision on the compliance cost of the final Guidance, EPA developed cost estimates for two scenarios. Under one scenario, EPA assumed that additivity would be controlled if the total carcinogenic risk in a discharge was less than 10^{-5} and accounted for by assuming that individual criteria were based on a 10^{-5} risk level. Under the second scenario, EPA assumed that the additive effects from carcinogens would be accounted for if individual criteria were based on a 10^{-6} risk level.

The impact of the first scenario was relatively insignificant (less than 0.5 percent decrease in costs and just over 1 percent decrease in pollutant load reductions at both low- and high-end estimates). The relatively insignificant change in cost and load reductions is based on the fact that most facilities did not detect more than a few carcinogens in their discharge. As a result, the final Guidance estimates (based upon a total carcinogenic risk of 10^{-5} but accounted for by distributing the risk across all carcinogens in the effluent) did not represent more stringent WQBELs for carcinogens, as compared to only accounting for the risk through the individual criteria.

When the individual criteria risk level is adjusted down to a 10^{-6}, a more dramatic increase in costs occurs. EPA estimates that a 10^{-6} risk level for individual criteria would increase the low-end estimate of annual compliance costs for direct dischargers by $10.4 million. The associated load reductions do not increase as dramatically, accounting for only an additional 6,000 lb-eq/year. The reason a large pollutant reduction did not accompany the large increase in costs under the low-end scenario is the assumption that a significant number of facilities would pursue some sort of regulatory relief, for which there is no pollutant reduction credit, to meet the more stringent criteria based on a 10^{-6} risk level.

The same trend occurs at the high-end, where EPA estimates that costs will increase by over 30 percent, but pollutant load reductions will decrease by less than 1 percent. However, under the high-end scenario where variances are limited to categories that exceed the high-end cost trigger, the significant increase in costs is due to the costs associated with installing and maintaining end-of-pipe treatment for pollutants impacted by the more stringent criteria. The insignificant load reductions associated with the large increase in costs is due to the fact that some regulatory relief was still justified under the high-end. Further, for some pollutants with criteria below the analytical detection level, the shift from criteria based on a 10^{-5} risk level to criteria based on a 10^{-6} risk level resulted in criteria further below analytical detection levels, which had no impact on pollutant load reductions.

In summary, the additivity provision included in the final Guidance could have a significant impact on the cost to comply, depending upon how States and Tribes decide to implement the final additivity provisions. As a result, EPA provided implementation flexibility in the additivity provisions for the final Guidance to afford States and Tribes a broad range of alternatives, which will allow cost-effective decision-making under a variety of circumstances without sacrificing human health or environmental protection.

9. Other Study Costs

a. Comments

The majority of comments received by EPA related to the regulatory impact analysis for the proposed Guidance stated that EPA severely underestimated the costs to comply. One commenter stated that compliance costs are "likely to be 10, 20, or even 100 times higher" than the $232 million annually predicted by EPA. Many commenters supported the results of an independent impact study that estimated compliance costs to be between $710 million and $2.3 billion per year.

Many commenters provided their own estimates of the cost of the proposed Guidance, and in most instances, the cost estimates provided were far greater than the total cost estimated by EPA. The cost estimates provided by commenters for many individual facilities were most frequently on the order of $10 to $50 million in total capital investment costs alone; two different municipalities estimated total capital costs in excess of $100 million.

Many industry groups also provided compliance cost estimates that were significantly higher than those projected by EPA. One group representing the pulp and paper industry in the Great Lakes concluded that the proposed Guidance would require $1.25 billion for new capital equipment and $284 million in annual costs. Another group, representing Michigan POTWs, estimated that annual costs for the proposed Guidance would be $110 million. Another group representing the chemical industry in New York estimated that the proposed Guidance would cost from $45.2 million to $76.1 million in total capital costs, and between $9.6 million to $17.7 million in annual operation and maintenance costs.

b. Response

While EPA did not evaluate in detail the process-specific and plant-specific information submitted my the many commenters, EPA believes that several general observations can be made regarding these studies and how they differ from the EPA cost study.

EPA noted that most studies assumed that an intake pollutant provision would not be available in the Guidance, and thus several studies include costs to treat intake water. As discussed in section IX.C.3.c of this document, the final Guidance includes provisions for intake pollutants for discharges to both the same and different bodies of water. Further, in its analysis of intake pollutant options, EPA concluded that including intake pollutant provisions for discharges to the same body of water would decrease costs six-fold from the estimated cost of compliance.

Many commenters also assumed that the "no addition of mass" provision of the proposed Guidance would include, for example, metals leaching from intake pipes. As a result, these commenters assumed that there would be reasonable potential to violate water quality standards and the resulting outfalls would be subject to the proposed Guidance. The final Guidance retains the prohibition against "no addition of mass" to qualify for a determination that a reasonable potential to violate water quality standards does not exist. The final Guidance provides facilities in this situation relief in the form of allowing "no net addition" limits for discharges to non-attained waters if the source of the intake water pollutant and the point of discharge is to the same body of water. The final guidance gives permitting authorities discretion to determine how to assess compliance with a "no net addition" limit.

The majority of cost estimates provided by commenters include the costs for the addition of end-of-pipe treatment to achieve proposed Guidance-based WQBELs. This was particularly the case when WQBELs were expected to be below analytical detection levels. EPA disagrees that end-of-pipe treatment is necessary to achieve Guidance-based WQBELs in all cases. As discussed in section IX.C.3.b, there are documented cases where waste minimization techniques have been used to comply with existing permit limits established below detection levels. Although waste minimization is not always applicable, EPA assumes that a facility would first evaluate whether process changes or modifications are feasible, prior to incurring costs for adding treatment. Even so, as discussed in section IX.C.2.a, EPA estimates that the annual cost for all direct dischargers would be about $370 million with limited use of regulatory relief mechanisms and waste minimization as control options.

Finally, EPA agrees with the many commenters who included costs to comply with Tier II values. As discussed in section IX.C.1.b of this document, EPA included cost estimates to comply with the most prevalent and toxic pollutants for which Tier II values could be derived.

E. Benefits

1. Summary of Proposal

a. Introduction

The following discussion describes the methodologies and results of the benefits analysis that accompanied proposal of the Guidance in April, 1993. The benefits analysis was intended to provide insight into both the types and potential magnitude of the economic benefits expected to arise as a result of the proposed Guidance. A qualitative assessment of these benefits was provided. In addition to the qualitative assessment, empirical estimates of the potential magnitude of the benefits from controlling point sources were developed to the extent feasible, and then compared to the estimated costs of the proposal. This discussion was intended to demonstrate data needed and a methodology suitable for comparing benefits and costs. The qualitative and quantitative benefits assessments are summarized below.

b. Qualitative Assessment of Benefits

A qualitative assessment of the anticipated benefits of the proposed Guidance focused on: (a) the sensitivity and unique attributes of the receiving waters, (b) the nature of the toxic pollutants addressed by the proposed Guidance and some implications for human health and ecological risk reductions, and (c) an overview of exposed and sensitive populations. Substantial benefits were predicted from the proposed Guidance due to the significant health and ecologic risks posed by the chemicals addressed when combined with physical characteristics of the Great Lakes that cause them to be particularly vulnerable to bioaccumulative toxic pollutants. Given the long retention time, low sedimentation, low productivity in the Great Lakes System and the presence of self contained, vulnerable populations (and hence the persistence of toxic contaminants in this ecosystem), loadings reductions realized as a result of the proposed Guidance were expected to have lasting impacts on mortality risk and the reproductive success of many aquatic, avian, and mammalian species of concern. These benefits included increased productivity and protection of biological diversity of Great Lakes species including salmonids and other fish species, cormorants, eagles, osprey, and otters.

The persistence and toxicity of the compounds to be directly controlled from point sources under the proposed Guidance had important implications for the benefits analysis. The principal benefits are difficult to forecast because most of the direct benefits (1) are likely to be delayed for many years, and (2) are largely ecologic in nature. For example, the Guidance provides added protection for endangered species with provisions for site-specific criteria modification.

Fish and waterfowl consumption advisories are likely to be lifted as concentrations of toxic compounds are reduced. Such actions, and water quality improvements leading to those actions, would result in increased recreational fishing and hunting opportunities and increased values for recreational fishing and hunting days. According to the U.S. Fish and Wildlife Service's 1985 National Survey of Fishing, Hunting, and Wildlife-Associated Recreation (U.S. Department of Interior, Washington, D.C., 1989), the Great Lakes supported more than 46 million angler days in that year. Even a small increase in the number of angler days or the value associated with improvements in Great Lakes angling would provide significant annual benefits. Other recreational opportunities, including boating, swimming, and wildlife observation would also be expected to be enhanced as water quality and ecosystem health improve. Health risk reduction benefits are likely to be generated through reduced exposure from the consumption of fish and wildlife (particularly among subsistence populations relying on Great Lakes fish and wildlife as a primary food source). The value of these improvements would accrue not only to direct users of the Great Lakes, but also to nonusers who ascribe values to the ecologic benefits resulting from the implementation of the proposed Guidance.

c. <u>Quantitative Assessment of Benefits Analysis</u>

Quantitative benefits estimates were prepared for three case study sites: (1) the lower Fox River drainage, including Green Bay, located on Lake Michigan in northeastern Wisconsin; (2) the Saginaw River and Saginaw Bay, located on Lake Huron in northeastern Michigan; and (3) the Black River, located on Lake Erie in north-central Ohio. The case studies focused on empirically tractable benefit categories, and omitted several types of potential benefits. In addition, the numerical results were based on limited assessments of the extent to which the Guidance might contribute to improvements beyond baseline levels, and were not intended to illustrate sensitivity to modest changes in either the timing or stringency of water quality criteria and associated discharge permit limits.

Rather, the benefits analysis was geared toward indicating: (1) the types of benefits to be anticipated; (2) a general approach for describing and, as feasible, estimating these benefits; (3) the general magnitude of the monetized worth of several categories of benefits; and (4) an indication of how benefits compared to costs. These concepts and results are summarized below.

i. <u>Economic Concepts Applicable to the Benefits Analysis</u>

The term economic benefits refers to the dollar value associated with all of the expected direct positive impacts of the proposed Guidance; that is, all outcomes that lead to higher social welfare. Conceptually, the monetary value of benefits is embodied by the sum of the predicted changes in consumer (and producer) surplus. These surplus measures are standard and widely accepted terms of applied welfare economics, and reflect the degree of well-being enjoyed by people given different levels of goods and prices (including those associated with environmental quality).

This conceptual economic foundation raised three relevant issues and potential limitations for the benefits analysis of the proposed Guidance. First, the standard economic approach to estimating environmental benefits is anthropocentric--all benefit values arise from how environmental changes are perceived and valued by humans. Second, benefits of all future outcomes are valued by the present-day human population. Third, all near-term as well as temporally distant future physical outcomes associated with reduced pollutant loadings need to be predicted and then translated into the framework of present-day human activities and concerns.

The potential benefits associated with the proposed Guidance included two broad categories: use benefits and nonuse benefits (also referred to as passive use, or intrinsic benefits). The use benefit category embodies both direct and indirect uses of the impacted waters, and the direct use category embraces both consumptive (e.g., fishing) and non-consumptive (e.g., wildlife observation) activities. In most applications to pollutant reduction scenarios, the most prominent use benefit categories are those related to recreational fishing, boating and/or swimming.

Recreational use benefits may or may not reflect society's prime motivation for environmental protection measures; however, recreational activities are amenable to various non-market valuation techniques (e.g., travel cost models) and, accordingly, have received considerable empirical attention from economic researchers over the past two decades. Thus, there is a considerable body of knowledge relating to recreational fishing and related activities, and these generally indicate that water-based recreation is a highly valued activity in society. Accordingly, many benefits analyses focus on recreational values because they are well understood, there is a large body of empirical research to draw upon, and the associated benefits tend to be quite large.

Improved environmental quality can also be valued by individuals apart from any past, present or anticipated future use of the resource in question. Such nonuse (or intrinsic) benefits include aesthetic, bequest (preservation for future generations), and existence (e.g., ecologic) values. Nonuse values may be of a highly significant magnitude; but the benefit value to assign to these motivations often is a matter of considerable debate. Whereas human uses of a resource can be observed directly and valued with a range of technical economic techniques, nonuse values can only be ascertained from directly asking survey respondents to reveal their values. The inability to rely on revealed behavior to ascertain nonuse values has led to debates as to whether they exist for applicable changes in environmental quality and, if so, whether they are of an appreciable magnitude relative to use values. As described below, nonuse benefits were considered relevant and of appreciable magnitude for the proposed Guidance.

The category of nonuse values considered most important for the proposed Guidance was ecological benefits associated with decreasing the level of toxic compounds found in Great Lakes waters and sediment. Such ecological benefits are likely to embody reduced risks of direct mortality, and increased reproductive success, in a range of important fish and wildlife species. The species include, but are not limited to, bald eagles, cormorants, and other piscivorous avian species; mink, river otter and other mammalian species that feed on fish and crustaceans; and a wide range of aquatic species such as lake trout and other salmonid species.

ii. Benefits Methodologies

The quantitative case study benefits analyses utilized benefits transfer techniques. Benefits transfer is an approach to estimating benefits in which benefits estimated for one site are "transferred" to another site. The use of benefits transfer is not new to EPA; the resource-intensive demands associated with developing benefits estimates often leads EPA to use existing data sources and studies to prepare benefits estimates.

The empirical results presented in the case study analyses utilized benefits estimates from relevant research on water quality improvements. Several of these estimates included results derived from contingent valuation methodology (CVM) (as well as the travel cost methodology and other techniques). CVM is an approach in which hypothetical markets are constructed and presented to individuals in a survey format, with the responses used to infer prices and values for the goods and services being evaluated (such as those associated with different levels of environmental quality). Because the CVM approach relies on survey responses to hypothetical conditions and markets, there is controversy surrounding its validity. However, CVM is the only method available for estimating nonuse benefits.

Furthermore, a U.S. Department of Commerce, National Oceanic and Atmospheric Administration (NOAA) Blue Ribbon Panel (K. Arrow, R. Solow, P.R. Portney, E.E. Leamer, R. Radner, and H. Schuman, Report of the NOAA Panel on Contingent Valuation, NOAA, Rockville, Maryland, 1993) review of CVM to measure nonuse values concluded that CVM can produce reliable estimates for use in the litigation process to determine natural resource damages. The panel set forth a number of guidelines for CVM surveys considered to generate more reliable results. However, the NOAA panel evaluated CVM as a means of estimating nonuse values for use in litigation to determine the liability of a specific party. In comparison, the CVM estimates utilized in the case study analyses are used in an informational context, to compare benefits to costs. Strict conformance to the NOAA guidelines is not essential when using the methodology as a source of benefits information in a policy setting.

iii. <u>Results</u>

For each of the case studies, benefits estimates were derived in one of two fashions, depending on data availability: (1) the benefits of a discrete change in water quality beyond present day conditions were estimated (wherever feasible), and then a share of those benefits was apportioned to the proposed Guidance; or (2) the current value (at present water quality) of a benefit category was assessed, and then the benefits of the proposed Guidance were estimated based upon a range of plausible percentage increases in the level of benefits (as plausibly attributable to the proposed Guidance) beyond the current baseline.

Costs for the case studies were derived using the methodology developed to estimate the total costs of the proposed Guidance, but with application to the dischargers present in each specific watershed. Case study costs included costs to direct dischargers only. The results, as summarized in Table IX-5, indicated that the potential benefits of the proposed Guidance under the attribution assumptions applied appeared to be commensurate with the most likely cost estimate (Scenario 2). These results were, as noted throughout, sensitive to how water quality benefits were attributed to the proposed Guidance as opposed to other water quality-impacting actions that are in progress, or anticipated, absent the Guidance. In addition, the results in Table IX-5 are portrayed in annualized terms, and do not account for the discounting of potentially delayed benefits. However, a more standard form of net present value calculation, embodying delays in the realization of benefits, generated comparable results (e.g., present value costs being within the range of present value benefits). These results are summarized in Table IX-6.

TABLE IX-5

CASE STUDY BENEFIT-COST RESULTS FOR GREAT LAKES WATER QUALITY GUIDANCE[a]
(MILLIONS OF 1992 [FIRST QUARTER] DOLLARS PER YEAR)

BENEFIT CATEGORY	CASE STUDY SITE		
	FOX RIVER/ GREEN BAY	SAGINAW BAY	BLACK RIVER
Recreational Fishing	0.9 - 6.1	0.9 - 8.1	0.1 - 0.6
Recreational Boating and Swimming	+	+	0.0 - 0.1
Subsistence Fishing	+	+	+
Commercial Fisheries	0.2 - 0.3	0.2 - 0.7	
Waterfowl and Other Hunting	+	0.1 - 0.1	+
Nonconsumptive Use	1.3 - 1.8	0.2 - 0.7	+
Human Health Benefits	+	+	+
Nonuse/Ecologic Values	0.5 - 3.7	0.5 - 7.1	0.0 - 0.6
Total Benefits	2.9 - 11.9	1.9 - 16.7	0.1 - 1.2
Annualized Costs[b]	5.1	6.0	1.0

+ Positive benefits anticipated, but not estimated in monetary terms.
[a] See body of report for explanation of assumptions employed to attribute benefits to the Guidance, and their application to specific benefit estimates.
[b] Source: SAIC 1993, Cost Scenario 2.
Note: Numbers may not add to total due to rounding.
Source: Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance, April 1993.

TABLE IX-6
COMPARISON OF GUIDANCE POTENTIAL BENEFITS TO COSTS[a]
(MILLIONS OF 1992 [FIRST QUARTER] DOLLARS)

FOX RIVER CASE STUDY	BENEFITS RANGE	COST RANGE[b]	SCENARIO 2 COST[c]
Direct Annualized Comparison	$2.8 - $11.9	$2.7-$14.1	$5.1
Discounted Benefits and Costs[d]			
10 Year Phase-in of Benefits	$45.2 - $185.7	$24.8 - $194.1	$44.8
20 Year Phase-in of Benefits	$34.3 - $140.6	$24.8 - 194.1	$44.8
SAGINAW RIVER/BAY CASE STUDY	BENEFITS RANGE	COST RANGE[b]	SCENARIO 2 COST[c]
Direct Annualized Comparison	$1.9 - $16.7	$2.1 - $29.3	$6.0
Discounted Benefits and Costs[d]			
10 Year Phase-in of Benefits	$29.6 - $260.5	$31.5 - $537.8	$76.2
20 Year Phase-in of Benefits	$22.4 - $197.3	$31.5 - $537.8	$76.2
BLACK RIVER CASE STUDY	BENEFITS RANGE	COST RANGE[b]	SCENARIO 2 COST[c]
Direct Annualized Comparison	$0.1 - $1.2	$0.3 - $7.6	$1.0
Discounted Benefits and Costs[d]			
10 Year Phase-in of Benefits	$1.6 - $18.7	$4.5 - $142.8	$11.7
20 Year Phase-in of Benefits	$1.2 - $14.2	$4.5 - $142.8	$11.7

[a] See body of report for explanation of assumptions employed to attribute benefits to the Guidance, and their application to specific benefits estimates.
[b] Range over 4 cost scenarios (SAIC, 1993).
[c] Most likely cost scenario.
[d] Present value over 30 years, using a 7 percent discount rate.
Source: Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance, April 1993.

In conclusion, estimating the benefits of the proposed Guidance presented significant challenges. It was difficult to fully account for and portray the types of long-term ecologic benefits anticipated from the control of the toxic compounds addressed on the Tier 1 list. This was largely a result of the persistence and potential for bioaccumulation of these compounds, and the "nonuse" nature of benefits to Great Lakes species of concern (which are less easily quantified and monetized than direct consumptive uses). It also was difficult to empirically base attribution of the benefits of water quality improvements between current conditions and the baseline appropriate to the proposed Guidance. Given these caveats, however, the case study results suggested that under the attribution assumptions made explicit in the analyses and the most likely cost scenario, the projected benefits of the proposed Guidance were commensurate with its costs.

2. Major Issues/Comments and Responses

This section provides a summary of the major issues and public comments related to the benefits analysis and the economic impact of the proposed Guidance, and EPA's responses to these issues/comments. The discussion is organized by benefits topic areas.

a. Attribution of Benefits to the Guidance

The RIA described the basis by which a portion of the potential benefits illustrated in the case study analyses were attributed to the proposed Guidance, and the numerous sources of uncertainty surrounding these estimates. In general, baseline resource values and the value of water quality improvements were based on available data and applied research. However, data were not available on the potential contribution of the proposed Guidance towards such changes.

One uncertainty in the attribution of benefits relates to knowing the water quality baseline relevant to implementation of the Guidance. Assumably, this baseline is at some point cleaner than current conditions because of a number of regulatory actions that have been promulgated, but not yet fully implemented (e.g., efforts to comply with 303(c)(2)(B) of the Clean Water Act, guidance for nonpoint source controls in coastal areas). Similarly, at the other end of the water quality spectrum, it is not clear what water quality benchmark the Guidance will attain with respect to removing fish consumption advisories and moving towards a "toxic free" status.

Another important uncertainty in the attribution issue lies in the relative contribution of point sources to the problems addressed by the Guidance. That is, although the reduction in point source loadings expected to result from the Guidance is estimated, the contribution of point sources to total loadings of the relevant pollutants in the basin is not known.

Because of the lack of information on the attribution issue, benefits were attributed to the proposed Guidance in the case study analyses for illustrative purposes based on general information about the sites. For example, for the Fox River case study, the proposed Guidance was expected to reduce loadings of several chemicals of primary concern in the watershed, including PCBs, dioxins, and mercury. For the most significant benefits categories, 50 percent of future toxics-oriented benefits were attributed to the proposed Guidance. In addition, a sensitivity analysis was performed to show the impact of alternative attribution assumptions on the benefits estimates.

i. Comments

EPA received numerous comments related to attribution uncertainties. Some commenters stated that loadings reductions attributable to the proposed Guidance would be negligible, which will cause economic benefits to be negligible. It was stated that the benefits to Wisconsin from enhanced Lake

Michigan trout and salmon fisheries from a reduction in PCBs resulting from the proposed Guidance were overestimated. Similar remarks were directed at the Saginaw River/Saginaw Bay and Black River case studies.

One commenter believed that the proposed Guidance would be responsible for only very modest improvements in designated uses for aquatic life and fish consumption, and that the conclusion that benefits and costs are of the same order of magnitude arises from arbitrary and overly optimistic attribution assumptions. While the RIA assumes in one case study that the proposed Guidance might account for "as much as 50 percent of the potential incremental use value of a waterbody or as much as 20 percent of the current use value," one commenter stated that the loadings data suggest the value is at least an order of magnitude less.

Commenters felt that the benefits of the proposed Guidance were uncertain since EPA could not identify reliably the level of pollution reduction. Further, they noted that the RIA did not adequately consider the loadings reductions that will be achieved by existing programs and regulations, or those that are soon to be implemented.

ii. Response

EPA acknowledged the uncertainty surrounding the attribution of benefits to the Guidance, and subsequent research efforts were directed towards better quantification of the potential impact of the Guidance in bringing about future benefits from reducing toxicity. Efforts were focused on determining the potential contribution of point source loadings to the toxic-related problems in the basin. These efforts include the review of available literature and data on loadings of toxic pollutants in the basin, research to identify sources that might be ruled out as significant contributors to loadings of toxic pollutants in the basin, and the development of a generalized Great Lakes exposure and bioaccumulation model to estimate changes in fish tissue concentrations that might be expected to result from the Guidance. The results of these analyses are described in section IX.E.3.a.

b. Risk Assessment

In addition to the three economic benefit case study analyses, the RIA contained a preliminary assessment of health-related risks to Great Lakes Basin sport anglers, and potential risk reductions resulting from the proposed Guidance. This assessment was based largely on U.S. EPA's 1991 review draft Great Lakes Basin Risk Characterization Study. Carcinogenic and noncarcinogenic (systemic) risks due to PCB, DDT, mercury, and dieldrin exposure were evaluated.

i. Comments

Comments addressed two major components of the recreational angler risk assessment. First, it was noted that the scope of the project did not allow sampling of fish throughout the Great Lakes Basin. Data from 1989 on concentrations of contaminants in fish were applied as representative averages. Second, commenters questioned the appropriateness of the cancer slope factors used for PCBs and dieldrin.

ii. Response

The scope of the risk assessment did not enable sampling of fish throughout the basin to calculate average PCB and dieldrin concentrations. EPA acknowledges that there may be several orders of magnitude of difference between species and across lakes, and revised the analysis for the RIA of the final Guidance to use lake-specific fish tissue contaminant concentrations. Although contaminant concentrations in fish may vary within individual lakes, EPA's lake-specific approach is more representative of the potential exposure faced by sport fishermen then using a basinwide average concentration for all five lakes. EPA used standard cancer slope factors for PCBs and dieldrin. Epidemiological evidence of carcinogenicity is not available for dieldrin exposure. For PCBs, there are data that suggest PCBs may cause cancer in humans. Although it would be highly informative to have data regarding the carcinogenic effects of toxics in humans, it is impossible to perform studies of carcinogenic potency in humans. Therefore, it is standard practice to have the carcinogenic potency of compounds determined using experimental animals, and compounds causing cancer in animals are generally considered to be carcinogenic in humans unless the mechanism of carcinogenicity is not likely to occur in humans. It also is standard EPA policy to use available data to generate a dose-response curve from which the 95th percent confidence limit of the slope is calculated as the slope factor (the slope factor represents an upper 95th percent confidence limit on the probability of a carcinogenic response per unit intake of a chemical over a lifetime). This slope factor is used to determine cancer risks in accordance with EPA risk assessment guidelines.

EPA also updated the sport angler risk assessment to incorporate new data and information, including data on sport-fishing licenses sold in the Great Lakes Basin, minority and income-adjusted fish consumption levels, and fish tissue concentrations for additional pollutants. In addition to the chemicals listed above, risks were addressed for chlordane, hexachlorobenzene, 2,3,7,8-TCDD, and toxaphene. EPA also conducted a separate risk assessment for Native Americans engaged in subsistence fishing in the basin, but who would not be included in the exposed population of sport anglers; Native Americans are not required to purchase fishing licenses to exercise treaty fishing rights.

c. Valuation Approaches Used for the Proposed Benefits Analysis

The case study benefits analyses utilized benefits transfer methodology. Much of the estimated benefits are based on contingent valuation studies, including a study of Lake Michigan recreational anglers by Lyke (1992).

i. Comments

The benefits analysis was criticized for not including any original research. The statement was also made that the basis for the methodologies used in determining use and nonuse values varied so greatly that use and nonuse benefits should not be summed to calculate total benefits estimates.

One commenter noted that the use of methodologies such as the CVM forces the conclusion that costs and benefits are commensurate. Another commenter suggested that CVM suffers from serious flaws making it wholly inappropriate as a source of benefits information for the RIA.

ii. Response

EPA acknowledges that the benefits analysis contains no original research. However, the use of benefits transfer and other uses of existing research findings are often the only viable approaches available to EPA for estimating benefits. It is standard, accepted practice in economics to calculate benefits for different categories using different methods. CVM is currently the only method accepted by the U.S. Department of the Interior (DOI) to estimate nonuse values. The 1993 Blue Ribbon Panel convened by NOAA evaluated CVM and found it to be an appropriate methodology for measuring nonuse values, and the method has withstood Federal Court review for its use in litigation contexts. Hence, its use in a policy evaluation is clearly justified. The DOI also accepts the travel cost method as a best-available procedure to estimate use values. Economic values for different categories can be summed to calculate total value, regardless of the extent to which the conceptual bases for the different methodologies used to calculate the values, or the values themselves, may vary. In fact, the DOI regulations for natural resource damage assessment clearly state that "nothing in this section precludes the use of a combination of methodologies so long as the authorized official does not double count . . ." (43 CFR § 11.83 (c)(2)). Care was taken not to double count benefits for any category.

d. Limitations of the Case Study Approach and Specific Case Study Critiques

The benefits analysis of the proposed Guidance is based on a case study approach, using benefits transfer applied to three case study areas. The case study approach was used because it is more amenable to meaningful benefit-cost analyses than are studies of larger aggregate areas. Although the results obtained for a case study site may not apply uniformly to the entire Great Lakes Basin, the case study approach does provide policymakers with a pragmatic and realistic perspective of how a proposed program can generate benefits, the types of benefits anticipated, and how these benefits compare to costs.

The case studies were selected from a list of candidate sites (designated Areas of Concern in the Great Lakes Basin) on the basis of data availability and the relevance of the water quality problems to the Guidance (i.e., areas in which problems were more likely to be associated with on-going point source discharges rather than historic loadings from Superfund sites and other sources). Geographic diversity was also considered in selecting the sites so that the analyses might better promote a broad perspective of the Guidance's benefits and costs.

i. Comments

Commenters asserted that the benefits analysis is not representative of region-wide benefits because it is based on case studies of the three "hot spots." Further, it was suggested that contamination at the case study sites is related to historic practices and not necessarily current discharges from point sources.

One commenter stated that the value of fishery enhancements are inflated as ". . . most of the fish caught and consumed are in the unlimited consumption category, and . . . stressed fish compensate in various ways to maintain their population." Another commenter asserted that the yellow perch decline in the Fox River/Green Bay area was due to issues other than toxics, such as overharvesting, and that the Green Bay wildlife sanctuary is not suitably located to become "a haven for eagles, otters, minks, etc. . ." Commenters stressed that benefits from copper removal are "grossly overstated." Finally, a commenter asserted that the fish tissue concentration data for PCBs and dieldrin is inaccurate.

ii. Response

An inherent limitation of the case study approach is the inability to extrapolate from a limited set of river-based sites to the Great Lakes Basin as a whole. The choice of three of the basin's RAP areas was motivated by data availability, as noted above. RAP areas are typically well studied, thus, a wealth of relevant data are available. Data limitations usually preclude conducting case studies of less well known sites. However, there is no reason to believe that the selected sites are not reflective of other sites in the basin.

While RAP areas are hot spots and can be expected to have a higher proportion of potential benefits (as well as costs) associated with total cleanup, other sites are expected to have a greater share of benefits attributable to the Guidance. This is because contamination at hot spots typically results from historic problems and highly contaminated sediments would not be eliminated by the Guidance alone. As a result, the potential benefits attributable to the Guidance for hot spots are expected to be lower than for other sites, everything else constant.

EPA investigated two additional case study sites for possible inclusion in the benefits analysis: (1) the Ashtabula River in Ohio and (2) the St. Louis River in Minnesota. EPA determined that adding case studies would only offer limited insights, because sites with readily available data have profiles similar to the existing case studies (e.g., large historic sediment loads). Instead, EPA conducted an analysis of the representativeness of the case study sites. These results are presented in section IX.E.3.c.v.

The April 1993 RIA notes that the yellow perch fishery declines in Fox River/Green Bay are due to multiple causes and not dominated by Guidance-relevant toxics. The fishery values cited are reported as indicative of fishery values in the basin and are not the primary basis for the benefit estimate (which is largely based on a salmonid fishery study of Wisconsin's Great Lakes waters).

The assumption of a 50-percent reduction in pollutant loads was not applied uniformly at each case study site; loadings reductions were estimated for each case study relative to point source baselines, and evaluated based on the relative toxicity of the contaminants. The benefits estimates focused on the toxicity-impacted salmonid fishery, specifically, the impact of current consumption advisories on those fisheries. Potential benefits to "unlimited consumption" fisheries were not included (but may be appreciable). Fisheries benefits were based on an increase in consumer's surplus attributable to the reduction of toxic pollutants in fish; these benefits would accrue regardless of whether stressed fish compensate for pollution to maintain their populations.

The wildlife benefits in Green Bay were not based on the sanctuary becoming a "haven" for eagles and other wildlife, but on the potential increased participation in nonconsumptive recreation such as nature viewing resulting from ecologic improvements. The current level of activity at the sanctuary, which is on the order of one million visitor days per year, provides a benchmark basis for measuring potential increases in activity at that site.

EPA did not estimate significant benefits from the removal of copper. Copper reductions were estimated as incidental to controls of Tier I pollutants, but the toxicity weighted loadings reductions place relatively little weight on such reductions. In fact, copper reductions accounted for less than 0.6 percent of the toxic-weighted pollutant reductions in the Fox River/Green Bay case study (although higher percentages applied in other sites). Benefits from reduced loadings of copper were not monetized.

e. Economic Impacts of the Guidance

Economic impact analysis examines the direct and indirect effects of a stimulus throughout an economy through an analysis of complex interindustry linkages. Spending by industries impacted by the Guidance can result in positive impacts in the region by stimulating construction and/or output from pollution control technology producers located in the basin. However, Guidance-imposed costs may also result in the closure of some plants and a loss of spending by these firms and their employees in the local economy. The economic impact on the region must be evaluated by looking at both the positive and negative impacts of the imposed costs.

i. Comments

Commenters suggested that the Guidance will require immense expenditures, and that these costs will have drastic negative economic impacts in the Great Lakes Basin such as decreased competitiveness; inhibited economic growth, including the discouragement of efforts to expand production to prerecession levels; a loss of markets and jobs; increased manufacturing costs; and limits to existing zone businesses. One commenter suggested that the Guidance will "land a fatal blow" to already declining industries in the region such as steel, auto, paper, and petroleum. Commenters also indicated that costs were greatly underestimated in the RIA, and that major costs were omitted. Generally, commenters believed that the Guidance would impose enormous compliance costs on businesses, municipalities, and taxpayers, which will have a negative impact on the quality of life in the Great Lakes Basin.

ii. Response

Estimating the impact of the Guidance on the economy of the Great Lakes region requires a detailed econometric model of the region's economy. An econometric analysis was performed independent of the RIA for the Council of Great Lakes Governors (The Great Lakes Water Quality Initiative: Cost Effective Measures to Enhance Environmental Quality and Regional Competitiveness. DRI/McGraw-Hill, San Francisco, California, July 1993). This analysis showed a nearly imperceptible impact of the Guidance on the region's economy for a worst case scenario, a scenario with costs far exceeding those estimated by EPA. Manufacturing output was estimated to fall by 0.008 percent to 0.337 percent over a range of four scenarios evaluated, while personal income loss was estimated at between 0.002 percent and 0.094 percent for these scenarios. As a result, the region was considered able to "afford" the Guidance.

3. Revised Benefits Estimates

This section presents the additional research and analysis conducted by EPA in response to the comments described above, and the revised case study benefit-cost analyses. In addition, EPA updated the preliminary basinwide human health risk assessment presented in the April 1993 RIA. These results are also presented below.

a. Introduction

Based on the comments received on the benefits analysis of the proposed Guidance, EPA conducted several analyses related to the attribution issue which focused on better quantifying the potential impact of the Guidance in bringing about future toxic-oriented benefits in the basin. Specifically, EPA reviewed studies and data related to quantifying the contribution point sources make to total loadings of the relevant contaminants in the basin; conducted a screening analysis to gain information on other potentially significant sources of the contaminants in the basin; and modeled the relative contribution of point sources to fish tissue contaminant concentrations (for one site and one pollutant).

Inferences regarding the point source contribution to total loadings from all sources (e.g., sediments, atmospheric deposition) of Guidance-impacted contaminants can be made from studies and data related to the inputs of contaminants in the Great Lakes Basin. A significant amount of research has been conducted on the mass balancing of contaminants in the Great Lakes; however, appreciable data gaps remain. In general, this research indicates that there is insufficient data available to estimate total loadings (and thus calculate the point source contribution) for almost all of the contaminants impacted by the Guidance, and that results are likely to be highly site- and contaminant-specific.

For example, assessing the contribution of point sources to the toxic-related problems in the basin requires an estimate of total basin loadings for the relevant contaminants. Of the 138 pollutants of initial focus for the Guidance, EPA had sufficient information to estimate basinwide loadings for only four of these: mercury, lead, cadmium, and PCBs. Even for these contaminants, EPA considers the limitations of the studies used to develop the estimates to be significant. However, if these results are utilized to provide preliminary indication of the relative contribution of point sources (based on Permit Compliance System data for point source loadings), the estimated relative contribution of point sources ranges from approximately 2% to 40%, depending on the contaminant.

Research by Strachan and Eisenreich (1988) indicates that the lower Great Lakes receive a greater percentage of total loadings from point sources than the upper Great Lakes. The upper lakes are estimated to receive a much greater fraction of their total loadings of toxic contaminants from atmospheric sources than the lower lakes due to the relative lack of local sources and the larger surface area of the upper lakes. In comparison, the lower lakes receive extensive loadings from sources on the Detroit-St. Clair and Niagara River systems. Strachan and Eisenreich developed estimates of the relative contribution of atmospheric deposition to total loadings for PCBs, DDT, benzo(a)pyrene, lead, mercury, and mirex. Their results indicate that the role of atmospheric deposition (and, thus, the role of other sources) varies greatly by contaminant and lake.

For example, atmospheric deposition accounts for 90 percent of PCB loadings to Lake Superior but only 7 percent of PCB loadings to Lake Ontario; for benzo(a)pyrene, atmospheric deposition is attributed with 96 percent of loadings to Lake Superior, 80 percent of loadings to Lake Huron, and 72 percent of loadings to Lake Ontario. Moreover, Strachan and Eisenreich's results for PCBs indicated atmospheric deposition accounts for 58 percent of PCB loadings to Lake Michigan, however, the results of the Green Bay Mass Balance Study (GBMBS) showed a different site-specific result on the lake. The GBMBS, an estimated $12 million dollar study, showed sediment to be the dominant source of PCB loadings to Lake Michigan's Green Bay (over 90 percent). For the relative contribution of point sources to total loadings of lead and PCBs, Strachan and Eisenreich (1988) report a range of 0.7 - 1.5 percent for Lake Superior, and a range of 2.0 - 7.0 percent for Lake Huron. They suspect that their data underestimates point source loadings.

Based on the above findings, EPA developed assumptions regarding the relative contribution of point sources to total loadings for each lake. For Lake Superior, EPA assumed point sources account for between 1-2 percent of total loadings. For Lakes Michigan and Huron, EPA assumed point sources account for between 5-10 percent of total loadings. For Lakes Erie and Ontario, EPA assumed point sources contribute 10-15 percent of total loadings. These assumptions were used in the benefits analysis to attribute benefits to the final Guidance.

EPA also developed a generalized Great Lakes exposure and bioaccumulation model to estimate changes in fish tissue concentrations in response to model scenarios of reduced point source loadings and applied the model to PCBs in Green Bay. Reductions in point source loadings in Green Bay were shown to have a modest impact on fish tissue PCB concentrations and exceedences. For example, a 50% reduction in point source loadings reduces baseline exceedences from 10.6% to 8.9%. This result occurs because for this contaminant and this site, existing sediment contamination is the dominant source of PCB exposure to fish (point sources contribute only 9.4% to loadings), and baseline exceedences are only 10.6%. However, loading reduction estimates for the Fox River/Green Bay case study area indicate that the Guidance may reduce point source PCB loadings by 89.6%. A 90% reduction lowers exceedences of the human health threshold from 10.6% to 6.8%.

The model-estimated change in exceedences of the human health threshold of 2 ppm (relative percentage reductions) in response to point source loading reductions are 2%, 16%, and 36% under scenarios of 10%, 50%, and 90% reductions in point source loadings, respectively. Application to other sites and conditions may show greater benefits from point source reductions (i.e., Green Bay is considered a "worst case" scenario). Sites where point source loadings represent a greater percent of total loadings are expected to show a greater change from baseline conditions. For example, under a scenario of a 50% reduction in point source loadings, the estimated reduction in exceedences may increase from about 16% (with point sources contributing 9.4% of total loadings) to about 35% (where point sources contribute 20% of total loadings).

b. Updated Risk Assessments for Great Lakes Anglers

Executive Order (EO) 12898 established a presidential policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations. In order to assist in identifying the need for ensuring protection of populations who principally rely on fish and/or wildlife for subsistence, the EO directs agencies, whenever practicable and appropriate, to collect, maintain, and analyze information on their consumption patterns and to communicate to the public the risks of those consumption patterns. In accordance with EO 12898, EPA collected data and information on the consumption of Great Lakes Basin fish to conduct risk assessments for two populations at risk: Great Lakes sport anglers (including minority and low-income anglers) and Native Americans engaged in subsistence fishing in the basin.

i. Sport Angler Risk Assessment

EPA used data on fishing license sales in the basin to estimate the number of potentially exposed recreational anglers. Data from 1991 through 1993 (the most recent sales reports available for each state) indicated approximately 2.69 million fishing licenses were sold to residents in Great Lakes Basin counties. To the extent that anglers purchase their licenses outside the basin or share their catch with unlicensed family members, these data may result in an underestimate of the potentially exposed population.

EPA estimated the consumption of sport-caught fish based on a review of the literature on licensed angler consumption patterns in the Great Lakes Basin. These studies reflected a range of fishing locations, and water quality conditions that included the presence of fish consumption advisories. Nonetheless, fish consumption was shown to be significant. In addition, a relationship between consumption levels and socio-economic characteristics was found: minorities exhibited higher fish consumption levels than whites in the basin; and the combination of minority status and relatively low income (annual income less than $25,000) resulted in the higher consumption levels (West et al., 1993).

Using census data to divide anglers by minority and income status, EPA applied the average minority- and income-adjusted consumption levels found by West et al. (1993) (43.1 grams/person/day (gpd) for low-income minorities and 11.7 gpd for other minorities) to sport anglers in counties in closest proximity to the Great Lakes (the contiguous lakeshore counties). For the remaining sport-angler population in the lakeshore counties and in the remaining counties of the basin, fish intake was assumed to be 16.7 gpd (also based on West et al., (1993)). There are an estimated 92,000 low-income minorities in lakeshore counties; 65,000 other minorities in lakeshore counties; and 2.5 million other sport anglers in the basin.

Health risks were calculated based on exposure to chlordane, DDT, dieldrin, hexachlorobenzene, mercury, PCBs, 2,3,7,8-TCDD, and toxaphene in fish tissue. These chemicals were chosen based on their potential to cause adverse human health effects (i.e., cancer or disease) and the availability of information on fish tissue contaminant concentrations. Chemical-specific toxicity factors were drawn primarily from EPA's Integrated Risk Information System (IRIS); other sources were utilized as needed. Fish tissue contaminant levels were estimated by lake, based on data from several sources. To the extent that not all fish may contain all contaminants at the concentrations shown, exposures and risks may be overestimated; however, data were only available for a small portion of the contaminants covered by the Guidance, which could result in the underestimation of risks. Standard EPA assumptions were used regarding length of residence (i.e., 70 years; by convention) and body weight (70 kilograms).

Baseline cancer risks for low-income minorities ranged from $2.5x10^{-3}$ (Lake Superior) to $1.2x10^{-2}$ (Lake Michigan); for other minorities, baseline cancer risks ranged from $6.5x10^{-4}$ (Lake Superior) to $3.0x10^{-3}$ (Lake Michigan); and for all other sport fishermen, these risks ranged from $9.7x10^{-4}$ (Lake Superior) to $4.5x10^{-3}$ (Lake Michigan). Baseline cancer risks were driven by fish tissue PCB concentrations, which were highest in Lake Michigan and lowest in Lake Superior. For all lakes combined at baseline fish contaminant concentrations, low-income minorities in lakeshore counties would have 10.1 potential excess cancer cases per year, other minorities in lakeshore counties might expect 1.9 excess cancer cases per year, and for other sport fishermen, 100.5 excess cancer cases per year might be observed.

EPA calculated the potential reduction in baseline risk levels using revised estimates of the reduction in point source contaminant loadings due to the Guidance and the relative contribution of point sources to total loadings in the basin. As described above, the relative contribution of point sources was estimated by lake, based on available data and EPA's analyses related to the attribution issue (1-2 percent for Lake Superior; 5-10 percent for Lakes Michigan and Huron; and 10-15 percent for Lakes Erie and Ontario). Estimated point source loadings reductions due to the Guidance ranged from 68 percent for chlordane to 0 percent for PCBs and dioxin.

Table IX-7 presents the results of the sport angler risk assessment. The Guidance is estimated to result in a reduction of annual excess lifetime cases of 2.2 to 4.1 for low-income minorities in lakeshore counties; 0.4 to 0.8 for other minorities in lakeshore counties; and 21.9 to 41.9 for all other sport anglers. These results represent a total reduction of 24.6 to 46.8 excess lifetime cancer cases)potential cancer cases assuming a 70-year lifetime exposure period). On an annualized basis, these risk reductions represent potential benefits attributable to the Guidance of between $0.7 million and $6.6 million per year (based on the estimated value of a statistical life of between $2.0 million and $10.0 million). Not all excess cancer cases will necessarily result in mortality, therefore, the monetized benefits estimate may be overstated.

The estimated reductions in risks due to the Guidance are small since baseline risks are driven by PCB exposure, and the modeled basinwide loadings reductions show no reduction of PCBs due to the Guidance. However, these results are based on 59 sample facilities, and may result in conservative estimates of actual basinwide reductions. Indeed, estimated loadings reductions for the Fox River and Green Bay and Saginaw River/Bay case study areas, which are based on examination of all facilities in the areas, show an 89 percent reduction in PCBs from baseline levels. Thus, the potential risk reduction benefits of the Guidance may be underestimated at the basin level.

For example, recalculating the above results using an average of the estimated loadings reductions for the three case study areas instead of the modeled basinwide reductions results in a greater estimate of benefits. PCB loadings are estimated to be reduced by 89.6% in the Fox River case study area, 89.4% in the Saginaw Bay/River case study area, and by 0.0% in the Black River case study area, giving an average PCB reduction of 59.7%. Using this result, and the resulting average reductions for the additional contaminants included in the risk assessment, sport anglers are estimated to have a potential reduction of 3.3 to 6.0 excess cancer cases per year. This corresponds to potential benefits of between $6.6 million and 60.1 million per year.

TABLE IX-7

POTENTIAL REDUCTION IN SPORT ANGLER EXCESS CANCER CASES DUE TO THE GREAT LAKES WATER QUALITY GUIDANCE[a]

	POST-GUIDANCE INDIVIDUAL EXPECTED RISK LEVEL[b]	REDUCTION IN CANCER CASES[c]	
		YEARLY CASES	LIFETIME CASES
LAKE ERIE			
Low Income Minorities[d]	3.7×10^{-3}	0.01	0.27-0.41
Other Minorities[d]	9.5×10^{-4}	0.00	0.04-0.07
Other Sportfishermen	1.4×10^{-3}	0.03-0.04	1.80-2.80
Total		0.04-0.05	2.11-3.28
LAKE HURON			
Low Income Minorities[d]	5.5×10^{-3}	0.00	0.03-0.07
Other Minorities[d]	1.4×10^{-3}	0.00	0.01-0.02
Other Sportfishermen	2.1×10^{-3}	0.04-0.08	2.70-5.40
Total		0.04-0.08	2.74-5.49
LAKE MICHIGAN			
Low Income Minorities[d]	1.2×10^{-2}	0.03-0.05	1.70-3.40
Other Minorities[d]	3.0×10^{-3}	0.01	0.34-0.69
Other Sportfishermen	4.5×10^{-3}	0.20-0.40	15.00-30.00
Total		0.24-0.46	17.04-34.09
LAKE ONTARIO			
Low Income Minorities[d]	7.5×10^{-3}	0.00	0.17-0.25
Other Minorities[d]	1.9×10^{-3}	0.00	0.03-0.05
Other Sportfishermen	2.9×10^{-3}	0.03-0.05	2.30-3.40
Total		0.03-0.05	2.50-3.70
LAKE SUPERIOR			
Low Income Minorities[d]	2.5×10^{-3}	0.00	0.00-0.01
Other Minorities[d]	6.5×10^{-4}	0.00	0.00
Other Sportfishermen	9.7×10^{-4}	0.01	0.14-0.28
Total		0.01	0.14-0.29
ALL LAKES			
Total Low Income Minorities		0.04-0.07	2.17-4.14
Total Other Minorities		0.01	0.42-0.83
Total Other Sportfishermen		0.31-0.58	21.90-41.90
Grand Total All Lakes		0.36-0.66	24.50-46.90

[a] Based on estimated reductions in basinwide loadings which suggest that PCBs will not be reduced by the Guidance. Results for two case studies, however, indicate that PCBs are reduced by 89% by the Guidance.
[b] Based on upper estimate of reduction in fish tissue concentrations.
[c] Range over estimated range of reduction in fish tissue concentrations.
[d] Lakeshore counties only.
Note: Numbers may not add to total due to rounding.

ii. Native American Risk Assessment

Another group of anglers in the basin, Native Americans, are not required to buy fishing licenses and, therefore, would not be accounted for by the sport angler risk assessment. Native American tribes hold extensive fishing rights in the basin and many practice a traditional subsistence fishing lifestyle.

EPA researched the treaty rights of the Great Lakes Tribes and contacted tribal representatives to confirm which tribes are engaged in subsistence fishing. Of the 38 tribes in the basin, 24 are currently engaged in subsistence fishing. The potentially exposed population for these tribes was estimated to be 13,648 based on the on-reservation population reported in the 1990 census. The tribes engaged in subsistence fishing are located in Minnesota, Michigan, and Wisconsin; tribes located in New York are not subsistence fishing. For at least one of the New York tribes, the St. Regis Mohawk, subsistence fishing has been curtailed by fish consumption advisories.

EPA estimated consumption of fish by Native Americans based on a review of the literature on fish consumption by Native Americans and subsistence anglers. Based on these studies, low, moderate, and high estimates of fish intake (31.5, 57.8, and 140.0 gpd, respectively) were used to estimate risks. Native Americans were assumed to reside permanently in the area. Standard EPA assumptions were used regarding body weight.

Risks were estimated by lake to more accurately match fish tissue concentrations with the exposed population. The chemicals used to evaluate risks were chlordane, DDT, dieldrin, hexachlorobenzene, mercury, PCBs, 2,3,7,8-TCDD, and toxaphene. These chemicals were chosen based on their potential to cause adverse human health effects (i.e., cancer or disease) and the availability of information on fish tissue contaminant concentrations. Fish tissue concentrations were based on data from several sources which indicated that individual fish were, in fact, contaminated with numerous pollutants.

EPA calculated lifetime cancer risk due to the ingestion of contaminated fish at baseline conditions for the exposed population, using the low, moderate, and high estimates of fish ingestion. Average baseline cancer risks for all tribes using these ingestion assumptions are $5.3x10^{-3}$, $9.5x10^{-3}$, and $2.3x10^{-2}$, respectively. For the exposed population, these cancer risks translate into potential excess cancer cases over a lifetime of 51.5, 93.4, and 225.4, for low, moderate, and high estimates of fish ingestion, respectively. This is equivalent to 0.7, 1.3, and 3.2 excess cases per year, respectively. The greatest cancer risk is due to PCB contamination.

EPA estimated the potential reduction in baseline risk levels in the same manner as for sport anglers. Table IX-8 presents the results for Native Americans. The Guidance was estimated to result in a reduction of excess lifetime cancer cases of 0.1 to 0.3 for the low fish ingestion scenario; 0.2 to 0.5 for the moderate fish ingestion scenario; and 0.5 to 1.1 for the high fish ingestion scenario. On an annualized basis, these risk reductions represent potential benefits of the Guidance of between $20,000 and $100,000 per year (based on the estimated value of a statistical life of between $2.0 million and $10.0 million). Not all excess cancer cases will necessarily result in mortality, however, and as such, the monetized benefits estimate may be overstated.

TABLE IX-8

POTENTIAL REDUCTION IN NATIVE AMERICAN EXCESS CANCER CASES DUE TO THE GREAT LAKES WATER QUALITY GUIDANCE[a]

FISH CONSUMPTION SCENARIO	POST-GUIDANCE INDIVIDUAL EXPECTED RISK LEVEL[b]	REDUCTION IN CANCER CASES[c]	
		YEARLY CASES	LIFETIME CASES
LAKE MICHIGAN			
Low (32 gpd)	8.6×10^{-3}	0.00	0.11-0.23
Moderate (58 gpd)	1.6×10^{-2}	0.00-0.01	0.20-0.41
High (140 gpd)	3.8×10^{-2}	0.01	0.49-0.98
LAKE SUPERIOR			
Low (32 gpd)	1.9×10^{-3}	0.00	0.01-0.02
Moderate (58 gpd)	3.4×10^{-3}	0.00	0.02-0.04
High (140 gpd)	8.1×10^{-3}	0.00	0.05-0.09
TOTAL			
Low (32 gpd)		0.00	0.12-0.25
Moderate (58 gpd)		0.00-0.01	0.22-0.45
High (140 gpd)		0.01	0.54-1.10

[a] Based on estimated reductions in basinwide loadings which suggest that PCBs will not be reduced by the Guidance. Results for two case studies, however, indicate that PCBs are reduced by 89% by the Guidance.
[b] Based on upper estimate of reduction in fish tissue concentrations.
[c] Range over estimated range of reduction in fish tissue concentrations.
Note: Numbers may not add to total due to rounding.

As for the sport angler risk assessment, the potential risk reductions due to the Guidance are small since baseline risks are driven by PCB exposure, and the modeled basinwide results show no reduction in PCBs. However, these results are based on 59 sample facilities. To the extent that the sample underestimates potential basinwide reductions (results for both the Fox River and Green Bay and Saginaw River/Bay case study areas showed an 89 percent reduction in PCBs from baseline levels), potential benefits of the Guidance may be underestimated. If the average loading reduction for the three case study areas is used instead of the modeled basinwide results, the Guidance would be attributed with a reduction in excess annual cancer cases ranging from 0.01 to 0.03 for the low fish ingestion scenario and 0.06 to 0.11 for the high fish ingestion scenario.

c. Revised Case Study Benefit-Cost Analyses for the Final Guidance

EPA revised the original case study benefits estimates to reflect its revised assumptions regarding the relative contribution of point sources to total basin loadings (5-10 percent for the lower Fox River/Green Bay site, 10-15 percent for the Saginaw River/Bay site, and 10-15 percent for the Black River site) and revised estimates of the reduction in point source loadings due to the Guidance. In addition, based on the data and information collected to conduct the basin wide risk assessments, human health risk reduction benefits were calculated for the Fox River and Saginaw Bay case study areas. These results are presented below in 1994 (first quarter) dollars.

i. Fox River and Green Bay Case Study

The final Guidance is expected to reduce toxic-weighted loadings in the Fox River case study area by an estimated 28.2 percent, including significant reductions in aluminum, benzo(a)pyrene, dieldrin, hexachlorobenzene, mercury, and other chemicals. Revised benefit categories for this case study include human health, recreational fishing, nonconsumptive recreation (e.g., wildlife viewing), commercial fishing, and nonuse (e.g., intrinsic benefits placed on natural resources). EPA estimates that the annual potential benefits of the Guidance will range from $27,000 to $3.8 million for recreational fishing, $22,000 to $173,000 for nonconsumptive recreational use, $19,000 to $120,000 for commercial fishing, and $32,000 to $1.9 million for nonuse values. In addition, potential annual human health benefits of between $250,000 and $2.5 million are estimated to result from a reduction of between 0.12 and 0.25 excess cancer cases per year. Thus, the annual potential benefits of the Guidance associated with these categories total $349,000 to $8.5 million.

ii. Saginaw River/Saginaw Bay Case Study

The final Guidance is anticipated to reduce toxic-weighted loadings by an estimated 60.5 percent in the Saginaw River case study area, including significant reductions in aluminum, arsenic (III), DDT, lindane, mercury, PCBs, and other chemicals. Revised benefit categories include human health, recreational fishing, nonconsumptive recreation, waterfowl and other hunting, commercial fishing, and nonuse. EPA estimates that potential annual benefits of the Guidance are $60,000 to $4.7 million for recreational fishing, $8,000 to $66,000 for nonconsumptive uses, $2,000 to $11,000 for hunting, $7,000 to $72,000 for commercial fishing, and $30,000 to $2.3 million for nonuse values. In addition, potential annual human health benefits of between $60,000 and $580,000 are estimated to result from a reduction of between 0.03 and 0.06 excess cancer cases per year. The total potential benefits of the Guidance associated with these categories range from $168,000 to $7.7 million.

iii. Black River Case Study

The final Guidance is anticipated to reduce toxic-weighted loadings by an estimated 36.6 percent for the Black River case study area, including significant reductions in fluoride, lindane, lead, and mercury. Revised benefit categories include recreational fishing; recreational boating, waterskiing, sailboarding, and swimming; and nonuse. Annual benefits of the Guidance are estimated to range from $251,000 to $719,000 for recreational fishing, $33,000 to $67,000 for nonconsumptive water-based recreation, and $126,000 to $667,000 million for nonuse values. Total annual potential benefits of the Guidance associated with these categories range from $0.4 million to $1.5 million.

iv. Comparison of Benefits and Costs for the Case Studies

Two methods were used to compare the estimated case study benefits to estimated compliance costs in the April 1993 RIA: 1) a direct comparison of annualized benefits and costs, and 2) a comparison of discounted benefits and costs. EPA discounted benefits and costs to incorporate a 10- and 20-year phase-in of annual benefits and the present value of a stream of annual costs. Capital costs were annualized using a 7 percent real interest rate, and annual costs and benefits were discounted by 3 percent each year. A comparison of the revised case study benefits and costs using these methods is presented in Table IX-9.

Benefits ranges across case study areas are roughly comparable. Annual benefits range from approximately $200,000 to several million dollars, reflecting the uncertainty in the benefits estimates. Annualized costs are commensurate with annual benefits; costs are approximately $2-$3 million per year for each of the case studies. The net present values of streams of benefits and costs over 30 years are also generally similar.

v. Case Study Representativeness

The representativeness of the case study sites was assessed by comparing the percentage of total benefits estimated to accrue in the case study areas to the percentage of basinwide costs they will incur. Benefits-related measures (such as population, recreational angling days, and nonconsumptive recreation days) were used in place of total benefits for this analysis because there is no estimate of benefits for the entire Great Lakes Basin.

Overall, there is no evidence to suggest that the three case studies reflect an unrepresentative level of benefits relative to costs. The three case studies combine to account for nearly 14 percent of the Guidance total cost, nearly 17 percent of the total loadings reductions, and between 4 percent and 10 percent of the benefits proxies (basin wide population, recreational angling, etc.). Thus, it may be that the three case studies represent a reasonably proportionate share of costs and benefits.

TABLE IX-9
COMPARISON OF THE POTENTIAL BENEFITS TO THE POTENTIAL COSTS
OF THE GUIDANCE FOR THE CASE STUDY AREAS
(MILLIONS OF 1994 [FIRST QUARTER] DOLLARS)

FOX RIVER CASE STUDY	BENEFITS RANGE	MIDPOINT OF BENEFITS RANGE	COSTS
Direct Annualized Comparison[1]	$0.3 - $8.5	$4.5	$3.6
Discounted Benefits and Costs[2]			
10-Year Phase in of Benefits	$5.4 - $133.9	$69.7	$71.8
20-Year Phase in of Benefits	$4.1 - $101.4	$52.7	$71.8
SAGINAW RIVER CASE STUDY	BENEFITS RANGE	MIDPOINT OF BENEFITS RANGE	COSTS
Direct Annualized Comparison[1]	$0.2 - $7.7	$4.0	$2.6
Discounted Benefits and Costs[2]			
10-Year Phase in of Benefits	$2.6 - $120.9	$61.7	$53.0
20-Year Phase in of Benefits	$2.0 - $91.5	$46.8	$53.0
BLACK RIVER CASE STUDY	BENEFITS RANGE	MIDPOINT OF BENEFITS RANGE	COSTS
Direct Annualized Comparison[1]	$0.4 - $1.5	$0.9	$2.1
Discounted Benefits and Costs[2]			
10-Year Phase in of Benefits	$6.4 - $22.7	$14.5	$42.7
20-Year Phase in of Benefits	$4.8 - $17.2	$11.0	$42.7

1 Based on annualized costs assuming a 10-year capital life and reflecting a 7 percent real interest rate on capital.
2 Present values (1994) over 30 years. Annualized costs (assuming a 10-year capital life and 7 percent real interest rate on capital) and benefits are discounted at a 3 percent real discount rate.

X. REGULATORY FLEXIBILITY ACT

Under the Regulatory Flexibility Act (RFA), EPA generally is required to conduct a final regulatory flexibility analysis (FRFA) describing the impact of the regulatory action on small entities as part of the final rulemaking. However, under section 605(b) of the RFA, if EPA certifies that the rule will not have a significant economic impact on a substantial number of small entities, EPA is not required to prepare a FRFA.

Implementation of the final Guidance is dependent upon future promulgation of provisions consistent with it by State or Tribal agencies or, if necessary, EPA. Until actions are taken to promulgate and implement these provisions (or equally protective provisions consistent with the final Guidance), there will be no economic effect of this rule on any entities, large or small. For that reason, and pursuant to section 605(b) of the RFA, EPA is certifying that this rule itself will not have a significant economic impact on a substantial number of small entities.

Although EPA is certifying that this rule will not have a significant economic impact on a substantial number of small entities, and therefore is not required to prepare a FRFA, it is nevertheless including a discussion for public information in the RIA of the possible economic effects to small entities that could result from State or Tribal implementation of the final Guidance. As discussed above, small facilities are projected to incur costs of only approximately $500 per facility to comply with subsequently promulgated requirements that are consistent with the final Guidance. Accordingly, EPA believes there will be no significant economic impact on a substantial number of small entities as a result of State or Tribal implementation of the final Guidance.

XI. ENHANCING THE INTERGOVERNMENTAL PARTNERSHIP UNDER EXECUTIVE ORDER 12875

In compliance with Executive Order 12875 (58 FR 58093, October 28, 1993), EPA has involved State, Tribal, and local governments in the development of the final Guidance.

As described in section II above, the core elements of the Guidance were developed by the Great Lakes States, EPA, and other Federal agencies in open dialogue with citizens, local governments, and industries in the Great Lakes ecosystem over a five-year period through the Great Lakes Water Quality Initiative (GLWQI). The Initiative process marks the first time that EPA has developed a major rulemaking effort in the water program through a regional public forum. The process is described further in the preamble to the proposed Guidance (58 FR 20820-23).

In addition to the participation by State and local governments in the initial development of the Guidance and in the public comment process, several activities have been carried out since the publication of the proposed Guidance. These include:

(1) On April 26, 1994, EPA held a public meeting to solicit additional information from interested parties on the proposed Guidance. As part of EPA's outreach efforts to State, Tribal and local governments, a special invitation was sent inviting elected officials and other State, Tribal and local representatives to participate in the public meeting. EPA specifically welcomed Tribal and local officials and opened the floor to them to hear and discuss their specific concerns and views on the final Guidance.

(2) A series of meetings and teleconferences were held with Great Lakes States in early 1994 to discuss their comments on several issues, including development of water quality criteria, state adoption requirements, whole effluent toxicity, bioaccumulation factors, additivity, compliance schedules, anti-backsliding, nonpoint sources, and international concerns.

(3) In October, 1994, EPA met with each individual State in the Great Lakes basin to discuss the nature, form, and scope of the draft Guidance, and State concerns with implementation of the provisions under consideration. The following issues were discussed at each of the meetings: intake credits, antidegradation and existing effluent quality, wildlife criteria, excluded pollutants (ammonia and chlorine), elimination of mixing zones, site-specific variances, fish consumption, appropriate degrees of flexibility for implementation (e.g., guidance vs. regulation), and implementation procedures.

(4) In 1994 and 1995 EPA met with representatives of the National Wildlife Federation to discuss EPA's activities in developing the final Guidance in accordance with the terms of a consent decree governing the schedule for development of the final Guidance.

(5) In 1994 EPA also met with elected officials and other representatives from several local communities in the Great Lakes basin to discuss issues regarding the economic impact of the proposed Guidance on local communities and publicly owned treatment works. Issues discussed include cost impacts associated with implementing water quality criteria, methodologies, and implementation procedures; dealing with pollution from nonpoint sources; public outreach to control pollutants such as mercury instead of costly end-

of-pipe treatment; and applicability of provisions in the Guidance to the National water quality program.

(6) EPA held an additional 18 consultations with the regulated community throughout 1994. Such meetings allowed representatives of dischargers to share additional data, which has been placed in the docket for this rulemaking, and concerns about a range of issues the dischargers expect to arise in implementation of the Guidance, including cost concerns.

(7) In 1994 EPA met with State representatives to conduct initial planning for implementation of the GLI Clearinghouse. All Great Lakes States agreed to participate in this effort, which will involve sharing of toxicological and other data to assist in development of additional water quality criteria and values.

The results of the above efforts have assisted in development of the final Guidance through broad communication with a full range of interested parties, sharing of additional information, and incorporation of features to improve the implementation of the Guidance.

EPA has estimated the total annual State government burden to implement the Guidance as approximately 5,822 hours, resulting in a State government cost of $156,029 annually. Such burden and costs were estimated based upon the burden and costs associated with developing water quality criteria, review of antidegradation policy demonstrations, reviewing approvable control strategies and bioaccumulative chemicals of concern monitoring data, and review of variance requests. The total annual local government burden is estimated to be 5,595 hours with an associated cost of $1,858,243. All of the burden and costs to local governments are associated with being a regulated entity as an operator of a publicly owned treatment works (POTW).

XII. PAPERWORK REDUCTION ACT

The information collection requirements in this final Guidance have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. EPA Has prepared an Information Collection Request (ICR) document (ICR No. 1639.01). Copies of the ICR may be obtained from the address given at the beginning of this document.

The public reporting and record keeping burden for this regulation is estimated to be 128,901 hours for the 3,795 permittees, or an average 34 hours. The total annual burden to local governments as publicly owned treatment works operators is estimated to be 45,296 hours. The total annual burden to State governments is estimated to be 5,886 hours.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

In this rulemaking EPA is also amending the table of currently approved ICR control numbers issued by OMB for various regulations. This amendment updates the table to accurately display those information requirements promulgated under the Clean Water Act. The affected regulations are codified at 40 CFR parts 122, 123, 131, and 132. EPA will continue to present OMB control numbers in a consolidated table format to be codified in 40 CFR 9 of EPA's regulations, and in each 40 CFR volume containing EPA regulations. The table lists the section numbers with reporting and recordkeeping requirements, and the current OMB control numbers. This display of the OMB control numbers and their subsequent codification in the Code of Federal Regulations satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) and OMB's implementing regulations at 5 CFR part 1320.

The ICR for this rulemaking was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is "good cause" under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

For further information on this amendment to 40 CFR 9, contact Sandy Farmer (telephone 202-260-2740).