Regulatory Determinations Support Document for Selected Contaminants from the Second Drinking Water Contaminant Candidate List (CCL 2)

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Disclaimer

This document is designed to provide technical background information for the regulatory determinations being made on the second drinking water Contaminant Candidate List (CCL 2).

This document is not a regulation itself, and it does not substitute for the Safe Drinking Water Act (SDWA) or the Environmental Protection Agency's (EPA's) regulations. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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Executive Summary

This document provides background information to support the Environmental Protection Agency's (EPA) regulatory determinations for drinking water contaminants on the second Contaminant Candidate List (CCL 2). The final regulatory determinations are presented formally in the *Federal Register*. This report itself does not constitute regulation.

This regulatory support document is divided into three Parts and fourteen Chapters. Because EPA understands that members of the public with varied concerns might be more interested in certain contaminants and less interested in others, the document is designed in such a way that individual chapters are more or less self-contained and can be distributed separately.

Part I, which includes the first two Chapters, provides preliminary information. Chapter 1 is an introduction to the CCL and regulatory determination process. Chapter 2 provides general information on the most important sources of data used to evaluate contaminants.

Chapters 3 through 11, in Part II, discuss eleven of the 51 CCL 2 contaminants for which EPA is making a regulatory determination. These contaminants are: boron, dimethyl tetrachloroterephthalate (DCPA) mono- and di-acid degradates, 1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene (DDE), 1,3-dichloropropene, 2,4- and 2,6-dinitrotoluene, s-ethyl dipropylthiocarbamate (EPTC), fonofos, terbacil, and 1,1,2,2,-tetrachloroethane. Each chapter includes information on contaminant properties and sources, environmental fate and behavior, health effects, use and environmental release, known occurrence in ambient water and drinking water, and available analytical methods and treatment technologies. For each of these contaminants, EPA has made a determination that in light of available data, a national primary drinking water regulation (NPDWR) is not warranted. Those decisions are presented formally in the *Federal Register*. In some cases, EPA intends to update existing Health Advisories and/or provide guidance to states that face local contamination problems.

EPA has not made final regulatory determinations for the remaining CCL 2 contaminants. Because EPA understands that members of the public may have a particular interest in other CCL 2 contaminants, Chapters 12 through 14, in Part III, discuss the status of EPA's evaluation of metolachlor, methyl tert-butyl ether (MTBE), and several microbiological contaminants. EPA is not precluded from making regulatory determinations on any of these contaminants before the next round of formal CCL regulatory determinations. EPA anticipates developing a regulatory support document for perchlorate when the Agency develops its regulatory determination for this compound.

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Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
CCL	Contaminant Candidate List
CCL 1	First Contaminant Candidate List
CCL 2	Second Contaminant Candidate List
DCPA	Dimethyl Tetrachloroterephthalate
DDE	1,1-Dichloro-2,2-bis(*p*-chlorophenyl) ethylene
EPA	Environmental Protection Agency
EPTC	s-Ethyl dipropylthiocarbamate
FR	Federal Register
HRL	Health Reference Level
IRIS	Integrated Risk Information System
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MTBE	Methyl Tertiary-Butyl Ether
NAS	National Academy of Sciences
NDWAC	National Drinking Water Advisory Council
NPDWR	National Primary Drinking Water Regulation
NRC	National Research Council
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
PWS	Public Water System
RED	Reregistration Eligibility Decisions
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
SRMD	Standards and Risk Management Division
TAB	Targeting and Analysis Branch

1 Introduction

1.1 Purpose and Scope

The 1996 Safe Drinking Water Act (SDWA) Amendments (section 1412(b)(1)) direct EPA to publish a list of currently unregulated contaminants that may pose risks for drinking water (referred to as the Contaminant Candidate List, or CCL) and to make determinations on whether to regulate at least five contaminants from the CCL with a national primary drinking water regulation (NPDWR). This regulatory determination support document provides:

(1) a summary of the statutory requirements and previous activities related to the contaminant candidate list and regulatory determinations,

(2) the approach used to identify and evaluate contaminants for the Agency's second round of regulatory determinations,

(3) information and data on the physical and chemical properties, use and environmental release, environmental fate, potential health effects, and occurrence and exposure estimates for each of the 11 contaminants that the Agency evaluated,

(4) the final determination for each of the 11 contaminant candidates, and

(5) the Agency's rationale for its regulatory determination for these 11 contaminants.

The 11 regulatory determination candidates discussed in this document include boron, the dacthal mono- and di-acid degradates, 1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene (DDE), 1,3-dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, s-ethyl dipropylthiocarbamate (EPTC), fonofos, terbacil, and 1,1,2,2-tetrachloroethane.

Additionally, this support document includes information and data on several contaminants for which no regulatory determination has been made at this time. These include metolachlor, methyl tertiary-butyl ether (MTBE), and nine microbial contaminants.

1.2 Background on the CCL and Regulatory Determinations

1.2.1 Statutory Requirements for CCL and Regulatory Determinations

The specific statutory requirements for the CCL and regulatory determinations can be found in SDWA Section 1412(b)(1). The 1996 SDWA Amendments require EPA to publish the CCL every five years. The CCL is a list of contaminants that are not subject to any proposed or promulgated NPDWRs, are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA. The 1996 SDWA Amendments also direct EPA to determine whether to regulate at least five contaminants from the CCL every five years. SDWA requires EPA to publish a Maximum Contaminant Level Goal[1] (MCLG) and promulgate an NPDWR[2] for a contaminant if the Administrator determines that:

[1] The MCLG is the "maximum level of a contaminant in drinking water at which no known or anticipated adverse

(a) the contaminant may have an adverse effect on the health of persons;
(b) the contaminant is known to occur or there is substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern; and
(c) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

If EPA determines that all three of these statutory criteria are met, it makes a determination that an NPDWR is needed. In that case, the Agency has 24 months to publish a proposed MCLG and NPDWR. After the proposal, the Agency has 18 months to publish a final MCLG and promulgate a final NPDWR (SDWA section 1412(b)(1)(E)).[3]

1.2.2 The First Contaminant Candidate List (CCL 1)

Following the 1996 SDWA Amendments, EPA sought input from the National Drinking Water Advisory Council (NDWAC) on the process that should be used to identify contaminants for inclusion on the CCL. For chemical contaminants, the Agency developed screening and evaluation criteria based on recommendations from NDWAC. For microbiological contaminants, NDWAC recommended that the Agency seek external expertise to identify and select potential waterborne pathogens. As a result, the Agency convened a workshop of microbiologists and public health experts who developed criteria for screening and evaluation and subsequently developed an initial list of potential microbiological contaminants.

The first CCL process benefited from considerable input from the NDWAC, the scientific community, and the public through stakeholder meetings and the public comments received on the draft CCL published on October 6, 1997 (62 FR 52193). EPA published the final CCL, which contained 50 chemical and 10 microbiological contaminants, on March 2, 1998 (63 FR 10273). A more detailed discussion of how EPA developed CCL 1 can be found in the 1997 and the 1998 *Federal Register* notices (62 FR 52193 and 63 FR 10273).

1.2.3 The Regulatory Determinations for CCL 1

EPA published its preliminary regulatory determinations for a subset of contaminants listed on CCL 1 on June 3, 2002 (67 FR 38222). The Agency published its final regulatory determinations on July 18, 2003 (68 FR 42898). EPA identified 9 contaminants from the 60 contaminants listed on CCL 1 that had sufficient data and information available to make regulatory determinations. The nine contaminants were *Acanthamoeba*, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, and sulfate. The Agency

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effect on the health of persons would occur, and which allows an adequate margin of safety. Maximum contaminant level goals are nonenforceable health goals." (CFR 141.2)

[2] An NPDWR is a legally enforceable standard that applies to PWSs. An NPDWR sets a legal limit (called a maximum contaminant level or MCL) or specifies a certain treatment technique (TT) for public water systems for a specific contaminant or group of contaminants.

[3] The statute authorizes a nine month extension of this promulgation date.

determined that an NPDWR was not necessary for any of these nine contaminants. The Agency issued guidance on *Acanthamoeba* and health advisories for magnesium, sodium, and sulfate.

The decision-making process that EPA used to make its regulatory determinations for CCL 1 was based on substantial expert input and recommendations from different groups including stakeholders, the National Research Council (NRC), and NDWAC. In June 2002, EPA consulted with the Science Advisory Board (SAB) Drinking Water Committee and requested its review and comment on whether the protocol EPA developed, based on the NDWAC recommendations, was consistently applied and appropriately documented. SAB provided verbal feedback regarding the use of the NRC and NDWAC recommendations in EPA's decision criteria for making its regulatory determinations. SAB recommended that the Agency provide a transparent and clear explanation of the process for making regulatory determinations. The Agency took SAB's recommendation into consideration and further explained the CCL 1 regulatory determination evaluation process in the July 18, 2003 (68 FR 42898) notice and in the supporting documentation.

EPA has used the same approach for the present round of regulatory determinations. While this document includes a short description of the decision process used to make regulatory determinations (see section 1.3, below), a more detailed discussion can be found in the 2002 and the 2003 *Federal Register* notices (67 FR 38222 and 68 FR 42898).

1.2.4 The Second Contaminant Candidate List (CCL 2)

The Agency published its draft CCL 2 *Federal Register* notice on April 2, 2004 (69 FR 17406) and the final CCL 2 *Federal Register* notice on February 24, 2005 (70 FR 9071). The CCL 2 carried forward the 51 remaining chemical and microbial contaminants that were listed on CCL 1.

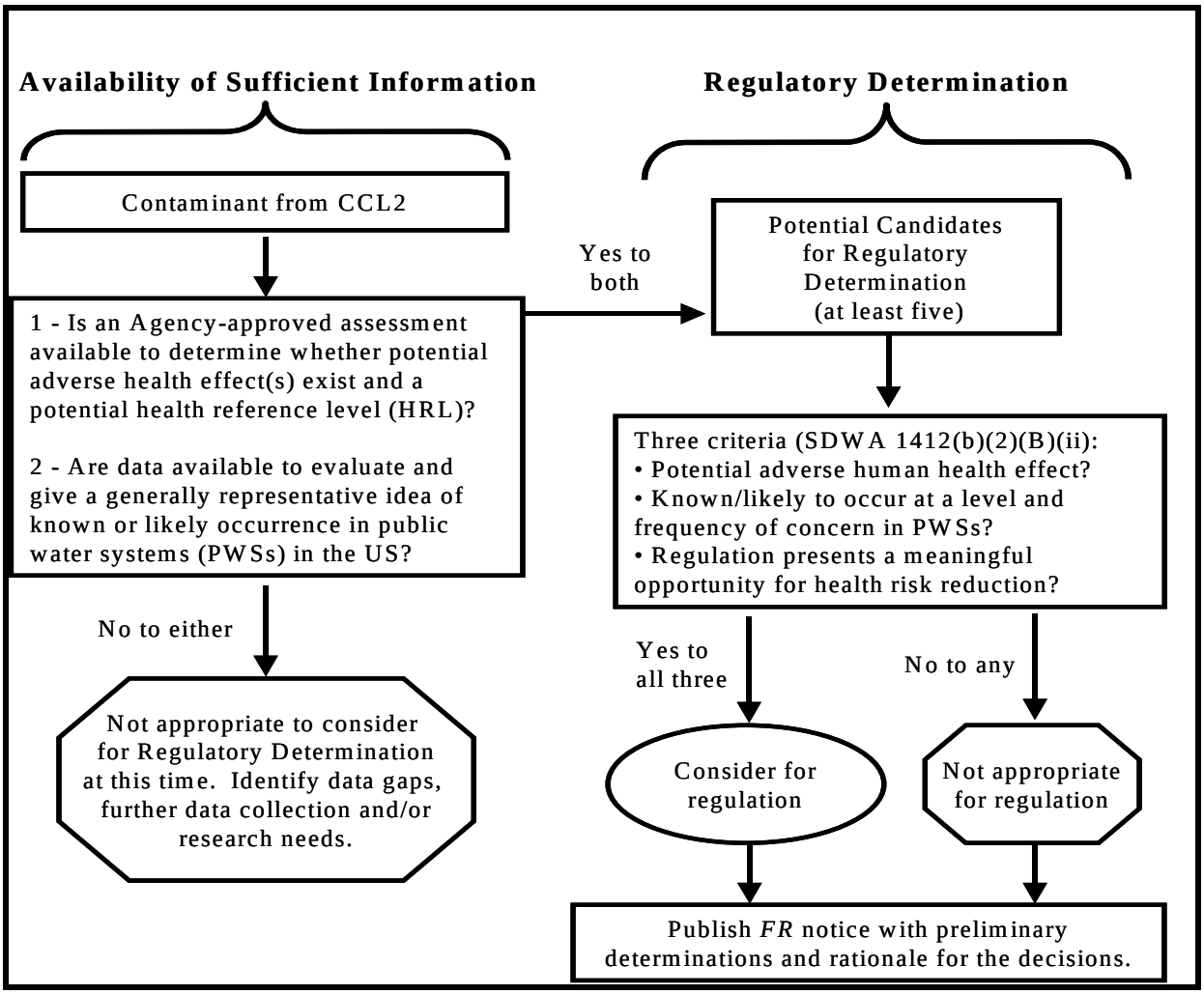
1.2.5 The Regulatory Determinations for CCL 2

The Agency published its preliminary regulatory determinations for contaminants listed on the CCL 2 *Federal Register* notice on May 1, 2007 (72 FR 24106). In the May 1, 2007 notice, EPA made preliminary determinations for 11 of the 51 contaminants listed on the CCL 2. As discussed in the following sections, EPA is finalizing the determinations for 11 of 51 contaminants listed on CCL 2.

1.3 Summary of the Approach Used to Identify and Evaluate Candidates for Regulatory Determination 2

Exhibit 1-1 provides a brief overview of the process EPA used to identify which CCL 2 contaminants are candidates for regulatory determinations and the SDWA statutory criteria considered in making the regulatory determinations.

Exhibit 1-1: General Overview of the Approach Used to Evaluate CCL 2 Contaminants for Regulatory Determinations



In identifying which CCL 2 contaminants are candidates for regulatory determinations, the Agency considered whether sufficient information and/or data were available to characterize the potential health effects and the known/likely occurrence in and exposure from drinking water. For health effects, the Agency considered whether an Agency-approved health risk assessment[4] was available to identify any potential adverse health effect(s) and derive an estimated level at which no adverse health effect(s) are likely to occur. For occurrence, the Agency considered whether available information/data provided a representative picture of known and/or likely occurrence in PWSs. If sufficient information/data were available to characterize adverse human health effects and known/likely occurrence in PWSs, the Agency identified the contaminant as a potential candidate for regulatory determinations. In addition to

[4] Health information used for the regulatory determinations process includes but is not limited to health assessments available from the Agency's Integrated Risk Information System (IRIS), the Agency's Office of Pesticide Programs (OPP) in a Reregistration Eligibility Decision (RED), the National Academy of Sciences (NAS), and/or the Agency for Toxic Substances and Disease Registry (ATSDR).

information/data for health and occurrence, EPA also considered the availability and adequacy of analytical methods (for monitoring) and treatment.

In cases where EPA chose a contaminant as a candidate for regulatory determination, the Agency considered the following in evaluating each of the three statutory criteria (listed above, in section 1.2.1).

For the current regulatory determination process, the Agency considered the following in evaluating each of the three statutory criteria.

(1) First statutory criterion - Is the contaminant likely to cause an adverse effect on the health of persons? The Agency evaluated the best available, peer-reviewed assessments and studies to characterize the human health effects that may result from exposure to the contaminant when found in drinking water. Based on this characterization, the Agency estimated a health reference level (HRL) for each contaminant. Section 2.1 provides more detailed information about the approach used to evaluate and analyze the health information.

(2) Second statutory criterion - Is the contaminant known or likely to occur in PWSs at a frequency and level of public health concern? To evaluate known occurrence in PWSs, the Agency compiled, screened, and analyzed data from several occurrence data sets to develop representative occurrence estimates for public drinking water systems. EPA used the HRL estimates for each contaminant as a benchmark against which to conduct an initial evaluation or screening of the occurrence data. For each contaminant, EPA estimated the number of PWSs (and the population served by these PWSs) with detections greater than one-half the HRL (> ½ HRL) and greater than the HRL (> HRL). To further evaluate the likelihood of a contaminant occurring in drinking water, the Agency considered information on the use and release of the contaminant into the environment and supplemental information on occurrence in water (e.g. ambient water quality data, State ambient or finished water data, and/or special studies performed by other agencies, organizations, and/or entities). Section 2.2 provides more details on the approach used to analyze the occurrence information/data.

(3) Third statutory criterion - In the sole judgment of the Administrator, does regulation of the contaminant present a meaningful opportunity for health risk reduction for persons served by PWSs? EPA evaluated the potential health effects and the results of the occurrence estimates, as well as exposure estimates (i.e., the population exposed and the sources of exposure) at the health level of concern to determine if regulation presents a meaningful opportunity for health risk reduction.

If the answers to all three statutory criteria are affirmative for a particular contaminant, then the Agency makes a determination that regulation is necessary and proceeds to develop an MCLG and an NPDWR for that contaminant. It should be noted that this regulatory determination process is distinct from the more detailed analyses needed to develop an NPDWR. Thus, a decision to regulate is the beginning of the Agency regulatory development process, not the end.

If the answer to any of the three statutory criteria is negative based on the available data, then the Agency makes a determination that an NPDWR is not necessary for that contaminant at that time.

1.4 Summary of Regulatory Determinations

In a May 1, 2007 FR notice, EPA made preliminary determinations that no regulatory actions are appropriate for the 11 contaminants evaluated for this second round of regulatory determinations. EPA is making regulatory determinations only on those CCL 2 contaminants that have sufficient information to support such a determination at this time. These 11 contaminants are discussed in detail in Chapters 3 through 11 in Part II of this regulatory determination support document.

In addition, the Agency is evaluating the remaining contaminants on CCL 2 as part of the new CCL 3 classification process. The new process is an expanded comprehensive system that evaluates a wider range of existing information, including data published after the CCL 2 preliminary regulatory determinations. EPA anticipates determining future research needs once the CCL 3 is finalized. However, some of the remaining contaminants are discussed in Chapters 12 through 14 in Part III of this document. The Agency is not precluded from taking action when information becomes available and will not necessarily wait until the end of the next regulatory determination cycle before making other regulatory determinations.