



Consideration of Other Regulatory Revisions for Chemical Contaminants in Support of the Six-Year Review of the National Primary Drinking Water Regulations

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Chemical Contaminants in Support of the
Six-Year Review of the
National Primary Drinking Water Regulations**

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List of Acronyms and Abbreviations

ASDWA	Association of State Drinking Water Administrators
BAT	Best Available Technology
CCR	Consumer Confidence Report
CFR	Code of Federal Regulations
CMR	Chemical Monitoring Reform
CWS	Community water system
EPA	United States Environmental Protection Agency
EPTDS	Entry point to the distribution system
FR	<i>Federal Register</i>
GUDI	Ground water under the direct influence of surface water
HQ	EPA Headquarters
ICC	Interstate carrier conveyance
IOC	Inorganic chemical
LCCA	Lead Contamination Control Act
LCR	Lead and Copper Rule
MCL	Maximum Contaminant Level
mg/L	Milligrams per liter
NPDWR	National Primary Drinking Water Regulation
NTNCWS	Non-transient, non-community water system
PN	Public Notification
PWS	Public water system
RTC	Return-to-Compliance
SDWA	Safe Drinking Water Act
SMCL	Secondary Maximum Contaminant Level
SMF	Standard Monitoring Framework
SOC	Synthetic organic chemical
SWAP	Source Water Assessment and Protection
TNCWS	Transient Non-Community Water System
USEPA	U.S. Environmental Protection Agency
VOC	Volatile organic chemical
WQP	Water quality parameter

1.0 Background

1.1 Purpose of the Six-Year Review

Under the Safe Drinking Water Act (SDWA), the U.S. Environmental Protection Agency (EPA) must periodically review existing National Primary Drinking Water Regulations (NPDWRs) and, if appropriate, revise them. This requirement is contained in section 1412(b)(9) of the SDWA, as amended in 1996, which reads:

The Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this title. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.

To facilitate the quality and consistency of this regulatory review process, EPA performed a series of analyses at the beginning of each review cycle, intended to target those NPDWRs that are the most appropriate candidates for revision. The Agency plans to use available, scientifically-sound data to make decisions regarding whether or not to revise a regulation. During each review cycle, EPA will review the following key information to make decisions regarding regulatory changes: health risk assessments; technology assessments; other revisions related to implementation of the regulations; occurrence and exposure analyses; and economic considerations.

For its review of other regulatory revisions, EPA focused on issues that are not already being addressed, or have not been addressed, through alternative mechanisms (e.g., as a part of a recent or ongoing rulemaking). Where appropriate alternative mechanisms did not exist, EPA considered these implementation-related concerns if the potential revision met the following criteria:

- (1) It indicated a potential change to an NPDWR, as defined under section 1401 of SDWA¹;
- (2) It was "ready" for rulemaking – that is, the problem to be resolved has been clearly identified and specific option(s) have been formulated to address the problem; and
- (3) It met at least one of the following conditions:
 - clearly improved the level of public health protection; and/or

¹ The subject of the Six-Year-Review, as specified in section 1412(b)(9) of the SDWA, is "each national primary drinking water regulation," as defined under section 1401 of the SDWA. Therefore, EPA has modified the above criteria to clarify that revisions the Agency will consider are those "to an NPDWR, as defined under section 1401 of SDWA" rather than "in the 40 CFR 141 requirements."

- represented a meaningful opportunity for cost savings while not lessening public health protection.

1.2 Purpose of this Document

In December of 2000, EPA Headquarters (HQ) circulated a memorandum to its Regional offices requesting feedback on issues relating to the implementation of its drinking water regulations. Although the memorandum specified a "potential set of issues" for consideration (Appendix, Table 1), Regions were asked to identify any other known issues related to regulatory implementation. In addition, the Association of State Drinking Water Administrators (ASDWA) was asked to confer with the States regarding implementation issues that they felt needed to be reviewed or addressed.

The number and extent of responses from EPA Regions and States were limited. In response to the memorandum and the request to the ASDWA, EPA received feedback from: nine EPA Regions, seven States, and ASDWA. Of the written communications received, a few discussed issues that have already been addressed in the recently published arsenic and radionuclides NPDWRs (66 FR 6975, January 22, 2001 (USEPA, 2001); 65 FR 76707, December 3, 2000 (USEPA, 2000b)), and others are being addressed through ongoing mechanisms. This document summarizes the implementation issues that were discussed in this written (and some verbal) feedback from EPA Regions and States (Appendix, Table 2). Copies of these written communications, as well as the memorandum that was sent to Regions requesting feedback, are available at the Six-Year Review [OW-2002-0012] Water Docket, U.S. Environmental Protection Agency; 1301 Constitution Avenue, NW, EPA West, Room B-102, Washington, DC 20460; (202) 566-2426 between 8:30 a.m. and 4:30 p.m. Eastern Time, Monday through Friday, excluding Federal holidays.

The regulatory implementation issues that EPA considered during the 1996-2002 review cycle are summarized in this report. In response to public comments received regarding the April 17, 2002 *Federal Register* notice in which EPA announced its preliminary revise/not revise decisions, this document has been amended to provide clarifications on Agency rationale and findings regarding the various implementation-related issues that were discussed by EPA Regions and States (67 FR 19030 (USEPA, 2002)). Specifically, EPA has added summary tables to this document (see Appendix), which provide a concise depiction of the issues raised and the Agency's current stance on these issues. Other clarifying language has also been added where necessary, throughout the document. The EPA Implementation Sub-Team Workgroup's (consisting of EPA HQ and Regional representatives) positions regarding each of the issues can be found within each of the topical sections of this document. In sections 2 through 8 of this document, a background issue description is provided, followed by a more detailed summary of the Region/State feedback, and EPA's positions on each of the issues raised.

Although EPA received some additional comments (Appendix, Table 3) from the public regarding implementation issues following the April *Federal Register* notice, most issues

overlapped with those raised prior to the Agency's preliminary decisions. For a summary of the public comments regarding implementation issues, and EPA's response to those comments, readers can reference the April 17, 2002, Federal Register notice, or they can obtain a copy of the document: *Public Comment and Response Summary for the Six-Year Review of National Primary Drinking Water Regulations* (USEPA, 2003).

2.0 Compliance Monitoring and Reporting

2.1 Issue Description

In developing the NPDWRs, EPA established monitoring requirements for contaminants, including frequency and location of sampling. The Agency's general monitoring framework for these chemical contaminants is referred to as the Standard Monitoring Framework (SMF). This framework consists of required compliance monitoring every three, six, and nine years, depending on the occurrence of regulated contaminants, and the issuance of waivers by States. EPA has allowed the use of grandfathered data for some contaminants, and has a process for allowing States to issue waivers to public water systems (PWSs) for the regulated chemical contaminants (see 40 CFR §§141.23 and 141.24).

Many commenters suggested that compliance monitoring schedules and waiver issuance, as currently structured, provide inadequate flexibility, and/or are inconsistently applied across different types of PWSs and different contaminant groups. Most commenters would like to see more consistent application of the regulations. Some commenters also expressed interest in reducing recordkeeping and reporting requirements to alleviate the burden on States and PWSs.

2.2 Summary of Comments and EPA Responses

2.2.1 Flexibility of Monitoring Schedules

Comment Summary: Several commenters suggested that current monitoring requirements (and more specifically, triggers for increased monitoring, reduced monitoring, and routine monitoring) provide inadequate flexibility, and/or are inconsistently applied across different types of PWSs (e.g., ground water vs. surface water, or community vs. non-community) and different contaminant groups. Several commenters stated that there is a need to have more consistent application of the regulations, particularly for chronic contaminants where maximum contaminant levels (MCLs) are based on lifetime exposure to contaminants. Related to this, commenters suggested that, to conserve State and PWS resources, new contaminant monitoring schedules should be coordinated with existing contaminant schedules in the SMF. Finally, others commented that the new rules should allow for reductions in monitoring for a variety of contaminants, particularly those determined to be chronic or naturally-occurring (e.g., arsenic and fluoride), and that such contaminants should not need to be monitored quarterly.

Agency Response: The Agency agrees that consistency across regulations is desirable to the extent that it does not jeopardize public health protection or the environment. As part of the Advanced Notice of Proposed Rulemaking (ANPRM) for the Chemical Monitoring Reform (CMR) (62 FR 36099, July 3, 1997 (USEPA, 1997a)), EPA considered some of these consistency issues. However, during the comment period for the CMR, stakeholders generally indicated that the existing monitoring framework was sufficient. Most State commenters indicated that it would be too burdensome to adopt CMR. As a result, the Agency decided to take no further action on the CMR. However, the Agency established an SMF which applies to all of the regulated chemical and radiological contaminants (except lead and copper). The new chemical and radiological rules that EPA has promulgated (e.g., arsenic and radionuclides) are coordinated with the SMF. The Agency made special efforts to ensure that the reduced monitoring periods are in line with the three-year compliance periods in the SMF.

EPA intends to consistently implement compliance determination provisions for inorganic chemicals (IOCs), synthetic organic chemicals (SOCs), and volatile organic chemicals (VOCs) for all non-transient, non-community water systems (NTNCWSs) and community water systems (CWSs), as described in the preamble to the Final Arsenic Rule (66 FR 6975 at 6990, January 22, 2001 (USEPA, 2001)). The rule requires compliance determinations to be based on a running annual average. The clarifications to compliance determinations for SOCs, IOCs, and VOCs are based on the average of the initial MCL exceedance and any subsequent State-required confirmation samples. States have the flexibility to require confirmation samples and more frequent monitoring, in addition to required quarterly samples. The average of the exceedance and confirmation samples constitutes the first quarterly sample. Compliance with the MCL is based on the average of the first quarterly sample and three additional samples over a period of one year, unless any one quarterly sample would cause the running annual average to exceed the MCL. Then the system is out of compliance immediately.

With respect to flexibility for States in determining reduced monitoring schedules: although the Agency understands the need for PWSs to reduce monitoring where possible, if a PWS is exceeding an MCL, there is a public health threat and the PWS should monitor on a quarterly basis or install treatment. Moreover, for an acute contaminant, such as nitrate, the Agency believes that regular monitoring is important to characterize any variations in contaminant concentrations that may exceed levels of public health concern. Quarterly monitoring is a tool for States and EPA to track non-compliance with MCLs, as well as to encourage systems to rectify the problem as expeditiously as possible. However, States have the flexibility to evaluate situation-specific circumstances and reduce monitoring, and/or waive the sampling requirements for any given contaminant after minimum criteria are met to demonstrate that the system is reliably and consistently below the MCL and/or not vulnerable to contamination.

Commenters expressed interest in reducing recordkeeping and reporting requirements to alleviate the burden on States and PWSs. State-related reporting and recordkeeping requirements are part of 40 CFR §142, and thus are outside the scope of the Six-Year Review.

The subject of the Six-Year Review, as specified in section 1412(b)(9), is "each national primary drinking water regulation." The NPDWRs are found in part 141. Part 142 governs largely procedural matters, such as primacy, variances and exemptions. While EPA can and does periodically consider changes to the part 142 provisions, such review is not governed by section 1412(b)(9) and so is not part of the Six-Year Review protocol.

2.2.2 Waiver Issuance and Vulnerability Assessment

Comment Summary: Several commenters pointed to a need for broader flexibility in determining not only the appropriate timing for contaminant monitoring, but also in identifying which contaminants need to be monitored. Specifically, commenters indicated that systems should not be required to monitor for contaminants that are not found in their geographic areas, as based on previous monitoring results, source water assessment data, vulnerability assessments, and hydrogeology. Commenters also indicated the need for flexibility in setting the vulnerable times for pesticide monitoring, based on area-specific temporal patterns.

Agency Response: EPA believes that the existing waiver provisions in the SDWA regulations give States sufficient flexibility to reduce or potentially eliminate monitoring of a chemical contaminant, where appropriate. States that have primacy for the drinking water regulations are responsible for their waiver programs and can grant waivers if a particular pesticide or herbicide has not been previously used, manufactured, stored, transported, or disposed in the area; a system's source water is not susceptible to contamination from the chemical; or the State has determined the system is not vulnerable. The State can grant waivers for individual contaminants, a group of contaminants, or issue an area-wide waiver (see 40 CFR §§141.23 (b) and (c), and 141.24 (f) and (h)). In addition, States can adopt alternative monitoring strategies, as long as the approach is as stringent as the Federal requirements (USEPA, 1997b).

With respect to flexibility in determining vulnerable periods for pesticides: the Agency notes that statistical studies of sampling strategies in surface water (Battaglin and Hay, 1996) have shown that incorporating sampling during spring and early summer runoff periods provides a more accurate representation of annual occurrence than random quarterly sampling (that may avoid these months). Ground water studies (Pinsky *et al.*, 1997) suggest that the more vulnerable ground water settings also show peaks during these periods. EPA is currently looking at the vulnerability assessment issue through another mechanism. The Agency will prepare a comprehensive report on PWS vulnerability to the range of potential drinking water contaminants. The comprehensive report will present approaches to applying vulnerability concepts to drinking water programs.

3.0 Lead and Copper Rule Requirements

3.1 Issue Description

EPA published revisions to the Lead and Copper Rule (LCR) on January 12, 2000 (65 FR 1950 (USEPA, 2000a)). The revisions were designed to streamline monitoring and reporting burdens for PWSs and State drinking water agencies. As part of these revisions, EPA added language to the LCR which clarifies requirements and corrects oversights in the original rule. The revisions do not affect the lead and copper maximum contaminant level goals, action levels, or other basic regulatory requirements for monitoring of lead and copper at the tap and optimizing corrosion control.

Commenters made numerous suggestions for further streamlining the monitoring, recordkeeping, and reporting requirements of the LCR. As noted above, State recordkeeping and reporting requirements are outside the scope of the Six-Year Review, as they are part of 40 CFR §142.

3.2 Summary of Comments and EPA Responses

3.2.1 Suggestions for Cost and Burden Reduction

Comment Summary: Commenters made several suggestions on ways to reduce burden to PWSs and States, including: reducing monitoring requirements, providing monitoring waivers, discontinuing the copper NPDWR or changing it to a secondary standard, and moving lead and copper onto the SMF schedule of sampling once every 3/6/9 years. Commenters suggested that EPA review the NTNCWS sampling and mitigation requirements to allow for meaningful application of the rule at these systems.

Agency Response: EPA reduced the monitoring requirements for lead and copper in the January 2000 revisions to the LCR and does not believe that further reductions, particularly for copper, can be made without undermining the level of public health protection, which is prohibited by SDWA. Regarding monitoring requirements for lead in the LCR, the Agency believes that any further reductions in monitoring would not provide adequate public health protection for members of sensitive populations (*i.e.*, pregnant women and children six years of age or younger). However, if new peer-reviewed scientific information becomes available, it will be considered.²

² Peer-reviewed data are studies/analyses that have been reviewed by qualified individuals (or organizations) who are independent of those who performed the work but who are collectively equivalent (*i.e.*, peers) to those who performed the original work. A peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternative interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific major scientific and/or technical work products and of the documentation that supports them (USEPA, 2000c).

EPA considered special allowances for NTNCWSs as part of the January 2000 revisions to the LCR. However, EPA decided at that time to retain the original requirement because the Agency did not have sufficient scientific data that would support reasonable alternatives for all NTNCWSs.

The issues raised by the commenters were already considered by the Agency for the January 2000 revision to the LCR. At this time, the Agency has not received significant new information that suggests it is appropriate to revisit the LCR requirements. The Agency recognizes that the LCR is a challenging rule, but continues to believe that the public health objective addressed by the rule is as important and essential today as it was when the rule was first promulgated. However, the Agency recognizes that more research would be useful to obtain additional information that could be utilized to address some of the issues associated with the implementation of this rule.

3.2.2 Sampling Methodology and Strategy

Comment Summary: Commenters suggested that the current sampling strategy limits a PWS operator's ability to identify sampling sites. The commenters noted that the current "tiered approach" to sampling plans, which is designed to target sites likely to have high levels of lead at the tap, has raised public concern about why locations where children are more likely to be exposed to lead and copper (such as schools and day care centers) are not better sampling points. In addition, a commenter indicated that the current corrosion control strategies are marginally effective at preventing particulate lead and copper from entering the water supply and recommended that EPA consider methods for mitigating the release of insoluble components from plumbing fixtures. Commenters also recommended that water systems be allowed to conduct water quality parameter (WQP) monitoring in lieu of continued lead and copper tap monitoring.

Agency Response: The Agency considered modifying the sampling protocol as a part of the January 2000 revisions to the LCR but did not believe that there was sufficient scientific data on which to base a revised protocol. EPA currently believes that regularly utilized household taps are the most appropriate sampling locations to determine whether consumers are being exposed to high levels of lead and copper in drinking water. If a PWS does not have enough sites that meet the tiering criteria, the January 2000 revisions to the LCR provide PWSs with the authority to complete their sampling pool with representative sites throughout the distribution system. At this time, EPA does not have any new information that demonstrates that sampling at other locations (which might be more within the control of the PWS operator), or that modifying the sampling protocol would maintain the same level of public health protection. However, if new peer-reviewed scientific information becomes available, it will be considered.

Regarding the suggestion that schools or day-care centers may be better sampling sites, the Agency notes that the LCR is designed to address system-wide problems with lead and copper contamination. The rule does not specifically target particular structures, such as

schools, but rather contains a monitoring protocol designed to ensure that the overall levels of lead and copper system-wide are minimized. Once optimal treatment is implemented, any remaining problems with elevated lead levels in schools may be due to plumbing, coolers, or other materials in the building. These potential sources of lead in schools are of concern and for this reason are explicitly addressed under the provisions of the Lead Contamination Control Act of 1988 (LCCA) (sections 1461 to 1465 of SDWA). The LCCA directed EPA to publish a guidance manual and testing protocol to assist States and schools in identifying sources and determining the extent of lead contamination in school drinking water and, if necessary, in remediating such contamination. In January 1989, the Agency published and distributed the guidance manual, "Lead in School's Drinking Water," to States and schools. In 1994, the Agency updated and revised the guidance manual entitled "Lead in Drinking Water in Schools and Non-residential Buildings." A copy of this manual may be obtained from the Safewater website <http://www.epa.gov/safewater/consumer/leadinschools.html>. In addition, the LCCA imposed a ban on the manufacture and sale of water coolers that are not lead free. The LCCA requirements are independent of the NPDWRs and therefore are not addressed under the Six-Year Review process. However, the Agency is continuing to work with schools and States to address problems dealing with lead in school drinking water.

EPA recognizes that the release of insoluble particulate material containing lead and copper can be an issue in some water systems. While more research may be of interest to improve optimization of corrosion control approaches with respect to this source, EPA expects that evaluations and pilot studies by water systems should include testing and consideration of the relative effectiveness of different treatments towards particulate release in systems for which it is important.

EPA does not feel that WQP monitoring is an appropriate substitute for lead and copper tap monitoring. Significant treatment changes or water chemistry disturbances (such as new water sources, major pH/coagulation changes, disinfectant changes, or seasonal water/treatment changes) can influence the effectiveness of corrosion control, which in turn will require appropriate adjustments of treatment. Current regulations require water systems to continue monitoring lead and copper levels to assure that water quality changes adversely affecting the presence of these contaminants in the drinking water are detected and to assure that appropriate adjustments to maintain optimal corrosion control are made.

4.0 Monitoring for Cyanides

4.1 Issue Description

EPA published the current NPDWR for cyanide on July 17, 1992 (57 FR 31776 (USEPA, 1992)). Under this regulation, PWSs may receive a waiver for cyanide monitoring. Without a waiver, ground water systems are required to monitor for cyanide once every three years, while

surface water systems are required to monitor annually. All samples must currently be collected from the entry point to the distribution system (EPTDS).

Comments regarding cyanide addressed the possibility of raw water monitoring due to possible formation of cyanogen chloride after chlorination. Other commenters identified the need for a rule revision relating to an error in the Best Available Technology (BAT) specified for cyanide in the Code of Federal Regulations (CFR).

4.2 Summary of Comments and EPA Responses

Comment Summary: A variety of comments were received on the cyanide issue, ranging from those that believe that no further expansion of cyanide monitoring is needed to a commenter who believes monitoring of cyanide and nitrites is the "second highest priority." It was suggested that the Agency consider requiring cyanide monitoring in raw water, since monitoring treated water (*i.e.*, after chlorine disinfection) provides no useful data on the presence of cyanogen chloride formation after chlorination. One commenter believed the treatment of raw water containing cyanide should be addressed as a regional issue, particularly for many western States. Another commenter expressed concern that monitoring for cyanide in raw water would "skew the analysis of risk reduction" and would potentially take away the ability to identify contaminant levels to which consumers are actually exposed. This commenter also recommended that it might be better to "use raw water monitoring as a screen, and only require treated water testing when there is a detect." One commenter pointed out that the BAT for cyanide had been clarified as being alkaline chlorination in an EPA advisory, and should be changed in the regulation.

Agency Responses: Regarding cyanide monitoring issues: EPA has not received any new data and recognizes that more research may be needed to determine the extent of the problem. If further research indicates this is a widespread and high-priority issue, then the Agency may consider it in an upcoming rulemaking (e.g., Distribution System Rule). EPA suggests that PWSs and States with cyanide and/or cyanogen chloride problems should take advantage of information in the "Public Water System Warning" Memo (USEPA, 1994), which deals directly with this issue. In addition to the required monitoring, States also have the flexibility to monitor raw source water samples for cyanide as well as monitor for cyanogen chloride in the distribution system.

EPA acknowledges that in 40 CFR §141.62(c), the BAT incorrectly specifies "chlorine" for cyanide. It should specify "alkaline chlorination." EPA plans to correct this error through a technical amendment to the cyanide NPDWR in the future. In the meantime, water systems and States should continue to be guided by the small system compliance technology list published September 1998, which correctly lists the technology as alkaline chlorination and the "Public Water System Warning" Memo (USEPA, 1994; USEPA, 1998).

5.0 Monitoring for Nitrites

5.1 Issue Description

EPA published the current NPDWR for nitrite on January 30, 1991 (56 FR 3526 (USEPA, 1991)), establishing an MCL of 1.0 mg/L, and the requirement that all PWSs must monitor for nitrite at each EPTDS. States cannot issue waivers for nitrite monitoring. The federal regulations required that one nitrite sample be collected in the 1993 to 1995 compliance period. If results were less than ½ the MCL, future nitrite monitoring was left to the discretion of the State. Many States do require their PWSs to monitor for nitrite once every three years, on the same monitoring schedule as all other IOCs (except nitrate, which, based on monitoring results, is required quarterly or annually for all systems). As with cyanide monitoring, nitrite samples are required by the federal regulations to be collected at the EPTDSs. However, for PWSs which have a sufficiently high level of ammonia in their water, nitrite may be found at elevated levels in distribution systems, not at the EPTDSs. In the presence of a sufficient amount of a strong oxidant (e.g., chlorine dioxide, free chlorine, or ozone), nitrite can be oxidized to nitrate.

Comments regarding nitrite monitoring included requests for more flexibility in determining sampling location. With more flexibility, commenters suggested that States could make situation-specific adjustments to monitoring location based on monitoring results or concern over elevated nitrite levels due to chloramination.

5.2 Summary of Comments and EPA Responses

Comment Summary: Several commenters recommended that EPA provide States with the flexibility to require routine nitrite monitoring in the distribution system (rather than the EPTDS) when it appears to be the most appropriate location for that contaminant, and to require raw water sampling for ammonia when appropriate. Commenters believe that changing the sampling point from the EPTDS to some point in the distribution system will affect PWSs with high levels of ammonia in raw water, especially if treatment installation is required. Another commenter recommended that EPA consider requiring distribution monitoring if an entry point result is greater than 50 percent of the MCL. Other commenters reported that chloramination may increase the likelihood of finding elevated nitrite levels in distribution systems, and that it would therefore seem reasonable to require monitoring in finished water where nitrite levels would be highest.

Agency Responses: As stated above, although free chlorine and other strong oxidant disinfectants will usually oxidize nitrite to nitrate in a water sample, EPA believes that this may not occur in all chlorinated water supplies. This issue was addressed by the Agency in the *Federal Register* notice entitled *Analytical Methods for Chemical and Microbiological Contaminants and Revisions to Laboratory Certification Requirements* (64 FR 67449, December 1, 1999 (USEPA, 1999)). Some research is underway, as part of the Distribution System Rule

development, to look at the nitrification issue. However, EPA recognizes that more data/research may be necessary. If further research indicates that this is a widespread issue, the Agency may consider it in an upcoming rulemaking.

6.0 Monitoring and Public Notification for Fluoride

6.1 Issue Description

Fluoride is unique as a drinking water contaminant because of its beneficial effects at low level exposures, and because it is voluntarily added to some drinking water systems as a public health measure for reducing the incidence of cavities among the treated population. EPA is currently reviewing the health effects of fluoride.

As part of the review of possible "other regulatory revisions," EPA has identified two possible issues related to the regulation of fluoride in drinking water. The first issue is related to the timeliness of the public notification requirement associated with exceedances of the secondary maximum contaminant level (SMCL). PWSs are required to notify the public if the fluoride SMCL is exceeded within 12 months of the initial exceedance.

The second pertains to the issue that current monitoring for fluoride may not be sufficient for systems that fluoridate. Under the current regulations, ground water systems are required to monitor for fluoride once every three years and surface water systems to monitor annually. This monitoring scenario is consistent with monitoring requirements for other naturally-occurring IOCs (other than lead and copper) but does not consider the addition of fluoride for beneficial purposes that occurs at some water systems.

6.2 Summary of Comments and EPA Responses

Comment Summary: Commenters expressed concern about the timeliness of the public notification (PN) requirement associated with exceedances of the SMCL. Currently, as stated above, PWSs that exceed the fluoride SMCL of 2.0 mg/L are required to notify their customers within 12 months of the exceedance. Concern has been raised that this requirement is not sufficiently timely since dental fluorosis occurs as a result of exposure to high levels of fluoride while the tooth enamel is being laid down. Waiting 12 months to provide PN means that young children may be exposed to high levels of fluoride during the time at which they are most vulnerable.

Commenters raised concern that the current monitoring for fluoride may not be sufficient for systems that fluoridate. More frequent monitoring may be necessary for systems that fluoridate because fluoride does not degrade or decrease in concentration in the distribution system (unlike chlorine). In particular, concentrations of fluoride may increase above acceptable

levels where evaporation of water may occur, such as in a storage tank. Thus, commenters are suggesting that more frequent monitoring may be appropriate to ensure that this does not occur.

Agency Response: Although PN requirements are not part of the NPDWR for fluoride, and are thus outside of the scope of this review, EPA will consider revisions to the fluoride PN requirements only if it becomes appropriate to revise the fluoride NPDWR in the future. As noted above, EPA is currently evaluating the health effects of fluoride and will reconsider whether to revise the fluoride NPDWR as part of the next Six-Year Review once the health effects review is completed. Similarly, when EPA reconsiders the fluoride NPDWR based on the health effects review, EPA will consider the suggestion that more frequent monitoring may be necessary for systems that fluoridate because fluoride does not degrade or decrease in concentration in the distribution system.

7.0 Consumer Confidence Report and Public Notification Requirements

7.1 Issue Description

EPA requires CWSs to develop annual drinking water quality reports for distribution to their customers. Consumer Confidence Report (CCR) and PN requirements are national in scope, with CCR issues affecting only CWSs, and PN issues affecting all PWSs. Changes to CCR and PN requirements affect State drinking water agency oversight and compliance determination activities, and affect the level of reporting burden for PWSs nationwide. CCR requirements do not apply to NTNCWSs and transient, non-community water systems (TNCWSs).

7.2 Summary of Comments and EPA Responses

Comment Summary: Several commenters believed that CCR language requirements are too prescriptive, and do not provide States with enough flexibility. Commenters believed that EPA should review the CCR requirements to ensure that flexibility is retained. Some commenters expressed concern that the inclusion of mandatory language reduces the "readability" of the document for the general public. Commenters also believed that CCR and PN requirements should be consistent with one another, and that PN requirements should be simplified, or even eliminated, because the PN requirements generate additional paperwork and create unnecessary violations that have no impact on public health.

Agency Response: The Agency does not consider the recently published CCR and PN Rule requirements to be part of the NPDWRs, as defined under section 1401 of SDWA. Moreover, these rules have only been recently promulgated or revised. As a result, many States are just beginning the adoption and implementation phases of the new rules. Therefore, revisions to the rules at this time would not be appropriate.

8.0 Re-Evaluation of Risk for Requiring NTNCWS Monitoring

8.1 Issue Description

In general, NTNCWSs are subject to the same monitoring and reporting requirements as CWSs. Some commenters suggested that EPA conduct risk and exposure assessments to determine whether NTNCWSs should continue to be regulated in the same manner as CWSs (which tend to serve a larger proportion of the population over longer time periods).

8.2 Summary of Comments and EPA Responses

Comment Summary: Some commenters suggested that EPA conduct additional research on the amount and percentage of water consumed at NTNCWSs and establish a risk assessment for individuals using these types of systems. Others recommended that EPA work with States and other stakeholders to develop a consistent approach to regulating NTNCWSs. One specification was that EPA needs to review non-acute contaminants in order to assure that the limited exposure associated with NTNCWSs actually presents a health risk worthy of regulation.

Agency Response: NTNCWSs are traditionally regulated for chronic contaminants. However, the Agency is currently evaluating risk and exposure as they pertain to NTNCWS monitoring requirements. This review will not be completed in time for this Six-Year Review process. Until all the issues have been identified and specific options have been formulated, it will not be clear if a revision to regulations is indicated.

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APPENDIX

The following tables provide a brief summary of the major implementation issues that were identified by EPA HQ's, EPA Regions and States, along with EPA's general findings related to each issue.

Appendix Table 1: Implementation Issues Identified by Headquarters in the December 12, 2000 Memo to Regions			
Implementation Issues	Commenter(s)	Findings	Recommended Action
Monitoring for Cyanide	<p><i>Two Regions</i> - Need more data.</p> <p><i>One Region</i> - No. 3 Priority.</p> <p><i>One State</i> - Did not support.</p> <p><i>One State</i> - Need more data.</p> <p><i>One association</i> - Allow State flexibility to require if necessary.</p>	<p>Place in the "Need More Research" Box.</p> <p><i>OR</i></p> <p>Allow State flexibility to require source water samples but not mandatory monitoring.</p> <p>POSSIBLE Priority</p>	<p>Need more data or research to determine if this is a big issue. If further research indicates this is an issue. Possibly address in an upcoming rule (e.g., Dist. System Rule).</p>
Monitoring for Nitrites	<p><i>One Region</i> - No. 2 Priority.</p> <p><i>One Region</i> - Supports distribution system monitoring.</p> <p><i>One Region</i> - Chlorine residual oxidizes nitrite and systems should not be required to monitoring.</p> <p><i>One State</i> - Need more data.</p> <p><i>One State</i> - Supports.</p> <p><i>One association</i> - Supports but also had some State support for reducing frequency.</p> <p><i>One State</i> - Require dist. system samples if EPTDS is >50% MCL.</p> <p><i>One Region</i> - Need more data, but would support.</p> <p><i>One State</i> - Allow reduced monitoring (SMF).</p>	<p>Place in the "Need More Research" box.</p> <p><i>OR</i></p> <p>Allow State flexibility to require distribution system samples but not mandatory monitoring.</p> <p>POSSIBLE Priority</p>	<p>Some research is underway but need more data or research. If further research indicates this is an issue. Possibly address in an upcoming rule (e.g., Dist. System Rule).</p>
Pesticide Monitoring	<p><i>One Region</i> - Important to tailor monitoring requirements.</p> <p><i>One Region</i> - Support.</p> <p><i>One State</i> - Agree with tailored monitoring but difficult to implement.</p> <p><i>One State</i> - Compliance should be based on annual exposure, not one sample</p>	<p>Conceptually good idea but implementation road block.</p>	<p>No further action recommended.</p>

**Appendix Table 1: Implementation Issues Identified by Headquarters
in the December 12, 2000 Memo to Regions**

Implementation Issues	Commenter(s)	Findings	Recommended Action
	during vulnerable period. But would like flexibility to require targeted monitoring. <i>One association</i> - Support flexibility but not reg's. <i>One Region</i> - Agree, but difficult to implement.		
Period of compliance		Taken care of in Arsenic and Radionuclides Rules.	No further regulatory action required.
Waiver guidance	<i>One Region</i> - No comments. <i>One Region</i> - Supports use of Source Water Assessment and Protection (SWAP). <i>One State</i> - Supports use of SWAP. <i>One association</i> - Not a priority. <i>One Region</i> - Not a priority.	Program in place and operational. No action necessary. Existing tools are being used.	No further regulatory action required.
New system/source monitoring		Resolved in Arsenic and Radionuclides Rules.	No further regulatory action required.
PN for Fluoride Secondary Standard	<i>One Region</i> - No. 1 priority (believe national problem). <i>One Region</i> - Current requirement adequate. <i>One State</i> - Seems to prefer only one standard at SMCL. <i>One State</i> - Supports Tier 2 for SMCL violations (but notification close to time of occurrence). <i>One association</i> - Do not support. <i>One Region</i> - Defer to health effects team. <i>One State</i> - Does not support federal regulation.	Potential national issue - priority unclear.	Evaluate if fluoride selected for revision.

**Appendix Table 2: Additional Written and Verbal Implementation Issues
Submitted by EPA Regions and States**

Implementation Issues	Commenter(s)	Findings	Recommended Action
40 CFR 141 (System requirements)			
Violation determination <ul style="list-style-type: none"> Multiple entry points Provide regulatory clarification 	<i>One Region</i> <i>Two States</i>	Resolved in Arsenic and Radionuclides Rule for all chem/rads.	No further action needed.
Consistent Compliance Monitoring <ul style="list-style-type: none"> Triggers Frequency - increased, routine, reduced Simplify for all source, cont., system size, etc Allow monitoring at locations other than EPTDS 	<i>Two Regions</i> <i>Two States</i> <i>One association</i> <i>One State</i>	HIGH Priority but no new information provided since CMR dismissed. Also, most States have dismissed CMR as too much burden. Monitoring at EPTDS was addressed in Arsenic preamble. State may designate an alternate sampling location if approved in primacy package.	No further action on CMR related issues. Remaining high priority issues - keep in mind for future rule making.
Simplify Monitoring for IOC, SOC, and VOC <ul style="list-style-type: none"> Base on Health Risks More prescriptive language to assist in enforcement of monitoring Allow annual monitoring for IOCs that exceed the MCL 	<i>One Region</i> <i>One State</i> <i>One State</i>	These concepts already covered above - like CMR issues.	No further action on CMR related issues.
Require monitoring for seasonal Transient Non-Community Water Systems (TNCWS) prior to opening (more of an issue for microbials)	<i>Three Regions</i>	HIGH Priority	Possibly revise in a future rule (e.g., Total Coliform Rule (TCR) revisions).
New System/Source Monitoring Requirements <ul style="list-style-type: none"> No deadline to complete SWAPS 	<i>One Region</i> <i>Two States</i>	Resolved in Arsenic and Radionuclides Rule (Only for Chems/Rads, not for Pb/Cu), but most States have program.	No further regulatory action required at this time.
Regulatory Method Detection Limits' (MDLs) > trigger levels? (primarily SOCs - some States see this and some do not)	<i>Two Regions</i>	Resolved in workgroup - and decided to leave it alone because there have been memos and some guidance to address this. No new information provided to resolve issue.	No further action necessary at this time.

**Appendix Table 2: Additional Written and Verbal Implementation Issues
Submitted by EPA Regions and States**

Implementation Issues	Commenter(s)	Findings	Recommended Action
Revise PN language, CCR Requirements and notification requirements	<i>One Region Two States One association</i>	Refer to Chem/Rad Team for evaluation.	Evaluate in Chem/Rad Team Vehicle. Outside scope of Six-Year Review because not an NPDWRs.
Revise Lead and Copper Rule <ul style="list-style-type: none"> • Monitoring requirements and sampling locations • High lead source water • Systems w/ 1-4 taps? • Allow waivers • Make Copper-Action Level • Revise optimization requirements • Include lead and copper in SMF 	<i>One Region Three States One association</i>	Resolved in workgroup discussion to leave it alone; most of these issues were addressed in the Pb/Cu Minor Revisions rule (one way or another) and no new data has been presented to merit reopening.	No regulatory action required at this time; EPA placed in data gaps category to research LCR implementation issues
Reevaluate risk of requiring NTNCWS to monitor for all chronic contaminants	<i>Two Regions Three States One association</i>	HIGH Priority Consistency issue.	Being evaluated by a separate workgroup.
Evaluate Phthalate "false positives"	<i>Two Regions One State One association</i>	HIGH Priority	Use laboratory certification newsletters to remind laboratories of problem. Possibly address in a future methods update rule.
Extend GUDI (Ground Water Under Direct Influence) determination deadline	<i>One State</i>	Not a priority. Extending deadline is not more protective of public health.	No regulatory action at this time.
Eliminate POU/POE (Point-of-Use/Point-of-Entry) treatment alternate	<i>One State</i>	Evaluate in future rules.	Keep in mind for evaluation in future rules. Use of POU (Point-of-Use) is being evaluated by a separate workgroup.
Define Consecutive Systems <ul style="list-style-type: none"> • M/DBP - chlorine residual as it moves through dist. system 	<i>One Region</i>	Workgroup decided that we have no new information to evaluate to resolve.	FACA (Federal Advisory Committee Act) recommendation that EPA address in LT2 ESWTR (Long Term 2 Enhanced Surface Water Treatment Rule).

**Appendix Table 2: Additional Written and Verbal Implementation Issues
Submitted by EPA Regions and States**

Implementation Issues	Commenter(s)	Findings	Recommended Action
40 CFR 142 (State Primacy)			
State Specific Monitoring Waivers <ul style="list-style-type: none"> Use SWAP's for vulnerability assess Allow region to issue waivers Allow State wide waivers 	<i>One Region One State</i>	Outside scope of Six-Year Review because not an NPDWR requirement.	No further regulatory action required.
Revise Primacy Requirement <ul style="list-style-type: none"> Make less prescriptive 	<i>One State</i>	Outside scope of Six-Year Review because not an NPDWR requirement.	Evaluate in future rules.
Data reporting <ul style="list-style-type: none"> Limit reporting to critical data elements Have SDWIS operational within one month after FR Consistent reporting criteria for all similar rules 	<i>One Region Two States One association</i>	Outside scope of the Six-Year Review because part 142 - can be addressed through an alternative mechanism.	Referred to Strategic Information Plan - Stakeholder meeting held March 8-9, 2001 in Washington, DC.
Non-regulatory (EPA guidance)			
Definitions <ul style="list-style-type: none"> Return-to-Compliance (RTC) Compliance periods NTNCWS - # served No specific provisions for interstate carrier conveyances (ICCs) in 141 PWS and apartments Reliably and consistently below MCL 	<i>One Region One State One association</i>	<p>The Region and association strongly prefer regulatory language as opposed to guidance. BUT also want State flexibility.</p> <p>Address RTC and compliance periods in strategic plan for reporting requirements. Enforcement of these may be problematic.</p> <p>Leave NTNCWS and apartment PWS issues up to States. EPA guidance sufficient.</p>	Refer to Workgroup in place - Regions and States involved.
Implementation Guidance (IG) <ul style="list-style-type: none"> Finish IG within one week of final rule 	<i>One State</i>	Not a Six-Year Review issue. Refer to appropriate office.	Generally occurs 60 days after a final rule.

**Appendix Table 3: Implementation and Other Regulatory Revision Issues
Submitted as Comments to the April 17, 2002 *Federal Register* Notice**

Implementation Issues	Commenters	Summary of EPA Responses
Consistent Compliance Monitoring <ul style="list-style-type: none"> Use SMF 	<i>One association</i> <i>One State</i>	The SMF, established by EPA, applies to all of the regulated chemical and radiological contaminants (except lead and copper). In addition, the new chemical and radiological rules are coordinated with the SMF.
Simplify Monitoring for IOC, SOC, and VOC <ul style="list-style-type: none"> Consistent language for IOCs with VOC and SOC language from Arsenic Rule 	<i>Two associations</i> <i>One State</i>	EPA intends to consistently implement compliance determination provisions for IOCs, SOCs, and VOCs for all NTNCWSs and CWSs.
Public Notification and Consumer Confidence Report <ul style="list-style-type: none"> PN and CCR should be considered under the Six-Year Review 	<i>One State</i>	The CCR and PN Rules are not considered to be part of the NPDWRs, as defined under section 1401 of the SDWA.
Revise Lead and Copper Rule <ul style="list-style-type: none"> Release of insoluble components Use Water Quality Parameters as indicators/surrogate monitoring 	<i>One association</i> <i>One association</i> <i>One utility</i>	<ul style="list-style-type: none"> Evaluations and pilot studies by water systems should include testing and consideration of the relative effectiveness of different treatments towards particulate release in systems for which it is important. The Agency believes that the existing protocols as prescribed in the LCR, remain necessary and appropriate. EPA has placed LCR in data gaps category to research implementation issues.
Fluoride <ul style="list-style-type: none"> Do not require frequent monitoring for systems that fluoridate All fluoride issues should be determined at the local level 	<i>One association</i>	EPA is currently evaluating the health effects of fluoride and will reconsider whether to revise the fluoride NPDWR as part of the next Six-Year Review once the health effects review is completed.

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Consideration of Other Regulatory Revisions for Chemical Contaminants in Support of
the Six-Year Review of the National Primary Drinking Water Regulations