

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7529-1]

RIN 2040-AD67

National Primary Drinking Water Regulations; Announcement of Completion of EPA's Review of Existing Drinking Water Standards**AGENCY:** Environmental Protection Agency.**ACTION:** Notice.

SUMMARY: The Safe Drinking Water Act (SDWA) requires the United States Environmental Protection Agency (EPA) to conduct a periodic review of existing National Primary Drinking Water Regulations (NPDWRs). EPA has completed its review of 69 NPDWRs that were established prior to 1997, including 68 chemical NPDWRs and the Total Coliform Rule (TCR). The intended purpose of the review was to identify those NPDWRs for which current health risk assessments, changes in technology, and/or other factors, provide a health or technological basis to support a regulatory revision that will maintain or improve public health protection.

EPA published its protocol for the review of NPDWRs and its preliminary revise/not revise decisions for the 69 NPDWRs in the April 17, 2002, edition of the **Federal Register** (67 FR 19030 (USEPA, 2002g)) in order to seek comment from the public. Today's action briefly describes the major comments, other new information, and EPA's current revise/not revise decisions for the 69 NPDWRs.

ADDRESSES: The official public docket for this action is located at EPA West Building, Room B102, 1301 Constitution Avenue, NW., Washington, DC.

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I. General Information**A. Does This Notice Apply to My Public Water System?**

This action itself does not impose any requirements on anyone. Instead, it notifies interested parties of the availability of EPA's responses to comments received on EPA's Six-Year Review protocol and the Agency's current revise/not revise decisions for 69 NPDWRs.

B. How Can I Get Copies of Related Information?

1. Docket

EPA has established an official public docket for this action under Docket ID No. OW-2002-0012. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

2. Electronic Access

You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.B.1. Once in the system, select "search," then key in the appropriate docket identification number.

Abbreviations and Acronyms Used in This Action

BAT—best available technology
 CBI—confidential business information
 CCL—contaminant candidate list
 CFR—Code of Federal Regulations
 CMR—Chemical Monitoring Reform
 DACT—diaminobenzotriazine
 DEA—desethyl atrazine
 DEHA—di(2-ethylhexyl)adipate
 DEHP—di(2-ethylhexyl)phthalate
 DIA—desisopropyl atrazine
 EPA—United States Environmental Protection Agency

EPA/DC—EPA Docket Center
 FQPA—Food Quality Protection Act
 FR—**Federal Register**
 IOC—inorganic chemical
 IRED—interim reregistration eligibility decision
 IRIS—Integrated Risk Information System
 LCCA—Lead Contamination Control Act of 1988
 LCR—Lead and Copper Rule
 MCL—maximum contaminant level
 MCLG—maximum contaminant level goal
 MDL—method detection limit
 mg/kg/day—milligram(s) per kilogram of body weight per day
 mg/L—milligram(s) per liter
 MYP—multi-year plan
 NAS—National Academy of Sciences
 NCOD—National Contaminant Occurrence Database
 NDWAC—National Drinking Water Advisory Council
 NPDWR—National Primary Drinking Water Regulation
 NRC—National Research Council
 NTP—National Toxicology Program
 NTNCWS—non-transient non-community water system
 Occurrence Methodology Document—Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Review of Existing National Primary Drinking Water Regulations
 Occurrence Summary Document—Occurrence Summary and Use Support Document for the Six-Year Review of Existing National Primary Drinking Water Regulations
 OPP—Office of Pesticide Programs
 OW—Office of Water
 PE—performance evaluation
 PHS—Public Health Service
 PQL—practical quantitation level
 Protocol Document—EPA Protocol for Review of Existing National Primary Drinking Water Regulations
 RED—reregistration eligibility decision
 RfD—reference dose
 ROS—regression on ordered statistics
 RSC—relative source contribution
 SAB—Science Advisory Board
 SAP—Science Advisory Panel
 SDWA—Safe Drinking Water Act
 SOC—synthetic organic chemical
 TCR—Total Coliform Rule
 TMDLs—total maximum daily loads
 Treatment Feasibility Document—Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In Support of EPA Six-Year Review of National Primary Drinking Water Regulations
 TT—treatment technique
 VOC—volatile organic chemical
 WQP—water quality parameter
 WS—water supply

II. Background

A. What Is the Statutory Requirement for the Six-Year Review?

Under the Safe Drinking Water Act (SDWA), as amended in 1996, EPA must periodically review existing National Primary Drinking Water Regulations (NPDWRs) and, if appropriate, revise them. Section 1412(b)(9) of SDWA states:

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.

B. What Has the Agency Done To Address the Statutory Requirement?

The Agency developed a systematic process, or protocol, for the review of existing NPDWRs in accordance with the SDWA requirements and applied the protocol to the review of the NPDWRs for total coliforms and 68 inorganic and organic chemicals published prior to the SDWA 1996 Amendments (*i.e.*, pre-1997 NPDWRs). In the April 17, 2002, **Federal Register**, EPA provided:

- A description of the review protocol;
- A detailed discussion of how the protocol was applied in assessing each of the 69 pre-1997 NPDWRs;
- The preliminary results of each of the technical reviews, and the preliminary decision for each NPDWR; and
- A request for the public to comment on any aspect of the Agency's protocol and preliminary decisions.

Please refer to the April 17, 2002, **Federal Register** for the detailed discussion of EPA's revise/not revise decisions for each of the 69 NPDWRs. Today's action briefly summarizes the major public comments, other new information, and EPA's current revise/not revise decisions for the 69 NPDWRs. Today's action only discusses in detail those decisions or rationales that were affected by public comments or other new information that has become available since April 2002.

In June 2002, EPA consulted with the Science Advisory Board (SAB) Drinking Water Committee and requested their review and comment on whether the protocol EPA developed based on the National Drinking Water Advisory Council (NDWAC) recommendations was consistently applied and appropriately documented. The SAB provided verbal feedback regarding the transparency and clarity of EPA's

decision criteria for making its revise/not revise decisions under the current review. EPA has revised this protocol document to better explain how the decision criteria were applied and will also take the SAB comments into consideration when planning for the next review cycle.

III. EPA's Current Revise/Not Revise Decisions for the 69 Pre-1997 NPDWRs

EPA received comments from 44 commenters on its preliminary revise/not revise decisions in the April 17, 2002, **Federal Register**. The Agency responded to these comments in the "Public Comment and Response Summary for the Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2003e), which is available in the Water Docket in the EPA Docket Center and at the EPA Dockets Web site <http://www.epa.gov/epadocket/>. Other technical support documents¹ for the decisions discussed in today's action are also available in the Water Docket and at the EPA Dockets Web site <http://www.epa.gov/epadocket/> and the Safewater Web site <http://www.epa.gov/safewater/>.

Based on the Agency's preliminary review, as well as the public comments received and other new information, EPA believes that it is appropriate to revise the Total Coliform Rule (TCR). The Agency also believes that it is not appropriate to revise the 68 chemical NPDWRs at this time. However, for the reasons discussed in sections IV.B.7, IV.B.13, and IV.B.14 of today's action, the Agency has modified the basis of its not revise findings for 1,1-dichloroethylene, lead, and lindane, respectively. Table III-1 reflects the Agency's current revise/not revise decisions for the 69 NPDWRs. As indicated in Table III-1, EPA's decision not to revise an NPDWR at this time is based on one of the following reasons:

- Health risk assessment is in process: As of December 31, 2002, the Agency is currently conducting, or has scheduled, a detailed review of current health effects information. Because the results of the assessment are not yet available, or were not available in time for consideration under the 1996-2002 review cycle, the Agency does not believe it is appropriate to revise the NPDWR at this time. In these cases, EPA will consider the results of the updated

¹ These include: (1) EPA's overall protocol for the review of NPDWRs (USEPA, 2003c); (2) health effects (USEPA, 2003f); (3) analytical methods feasibility (USEPA, 2003a); (4) treatment technology (USEPA, 2003g); (5) consideration of other regulatory revisions (USEPA, 2003b); (6) occurrence and exposure (USEPA, 2003d; USEPA, 2002f); (7) and economic considerations (USEPA, 2002c).

health risk assessment during the 2002–2008 review cycle. If the results of the health risk assessment indicate a compelling reason to reconsider the maximum contaminant level goal (MCLG), EPA may decide to accelerate the review schedule for that contaminant's NPDWR.

- NPDWR remains appropriate after data/information review: The outcome of the review indicates that the current regulatory requirements remain appropriate, and therefore, no regulatory revisions are warranted. Any new information available to the Agency

either supports the current regulatory requirements or does not justify a revision.

- New information, but no revision appropriate at this time because:

- Low priority: In EPA's judgment, any resulting revisions to the NPDWR would not provide a meaningful opportunity for health risk reduction or result in meaningful cost-savings to public water systems and their customers. These revisions are a low priority activity for the Agency and, thus, are not appropriate for revision

at this time because of one or more of the following considerations: competing workload priorities; the administrative costs associated with rulemaking; and the burden on States and the regulated community to implement any regulatory change that resulted.

- Information gaps: Although results of the review support consideration of a possible revision, the available data are insufficient to support a definitive regulatory decision at this time.

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Table III-1: Current Revise/Not Revise Decisions for the 68 Chemical NPDWRs and the TCR

Not Appropriate for Revision at this Time	Risk assessment in process ¹ : chemical currently undergoing an EPA health risk assessment; includes the three initiated as a result of this review (34 NPDWRs)		Acrylamide Alachlor Antimony Asbestos Atrazine Benzo[a]pyrene Cadmium Carbofuran Carbon tetrachloride Copper Cyanide 2,4-D (2,4-Dichlorophenoxyacetic acid) 1,2-Dichlorobenzene 1,4-Dichlorobenzene 1,2-Dichloroethane Di(2-ethylhexyl)adipate Di(2-ethylhexyl)phthalate	Diquat Endothall Ethylbenzene Ethylene dibromide Glyphosate Methoxychlor Pentachlorophenol Polychlorinated biphenyls Simazine Styrene 2,3,7,8-TCDD (Dioxin) Tetrachloroethylene Thallium Toluene 1,1,1-Trichloroethane Trichloroethylene Xylenes
	NPDWR remains appropriate after data/information review (16 NPDWRs)		Barium Dalapon cis-1,2-Dichloroethylene trans-1,2-Dichloroethylene Dinoseb Endrin Epichlorohydrin Hexachlorocyclopentadiene	Mercury Monochlorobenzene Nitrate Nitrite Selenium 2,4,5-TP (Silvex) 1,2,4-Trichlorobenzene Vinyl chloride
	New information, but no revision appropriate because:	Low priority (14 NPDWRs)	Benzene Beryllium Chlordane 1,2-Dibromo-3-chloropropane 1,1-Dichloroethylene 1,2-Dichloropropane Heptachlor	Heptachlor epoxide Hexachlorobenzene Lindane Oxamyl Picloram Toxaphene 1,1,2-Trichloroethane
		Information gaps (4 NPDWRs)	Chromium Dichloromethane	Fluoride Lead
Candidate for Revision	Based on review of "other regulatory revisions" (1 NPDWR)		Total Coliform Rule (TCR)	

¹ As of December 31, 2002, the Agency is currently conducting, or has scheduled, a detailed review of current health effects information.

IV. Summary of Major Comments and New Information and the Agency's Response

This section summarizes the major public comments, including the Agency's response, and other new information, and explains any modifications to EPA's preliminary revise/not revise decisions. For a more detailed summary of the comments and the Agency's response, please refer to the document: "Public Comment and Response Summary for the Six-Year Review of National Primary Drinking Water Regulation" (USEPA, 2003e).

A. What Did Commenters Say Regarding the Reasonableness and Appropriateness of EPA's Six-Year Review Approach?

1. Overall Approach and Decision Criteria

a. Adequacy of the Review.

Commenters generally agreed that EPA had identified the appropriate key elements of the review. However, some commenters stated that the Agency could have done more in some areas (e.g., implementation) and a few commenters expressed the opinion that the Agency's review process contains weaknesses, or was not applied appropriately, because it did not identify any chemical NPDWRs for revision at this time.

EPA Response: The Agency believes that its basic review protocol and decision rationale are reasonable and appropriate. Even though EPA's application of the protocol did not identify any chemical NPDWRs for revision at this time, that is not a reason to reject or modify the protocol. The review did result in the initiation of health risk assessments for three contaminants and efforts to address data gaps/research needs for several other contaminants. Health risk assessments are underway for approximately half of the chemical contaminants addressed in today's action. The Agency expects most of these assessments to be completed within the next few years. When completed, these assessments will support further analysis that may result in different revise/not revise decisions as part of the ongoing Six-Year Review process.

b. Criteria for Deciding that an MCLG/MCL Revision is Appropriate and Definition of "Significant" and "Negligible." While some commenters agreed, others disagreed with the Agency's consideration of estimated changes in occurrence levels and available economic information whenever a health or technological basis exists to revise a standard. For example,

some commenters felt that EPA should revise the MCLG and, as appropriate, the maximum contaminant level (MCL), whenever a health basis exists, regardless of other considerations. A few commenters criticized the Agency for not defining what it considers "significant" and "negligible" gains in public health protection and/or cost-savings in terms of regulatory revision.

EPA Response: Section 1412(b)(9) of SDWA, as amended in 1996, provides the Administrator with broad discretion to determine when a revision to an NPDWR is appropriate. As a part of this determination, the Agency believes it is reasonable to consider whether a potential revision is likely to provide a meaningful opportunity for health risk reduction. This criterion is consistent with the statutory provisions governing the regulatory determination process under section 1412(b)(1)(A) for contaminants not currently regulated. EPA also believes it is reasonable to consider the extent of potential cost-savings for public water systems and their customers when determining whether revisions that potentially would result in a relaxed standard (i.e., where a health basis exists for a less stringent standard) or streamlined implementation are appropriate. These considerations allow the Administrator to better prioritize efforts that are most likely to result in a meaningful opportunity for health risk reduction or cost-savings to public water systems and their customers. Revisions that do not satisfy at least one of these criteria are a low priority activity for the Agency, and thus are not appropriate at this time because of one or more of the following considerations:

- Competing workload priorities;
- The administrative costs associated with rulemaking; and
- The burden on States and the regulated community to implement any regulatory change that resulted.

EPA believes that the determination of whether the impact of a potential revision is "significant" or "negligible" is a matter of judgment that depends on a number of variables, not all of which are amenable to precise definition. However, EPA recognizes that the use of "negligible/significant" terminology may imply more precision and quantitation in the determination than is possible. The Agency also understands that the use of the term "negligible" may imply to some that the Agency is belittling small gains in health risk reduction. This is not the Agency's intent. Accordingly, in today's action, the Agency has explained its rationale more clearly in terms of the criteria noted in the previous paragraph.

c. Authority to Relax an Existing Standard and Deregulation of Low/Non-Occurring Contaminants. Some commenters argued that the Agency should never consider relaxing a standard because doing so, by definition, would lessen the level of public health protection. Other commenters encouraged the Agency to actively consider deregulating contaminants that have low occurrence or do not appear to be occurring in finished water or, at a minimum, to further reduce the frequency of monitoring for these contaminants.

EPA Response: EPA disagrees with those commenters who oppose relaxing a standard for any reason. The legislative history of the SDWA Amendments of 1996 makes clear that Congress envisioned the possibility that a relaxed standard might be appropriate under circumstances that would not result in a lessening of the level of public health protection. In its discussion of potential revisions to an existing drinking water standard, Senate Report Number 104-169 (available electronically at <http://thomas.loc.gov/>) states:

Amendments made by the bill require that any future standard issued for a contaminant already regulated must maintain or provide for greater protection of the health of persons. Generally, this will preclude the promulgation of a revised standard for a contaminant that is less stringent than the standard already in place. However, there are circumstances under which a standard may be relaxed. The maximum contaminant level goal for a contaminant is set at a level at which there is no adverse effect on the health of persons with an adequate margin of safety. New scientific information may cause the MCLG to be revised and in some cases these revisions may be to less stringent levels. This may lead to a revision of the maximum contaminant level since it need be no more stringent than the MCLG. New information may also allow for a smaller margin of safety because it narrows the range of uncertainty for estimates of health risks. Finally, some substances which have been regulated as carcinogens for ingestion in drinking water may be reclassified (as asbestos has been in the most recent revision) or assigned a threshold for the effect based on new scientific information. In each of these cases, EPA may issue a revised standard for a contaminant that is less stringent than the one it replaces.

(S. Rep. 104-169, 104th Cong., 1st Sess. (1995) at 38)

However, because section 1412(b)(9) of SDWA requires that any revision to an existing NPDWR maintain or improve the level of public health protection, EPA believes that a clear, technically-based demonstration

regarding the absence of potential risk is necessary to deregulate a contaminant. EPA does not believe it is appropriate to deregulate any currently regulated contaminant at this time because the Agency is not able to make a determination, pursuant to section 1412(b)(9) of SDWA, that there would be no lessening of public health protection if the contaminant were deregulated. The Agency disagrees that evaluation of finished water data is sufficient to consider deregulation of low or non-occurring contaminants. The apparent low or non-occurrence of these contaminants in finished water may be the result of effective treatment processes in place rather than the lack of occurrence in source water.

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).

2. Health Effects Technical Review

a. Contaminants Undergoing Health Risk Assessments. A few commenters raised issues with respect to the 36 chemical contaminants for which health risk assessments were underway when EPA published its preliminary revise/not revise decisions in the April 17, 2002, **Federal Register**. In particular, these commenters wanted to know the process that EPA plans to follow to review each NPDWR once the risk assessment is completed, including when that review would occur and when an accelerated review would be appropriate.

EPA Response: Between April and August 2002, the Agency completed health risk assessments for 2 of the 36 contaminants: 1,1-dichloroethylene and lindane. The results of those assessments and the impact on the Agency's revise/not revise decisions are discussed in sections IV.B.7 and

IV.B.14, respectively, of today's action. NPDWRs for the remaining contaminants for which health risk assessments are in process will be reviewed as a part of the 2002–2008 review cycle. However, if in the Agency's judgment, a compelling reason exists to revisit the “not revise” decision sooner, EPA may accelerate the review cycle for that NPDWR. In reviewing these regulations, EPA expects to apply an approach consistent with the protocol used for the current review. That is, the Agency will consider the same key elements and apply the same basic decision tree for making a revise/not revise decision. The key elements of the review include health effects technical review, technology review, other regulatory revisions review, and, if appropriate, occurrence/exposure analyses and consideration of available economic information (*see* 67 FR 19030 at 19038, April 17, 2002 (USEPA, 2002g)).

b. Other Issues Related to the Health Effects Technical Review. One commenter stated that the Agency risk assessments underestimate risk because absorption of chemicals through the skin, lung, and nose is not “adequately” taken into account. Another commenter encouraged the Agency to evaluate the literature for potential reproductive and developmental effects for chemicals with zero MCLGs since risk management strategies, such as monitoring frequency or treatment requirements, may be affected by such information.

EPA Response: EPA disagrees that the Agency underestimates risk when deriving MCLGs. The Agency takes multiple routes of exposure into account by including a relative source contribution (RSC) in its calculation of an MCLG value. The RSC compares exposure from air, food, and drinking water and uses the data in allocating a portion of the total exposure to drinking water. When exposure data for the chemical are not available, EPA assumes that the RSC from drinking water is 20 percent of the total exposure. This allows 80 percent of the total exposure to come from sources other than drinking water, such as exposure from food, inhalation, or dermal contact.

EPA recognizes the possibility that some chemicals with zero MCLGs may also be of reproductive and/or developmental concern. EPA is investigating these endpoints and their potential impact on monitoring frequency or treatment requirements. However, the Agency does not believe the analysis can be completed during the current review cycle without significantly delaying the current revise/

not revise decisions. To the extent possible, EPA will consider the results of this analysis and any additional information during subsequent Six-Year Reviews.

3. Analytical Methods Feasibility Technical Review

Commenters generally supported the Agency's approach of using Performance Evaluation (PE) Water Supply (WS) data and the 10 times method detection limit (MDL) multiplier to evaluate possible changes in analytical feasibility for several of the contaminants under this Six-Year Review. A few commenters agreed that the WS data are a valuable source of information for evaluating interlaboratory performance and for developing practical quantitation levels (PQLs). However, the same commenters questioned whether the approach of using PE WS data will be possible for future reviews since the Agency's laboratory certification program that once collected this information has been externalized to private providers. These commenters questioned whether the externalized or privatized data would be sufficient for the determination and/or re-evaluation of PQLs. In addition, at least one commenter suggested that it may be appropriate (in the next Six-Year Review) to re-evaluate the policy of basing the PQL on only EPA Regional and State laboratory results, and recommended that the Agency include commercial and large utility laboratory results. According to the commenter, these laboratories (commercial and large utility) have demonstrated “significant innovation in method development and improved quantitation.”

EPA Response: EPA agrees that the WS studies have been a valuable source of information for determining PQLs. At this time, the Agency has not determined whether the privatized data will be sufficient for the purposes mentioned by the commenter. In addition, the Agency has not yet determined how best to gather data to determine and/or reassess PQLs for future reviews. The Agency is in the process of evaluating acceptable options. The policy for determining the most appropriate methodology for calculating PQLs for drinking water contaminants is outside the scope of the Six-Year Review.

4. Review of Treatment Technologies and Related Issues

Commenters suggested that, while EPA's review of existing NPDWRs was generally consistent with the NDWAC recommendations to EPA (NDWAC, 2000), the Agency's review of treatment

technologies which support the regulations should be expanded. Specifically, commenters recommended that EPA review all treatment technique (TT) requirements and allow for changing or expanding these TT requirements where new information warrants such a change.

EPA Response: EPA continues to believe its approach to reviewing TT requirements is appropriate. The "EPA Protocol for the Review of Existing NPDWRs" (Protocol Document) discusses when it is appropriate for the Agency to consider revisions to TT-type regulations (see sections II.C and III.B of the Protocol documents) (USEPA, 2002d; USEPA, 2003c). The Agency discussed the review of the four chemical treatment technique NPDWRs (*i.e.*, acrylamide, copper, epichlorohydrin, and lead) in both the draft and final "Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In Support of EPA Six-Year Review of National Primary Drinking Water Regulations" (Treatment Feasibility Documents) (USEPA, 2002b; USEPA, 2003g). The Agency has no specific information that provides a basis for revisions to TT requirements at this time. However, EPA believes that research data in a number of treatment-related areas may be useful in future reviews of NPDWRs. The Agency is committed to working with stakeholders to identify and prioritize treatment-related research needs, and to work with EPA's research partners to address the highest priority needs.

5. Review of Implementation-Related Issues

While several commenters felt overall that EPA's Six-Year Review protocol was reasonable and appropriate, they encouraged EPA to consider implementation-related modifications (*i.e.*, "other regulatory revisions") as a reason to revise a rule, even if there were no basis to revise the MCLG and/or MCL/TT requirements.

EPA Response: Implementation-related issues are the primary reason for the Agency's decision to revise the TCR at this time (67 FR 19030 at 19085, April 17, 2002 (USEPA, 2002g)), so it is clear that EPA considered implemented-related issues in its review. The Protocol Document (USEPA, 2002d; USEPA, 2003c) identifies the conditions under which the Agency will consider implementation-related revisions. EPA continues to believe these criteria are appropriate. During the current review, none of the identified potential implementation-related revisions pertaining to the chemical NPDWRs, in

EPA's judgment, met the stated criteria for reasons documented in EPA's final document, "Consideration of Other Regulatory Revisions for Chemical Contaminants in Support of the Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2003b).

6. Review of Occurrence and Exposure

a. Occurrence Database Concerns. A few commenters asked for information regarding next steps for the National Contaminant Occurrence Database (NCOD). Another commenter pointed out that States have been willing to assist EPA by providing occurrence data beyond what is required of them. However, the commenter raised concerns that he/she felt EPA needs to address to facilitate further data sharing.

Some commenters expressed concern about the completeness and representativeness of the 16-State data set used for the Six-Year Review. One commenter suggested that the Agency should have issued an Information Collection Request to obtain more complete data for the Six-Year Review analysis.

EPA Response: The Agency is updating the NCOD to provide sample data that have been quality checked and used in various EPA analyses. This update to NCOD includes unregulated occurrence data collected prior to 1999 as well as the latest Unregulated Contaminant Monitoring Rule data (64 FR 50556, September 17, 1999 (USEPA, 1999b)) reported by laboratories for public water systems required to report results. It also includes the data used for the Six-Year Review of regulated contaminants. EPA appreciates that some States are willing to share their full compliance monitoring records with the Agency, even though it is not required. The Agency and the States are continuing to work together to establish a protocol for data sharing, including safeguards to prevent misuse and misinterpretation of data.

The 16-State cross-section data set compiled for occurrence analyses for the Six-Year Review is the largest compliance monitoring data set for drinking water assembled by EPA to date. The design and construction of the 16-State cross-section data set was based on the fact that contaminant occurrence varies spatially (geographically) due to differing patterns of population, land use, chemical use, geology, hydrology, and climate. The detailed description of the "pollution-potential" and geographic diversity considerations, and the derived balanced cross-section of States (that was developed to be collectively indicative of national

occurrence) is included in the "Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Review of Existing National Primary Drinking Water Regulations" (Occurrence Methodology Document) (USEPA, 2003d). EPA selected its 16-State cross-section to be as representative as possible of national contaminant occurrence. In EPA's judgment, these States provide a reasonable cross-section of agricultural and industrial pollution potential, as described in the Occurrence Methodology Document, and also provide geographic coverage of the United States. Therefore, EPA believes that the data assembled from these States is the most representative data currently available of national contaminant occurrence.

The Agency did receive occurrence data from States other than those in its 16-State cross-section. However, many State data sets contained incomplete records (*e.g.*, no water type or population records specified) or had other quality problems. Therefore, they were not included in the analyzed data set.

b. Occurrence Analysis Methodology. One commenter noted that while the occurrence estimation methodology has several strengths, it also has a number of flaws. The commenter was concerned about the large proportion of non-detected observations in the occurrence data, and the difficulty of verifying the assumptions made by the Agency. The commenter agreed that EPA's occurrence analysis may represent a "decent" estimate given the limitations of the data. The commenter also noted that the occurrence estimation methodology is premised on "subjective decisions or qualitative observations * * * rather than documented, statistically-based quantitative ones" and would like to have seen alternate approaches used to provide confirmation of the estimates. In addition, the commenter questioned why the Agency used "modeled data sets to test the model rather than a standard statistical strategy of basing the model on a portion of the data set and using the remainder to test the model."

One commenter stated that the Stage 2 analysis (Bayesian analysis) was poorly described and that this conflicts with the transparency requirements of the 1996 SDWA Amendments. In addition, the commenter asked EPA to clarify how the occurrence data from other survey efforts, which are summarized in "Occurrence Summary and Use Support Document for the Six-Year Review of Existing National Primary Drinking Water Regulations"

(Occurrence Summary Document) (USEPA, 2002f), were used to inform the modeling effort.

EPA Response: EPA's occurrence model development work was significantly revised to reflect peer review comments prior to the March 2002 Occurrence Methodology Document (USEPA, 2002e) and the April 17, 2002, **Federal Register**. The additional work involved the development of a detailed simulation study to evaluate the Bayesian model. EPA evaluated the performance of the Bayesian estimator and an alternative occurrence estimation approach, the Regression on Ordered Statistics (ROS) method, against synthetic data (*i.e.*, data developed with known national contaminant occurrence distributions). This simulation study also enabled an explicit evaluation of the validity of the assumption of a log-normal distribution of the data.

The simulation study was conducted using varying conditions of a correctly and incorrectly specified model, and synthetic data sets developed with high and low amounts of non-detected data. The study findings indicated that the Bayesian estimator performed well at estimating the distributions of contaminant concentration means (especially in the upper tails), performed better than the alternate approach (*i.e.*, the ROS method), and accurately estimated the uncertainty of the distributional estimates. The Agency believes that this analysis supports the validity of EPA's analytical approach. The Bayesian model was tested against the ROS approach because the ROS method is an accepted drinking water contaminant occurrence estimation approach and was used to estimate occurrence for the recent arsenic rule. These findings were all included and described in the Six-Year Review's Occurrence Methodology Document.

EPA has attempted to make its occurrence analysis as clear as possible. In response to the concerns raised by the peer reviewers, a less technical description of the occurrence estimation methodology, aimed at the general reader, was added to the main body of the document. A detailed description of the analysis, intended for readers with technical expertise, including the complete computer code used for model analysis, was incorporated into an appendix of the document. EPA agrees that its estimation methodology is complex, but also believes that it is as transparent as possible while still providing a technically accurate description of the Agency's analysis. The use of simple national occurrence (statistical) assessments is not possible

at this time because there is no national database with a complete collection of regulated contaminant occurrence data. Thus, there is no ideal basis for comparison of national occurrence studies (*i.e.*, the true system contaminant means and national distributions of contaminant occurrence are not, and cannot, be known). The validation approach suggested by the commenter (*i.e.*, basing the model on a portion of the data set and using the remainder to test the model) is intended for a regression-type of model using observed system means to develop a model for system-specific predictions. This approach is not possible for the six-year occurrence assessments, since, to the best of EPA's knowledge, data on the true individual system contaminant mean concentrations and national distributions are not available.

Regarding the other survey studies included in the Occurrence Summary Document, few, if any, provide the quantitative analytical results and national, representative coverage that would enable direct comparison to, or inclusion in, the Six-Year Review estimation analyses conducted with the 16-State cross-section occurrence data.

c. Other Issues Related to the Occurrence Technical Review. One commenter stated that the Agency's current approach to estimate occurrence, employing a conservative methodology and making conservative simplifying assumptions in the absence of definitive data, was appropriate. On the other hand, the commenter argued that it was not appropriate for the Agency to conduct as massive a data collection and analysis project as was undertaken without clear quantitative objectives for the analysis identified a priori. The commenter noted that it was not apparent from either the April 17, 2002, **Federal Register** or the Occurrence Methodology Document (USEPA, 2002e) that the Agency undertook an effort to set performance objectives for the occurrence estimation.

The commenter felt that the Occurrence Methodology Document does not allow the reader to determine if the data are well apportioned among the categories for which results are reported. They also noted that they were unable to find indications in the support document that such an analysis was undertaken in preparation for constructing the Bayesian model. The commenter stated that the support document does not include actual numeric counts or ranges of detected values and suggested that it would be useful to have this information by contaminant, State, system size category, and water type, as well as an

explicit count of non-detects by this same matrix.

EPA Response: There are several general approaches when undertaking and designing studies that require large amounts of data. As the commenter states, a priori data quality objectives are part of one research approach where study objectives (including technical statistical performance measures) are set, determinations are made on how to meet those objectives, and then the study is designed and implemented accordingly. This ideal was not practical for the national occurrence study conducted for the Six-Year Review because EPA did not have the resources to generate original data, and was thus dependent on the data that could be obtained from the States. The approach taken by the Six-Year Review was to gather a large amount of data that, in aggregate, was expected to be indicative of national contaminant occurrence, develop an occurrence estimation model that built upon what has been learned from recent regulatory development work, and then evaluate how good the resulting model estimates are.

As discussed in section IV.A.6.b of today's action, the true national distributions of contaminant occurrence cannot be known. The 16-State national cross-section data set used for the Six-Year Review is the largest compliance monitoring database for drinking water compiled by EPA to date. The database represents approximately 37 percent of the total number of public water systems and 43 percent of the total population served by public water systems in the United States. External peer reviews assessed the approach for developing the national cross-section and its "representativeness" separately under the Chemical Monitoring Reform (CMR) project (in 1998/1999) (USEPA, 1999c) and the Six-Year Review project (USEPA, 2002e), and provided generally favorable comments.

The data management and cross-section development have been described in detail in the support documents for the CMR and the Six-Year Review. Further tabulations of the data have been generated and presented, as the commenter requested, in the final Occurrence Methodology Document (USEPA, 2003d). This information includes the numbers and percentages of analytical detections and non-detections for each contaminant in each of the system size and source water type categories. Generally, because of the large amount of data and the manner in which the Bayesian model handles data, the distribution of observations across the various categories does not significantly affect EPA's estimates. The

number of analytical records differed by contaminant. EPA evaluated 27,648 to 93,062 analytical records for the individual inorganic chemicals, 32,606 to 121,327 records for the synthetic organic chemicals, and 123,229 to 201,235 records for the volatile organic chemicals. Most importantly, the Stage 2 occurrence model also quantifies the uncertainty of the estimates in the different categories of system size and source water type. Hence, the statistical significance of differences in occurrence between the categories can be easily assessed. However, the Agency believes it is more appropriate to consider the universe of potentially affected systems within the 16-State cross-section, rather than individual system categories, when making its revise/not revise decisions as part of the Six-Year Review process.

7. Consideration of Available Economic Information

Some commenters stated that, while the Agency's review of NPDWRs was generally consistent with NDWAC recommendations to EPA (NDWAC, 2000), it is not clear how the Agency took economic factors into account.

EPA Response: An EPA memorandum, dated March 18, 2002, describes the Agency's qualitative evaluation of economic factors (USEPA, 2002c). This memorandum was cited in the April 17, 2002, **Federal Register** and is available in the docket for the Six-Year Review (Docket No. OW-2002-0012). It notes that detailed economic analyses were not deemed by the Agency to be necessary to support its decisions of whether or not to revise a particular NPDWR. Rather, a qualitative assessment, based on the extent of occurrence of a contaminant at the MCL, as well as at alternative levels, was undertaken to inform the Agency's judgment about whether possible changes to an MCL offered a meaningful opportunity for health risk reduction and/or cost-savings to public water systems and their customers. EPA has conducted this assessment for 15 of the chemical NPDWRs for which the Agency had determined that a potential health or technological basis may exist for considering a revision to the MCLG/MCL.² EPA compared the estimated occurrence and exposure values at the current MCL and at potentially revised regulatory level(s). For 14 of these chemical NPDWRs, the Agency's

assessment showed that the differences were small. In EPA's judgment, these differences are unlikely to provide a meaningful opportunity for health risk reduction or cost-savings to public water systems and their customers. After consideration of these factors, EPA decided that any revision would be a low priority activity for the Agency, and, thus, not appropriate to revise at this time because of: Competing workload priorities; the administrative costs associated with rule making; and the burden on States and the regulated community to implement any regulatory change that resulted. In the case of dichloromethane, the Agency did not have sufficient data to recalculate the PQL to support any potential regulatory revision and thus placed it in the data gaps category.³

B. What Comments or New Information Did EPA Receive on Chemical Contaminant-Specific Issues?

1. Alachlor

One commenter stated that the Office of Pesticide Programs (OPP) found that the chloroacetanilide pesticides (acetochlor, alachlor, and butachlor) should be considered as a group of chemicals having a common mechanism of toxicity due to their ability to cause nasal turbinate tumors. The commenter believes EPA therefore should adopt a strong total chloroacetanilide pesticide standard that would strengthen the current standards.

EPA Response: Butachlor and acetochlor do not presently have an NPDWR and thus, are not included in the Six-Year Review. However, acetochlor is included on the Contaminant Candidate List (CCL) and may in the future be considered as a candidate for regulation. Alachlor is a regulated drinking water contaminant and is included in the Six-Year Review. It is currently undergoing a risk assessment and, therefore, the Agency believes that revision of the NPDWR is not appropriate at this time.

If the Agency decides to regulate either acetochlor or butachlor in the future, EPA may consider regulating them as a group, including alachlor, following a cumulative risk assessment process for pesticides that have a

common mechanism of toxicity. It would be premature to propose a total chloroacetanilide pesticide standard until a cumulative risk assessment is completed because this analysis could impact the Agency's evaluation of specific members of this group, or the group as a whole.

2. Antimony

a. Health Effects. A number of commenters have suggested that the current MCLG and MCL of 0.006 milligrams per liter (mg/L) for antimony need to be revised. Some of the reasons given were:

- The study used to derive the current MCLG (Schroeder *et al.*, 1970) is not consistent with current good laboratory practice guidelines and there are several newer studies of antimony toxicity that should be considered in deriving a new reference dose (RfD).

- Animals used in the Schroeder *et al.*, 1970 study had a viral infection. To compensate for this infection, adjustments were made to the size of the animal groups in an attempt to salvage the data.

- The antimony compound used in the Schroeder *et al.*, 1970 study was potassium antimony tartrate, the most water soluble and toxic form of antimony. Antimony found in drinking water is likely to be in the form of less toxic trivalent and pentavalent antimony species. Therefore, basing the MCLG on the most toxic species of antimony (potassium antimony tartrate) is likely to overestimate the risk posed by antimony in drinking water.

EPA Response: EPA agrees that the MCLG and MCL for antimony may need to be re-evaluated. EPA is in the process of developing a new health risk assessment for antimony, taking into consideration new studies that have become available on the toxicity of antimony. EPA expects to complete the health risk assessment for antimony in the 2003–2004 time frame (68 FR 5870, February 5, 2003 (USEPA, 2003h)). As a result of the ongoing health risk assessment, a revision to the antimony standard is not appropriate at this time, and antimony will be re-evaluated as part of the next Six-Year Review process.

b. Treatment and Implementation Issues. Several commenters questioned the appropriateness of the antimony MCL, and the effectiveness of using the EPA-designated best available technologies (BATs) to meet the antimony MCL. A few small systems in Utah have levels of antimony in water at or above the MCL value of 0.006 mg/L. These systems were granted

² These 15 chemical NPDWRs are: Benzene; beryllium; chlordane; 1,2-dibromo-3-chloropropane dichloromethane; 1,1-dichloroethylene; 1,2-dichloropropane; heptachlor; heptachlor, epoxide; hexachlorobenzene; lindane; oxamyl; picloram; toxaphene; and 1,1,2-trichloroethane.

³ The other three NPDWRs in the data gaps category, chromium, fluoridated, and lead, were placed there for reasons other than occurrence and economic considerations. Chromium is in the data gaps category because of the studies being conducted by the National Toxicology Program studies. Fluoride is in the data gaps category pending a National Academy of Sciences update of the health risk assessment and review of the RSC assumptions. Lead is in the data gaps category based on consideration of public comments (see section IV.B.13 of today's action).

exemptions contingent upon testing and installation of treatment by March 2004.

These systems are investigating treatment options for the removal of antimony from their source water. Commenters submitted supporting data documenting the results of their testing and cost analyses. According to commenters, on-site testing indicated that the designated BATs (*i.e.*, reverse osmosis and coagulation/filtration) and most of the other tested treatments were ineffective and/or prohibitively expensive due to: raw water quality concerns; water conservation needs; current costs for water production; and other concerns, such as waste water management. However, commenters did identify treatment options that may be feasible, but these may require further investigation prior to full scale use.

EPA Response: As discussed in the April 17, 2002, **Federal Register** and as noted in the previous response in section IV.B.2.a, EPA does not believe it is appropriate to consider revisions to the NPDWR for antimony at this time because of the ongoing health risk assessment (67 FR 19030 at 19051 (USEPA, 2002g)).

When EPA initially promulgated the antimony NPDWR in 1992, the Agency estimated that 200 public water systems would be affected (USEPA, 1992). EPA recognizes that implementation of this standard may present challenges for a few localities. Although the use of the designated BATs for antimony may not be appropriate in some cases, as long as systems comply with the MCL, they are not limited to these technologies.

EPA believes that the treatment data generated by the commenters may be valuable and may provide insight into potential alternative treatment technologies. The Agency has revised the document, "Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In support of EPA Six-Year Review of National Primary Drinking Water Regulations" (Treatment Feasibility Document) (USEPA, 2003g) to refer to these preliminary test data as they may be applicable to the development of potential new treatment technologies for the removal of antimony and other contaminants.

3. Atrazine

a. Health Effects. Several commenters addressed the EPA decision not to consider revision of the MCL for atrazine at this time. Some of these commenters stated that EPA should use the risk assessment, released by OPP in May 2002, as a basis for reconsidering the atrazine NPDWR. One of the commenters noted that the 2002 risk

assessment is based on reproductive and developmental endpoints which represents a change from the toxicity endpoint that formed the basis of the current MCLG. Two commenters stated that the MCL for atrazine should be revised upward because of the results of the 2002 OPP risk assessment in which the RfD increased and the cancer classification changed from "possible human carcinogen" to "not likely to be a human carcinogen." The commenters stated that the change in the cancer assessment implies elimination of the additional 10-fold risk management factor used in 1991 to derive the MCLG/MCL for atrazine. Another commenter stated that atrazine should be regulated using a non-linear approach which recognizes that there is a level at which no known health effects occur and that these findings must be part of the new MCL.

Conversely, another commenter stated that there is substantial new evidence from epidemiological and occupational studies that atrazine poses a serious cancer risk, and that it is an endocrine disruptor at low levels. The commenter believes EPA should adopt a revised atrazine and total triazine standard lower than (*i.e.*, more stringent than) the current 0.003 mg/L standard for atrazine.

A commenter also urged the Agency to:

- Provide a definitive timetable for review of the standard;
- Outline a preliminary scope for its review of the standard; and
- State the underlying premise for the scope of the review.

Other commenters stated that the existing NPDWR only regulates the parent compound atrazine, and that a revised NPDWR should include the chloro-metabolite degradants (*i.e.*, diaminochlorotriazine (DACT), desethyl atrazine (DEA), and desisopropyl atrazine (DIA)). These commenters believe that inclusion of the chloro-metabolites would strengthen compliance monitoring programs for public water systems under SDWA and thereby strengthen public health protection. They stated that a regulation for atrazine and the chloro-metabolites should be developed and promulgated within the next 12 to 18 months.

Another commenter stated that since the Agency has found that atrazine, simazine, propazine, and the degradants DACT, DEA, and DIA have a common mechanism of toxicity, these should be regulated in a total triazine regulation.

EPA Response: EPA does not believe it is appropriate to consider revisions to the NPDWR for atrazine at this time because the revised risk assessment has

not been finalized. For purposes of the Six-Year Review protocol, EPA considers a risk assessment final when an Interim Reregistration Eligibility Decision (IRED), Reregistration Eligibility Decision (RED), and/or IRIS assessments are complete.⁴ Even though an IRED for atrazine was signed on January 31, 2003, an amended IRED is scheduled to be released in October 2003 which will include a Scientific Advisory Panel (SAP) peer review of new data related to health effects. Based upon the outcome of the SAP review, the October 2003 IRED may include additional information that could impact a revise/not revise decision. Therefore, EPA does not believe it is appropriate to consider possible revisions to the NPDWR at this time.

In reviewing the atrazine regulation, EPA will apply an approach consistent with the protocol used for the current review. The Agency will consider the same key elements (*i.e.*, health effects review, technology review, other regulatory revisions review, and, if appropriate, occurrence/exposure analyses and consideration of available economic information) and apply the same basic decision tree for making a revise/not revise decision.

To address the issue of regulating the triazines as a group, the Agency is evaluating the unregulated triazines as part of the CCL process. When the risk assessment is completed for atrazine, the Agency will consider whether or not there are compelling reasons for considering a revision to the atrazine regulation or to wait until the risk assessment for the triazines, which considers issues of cumulative risk, is finalized. EPA will use the CCL regulatory determination process in deciding whether the triazines should be regulated as a group.

b. Costs of Treatment. Commenters stated that the costs associated with not revising the MCL are great. These commenters are concerned that State agencies will be required to develop total maximum daily loads (TMDLs) based on 303(d)⁵ listings resulting from

⁴ The IRED is an intermediate decision for an individual pesticide that does not take into account cumulative risk issues for pesticides with a common mode of action. The RED does include cumulative risk. If an IRIS assessment is also in process when the IRED or RED is signed, EPA will make a case-by-case decision on whether to wait for the IRIS assessment before considering possible revisions to the NPDWR.

⁵ Section 303(d) of the Clean Water Act and the implementing regulations (40 CFR 130.7) require States to develop TMDLs for waters where required point and nonpoint source pollution controls are not stringent enough to attain or maintain compliance with State water quality standards after the application of technology-based and other

an outdated MCL which creates a burden on State and local government, its citizens, and diverts limited resources away from programs that provide real benefits. Some commenters also stated that the treatment costs to hundreds of community water systems are considerable. One commenter also stated that these are real dollars that would otherwise be available for emergency services, education, nutrition programs, and other vital programs that are the responsibilities of local and State agencies.

EPA Response: As stated in the previous response in section IV.B.3.a, EPA does not believe it is appropriate to revise the NPDWR for atrazine at this time because the risk assessment is not yet final. If EPA decides to revise the NPDWR for atrazine, economic factors, including feasibility and an assessment of costs and benefits, will be taken into consideration for the drinking water program.

4. Beryllium

Two commenters believed that the current drinking water standard for beryllium is more stringent than necessary for the protection of public health and felt that EPA should adopt a higher value for the beryllium standard. These commenters disagreed with EPA on the use of an uncertainty factor of 300 in deriving the 1998 RfD. The commenters stated the use of uncertainty factors of 3 for database uncertainty, 10 for extrapolating data from a dog study to humans, and 10 for intraspecies variation is inappropriate. The commenters stated that EPA has the authority to raise the current drinking water standards for beryllium based on new information that allows for a smaller margin of safety than the one used by EPA. The commenter felt that the current standard for beryllium is "lower than necessary to protect the public from beryllium toxicity and results in clean-up standards that are lower than naturally occurring level of beryllium in water sources and soils." This commenter also expressed concern that the local application of the Federal drinking water standard to private wells in some cases caused undue concerns among users of those wells.

EPA Response: One of the purposes of the Six-Year Review is to determine if the MCL of a chemical should be changed based on a revised RfD or cancer classification. Analytical methods and treatment technologies are

considered, as well as occurrence in public water systems. The RfD for beryllium was revised in 1998 based on extensive Agency internal and external reviews, and is unlikely to be revised in the absence of new data. The 1998 assessment also provided separate cancer classification for inhalation and oral exposures (USEPA, 1998). In the revised assessment, the carcinogenicity of beryllium by the inhalation route was described as "likely," while that by the oral route of exposure "cannot be determined." As discussed in the April 17, 2002, **Federal Register**, the Agency considered the occurrence of beryllium at both potentially higher and lower regulatory levels. EPA concluded that a revision to the NPDWR would not result in a meaningful opportunity for health risk reduction or cost-savings to public water systems and their customers. As a result, revision of this NPDWR is a low priority action for the Agency and is not appropriate at this time.

The goal of drinking water standards is to protect public health. Therefore, it does not matter whether the source of contamination is naturally-occurring or man-made. While EPA appreciates the information on private wells, the SDWA requirements do not apply to private wells (*i.e.*, wells that are not part of a "public water system"). The costs and benefits of a drinking water standard are assessed only with regard to the impacts on public water systems and their customers.

5. Carbofuran

Some commenters mentioned that the Agency concluded that N-methyl carbamates, including carbofuran, should be considered as a class because they have a common mechanism of toxicity. Therefore, they believe EPA should issue a stronger standard for total N-methyl carbamates, including carbofuran, which would be more stringent than the current carbofuran standard of 0.04 mg/L.

EPA Response: EPA is re-evaluating the toxicity of carbofuran. However, a final assessment has not been issued by EPA. The Agency considers N-methyl carbamate pesticides as a group of chemicals having a common mechanism of toxicity due to their ability to inhibit acetylcholinesterase. However, it is not appropriate to revise the NPDWR for carbofuran at this time because the Agency has not yet completed the final health risk assessment for carbofuran or the other N-methyl carbamates.

6. Chromium

One commenter requested that EPA move quickly in making a revise/not revise determination once the new data

on chromium become available from the National Toxicology Program (NTP) studies of the health effects of chromium VI.

EPA Response: The NTP studies that the commenter refers to should be available before the end of the next Six-Year Review cycle. Meanwhile, EPA is continuing to follow the progress of NTP in conducting subchronic and chronic studies of chromium VI.⁶ NTP made the data from the subchronic portion of the study available to the public in June 2002 (NTP, 2002). A peer review meeting was held at NTP on July 24, 2002. EPA will examine the peer review report covering the subchronic data once it becomes available. Once the subchronic and chronic studies are completed, the health effects data will be evaluated with regard to their impact on the present RfD and cancer assessment, and integrated with the occurrence and analytical method data before making a new revise/not revise decision.

7. 1,1-Dichloroethylene

In the April 17, 2002, **Federal Register**, the Agency preliminarily placed 1,1-dichloroethylene in the no revision category because a health risk assessment was pending at the time of publication. Since the publication of the April 17, 2002, **Federal Register**, the Agency has finalized the risk assessment for 1,1-dichloroethylene. The remaining paragraphs in this section include a brief background discussion about the original promulgation of the 1,1-dichloroethylene NPDWR, the results of the appropriate six-year technical reviews and the Agency's revise/not revise decision.

a. Background. EPA published the current NPDWR for 1,1-dichloroethylene on July 8, 1987 (52 FR 25690 (USEPA, 1987)). The NPDWR established an MCLG and an MCL of 0.007 mg/L. The Agency based the MCLG on an RfD of 0.009 milligram per kilogram of body weight per day (mg/kg/day) and a cancer classification of C, possible human carcinogen.

b. Technical Reviews. EPA updated the risk assessment for 1,1-dichloroethylene on August 13, 2002 (USEPA, 2002i). The new risk assessment established an RfD of 0.046 mg/kg/day, based on the same toxicological study as that of the MCLG, but using an uncertainty factor of 100

⁶ Since NTP is posting its progress on its internet site <http://ntp-server.niehs.nih.gov/htdocs/Studies/HexChromium/hexchromiumpg.html>, EPA and the public will be able to evaluate the new data relative to the existing EPA assessment for chromium VI as it is released.

required controls. A TMDL establishes the maximum amount of a pollutant that may be introduced into a waterbody while still ensuring attainment and maintenance of water quality standards.

instead of 1,000, and using benchmark dose modeling for the dose-response analysis. Under the 1986 cancer guidelines (51 FR 33992, September 24, 1986 (USEPA, 1986)), 1,1-dichloroethylene was assigned to Group C, possible human carcinogen. Under the draft revised "Guidelines for Carcinogen Risk Assessment" (USEPA, 1999a), the data for 1,1-dichloroethylene were considered inadequate for an assessment of human carcinogenic potential by the oral route.

Based on the change in RfD for 1,1-dichloroethylene, using a 20 percent RSC and a 10-fold risk management factor for possible carcinogenicity, EPA

used 0.03 mg/L as a level for evaluating the occurrence data. Without the use of the 10-fold risk management factor, EPA also used 0.3 mg/L as a level for evaluating the occurrence data.

Analytical or treatment feasibility do not pose any limitations for the current MCL and would not be a limiting factor at the 0.03 mg/L or the 0.3 mg/L level (USEPA, 2002a; USEPA, 2003g). The Agency's review of possible "other regulatory revisions" did not identify any issues that are specific to 1,1-dichloroethylene (USEPA, 2003b).

EPA evaluated the results of the occurrence and exposure analyses for 1,1-dichloroethylene to determine

whether possible changes to the standard would be likely to result in a meaningful opportunity for cost-savings to public water systems and their customers (USEPA, 2003d). Table IV-1 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for the current MCL (0.007 mg/L), and for two higher levels (0.03 mg/L and 0.3 mg/L). Based on the detailed analysis, it appears that 1,1-dichloroethylene is unlikely to occur at concentrations above 0.007 mg/L in the States used for the cross-section.

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Table IV-1: 1,1-Dichloroethylene Occurrence ¹					
Systems ²					
Level (in mg/L)	16-State Cross- Section - Total Systems with Data	Estimated # of Systems > Level Evaluated (credible intervals) ^{3,6}		Estimated % of Systems > Level Evaluated (credible intervals) ³	
Upper Level Evaluated (without 10-fold risk management factor) ⁴ 0.3	19,101	0	(0-0)	0.000%	(0.000% - 0.000%)
Lower Level Evaluated (with 10-fold risk management factor) ⁵ 0.03	19,101	0	(0-0)	0.000%	(0.000% - 0.000%)
Current MCL 0.007	19,101	3	(1-6)	0.0144%	(0.00518% - 0.0311%)
Population Served by Systems ²					
Level (in mg/L)	16-State Cross- Section - Total Population Served by Systems with Data	Estimated Population Served by Systems > Level Evaluated (credible intervals) ³		Estimated % of Population Served by Systems > Level Evaluated (credible intervals) ³	
Upper Level Evaluated (without 10-fold risk management factor) ⁴ 0.3	106,607,600	0	(0-0)	0.000%	(0.000% - 0.000%)
Lower Level Evaluated (with 10-fold risk management factor) ⁵ 0.03	106,607,600	0	(0-0)	0.000%	(0.000% - 0.000%)
Current MCL 0.007	106,607,600	14,400	(0 - 136,900)	0.0135%	(0.0000328% - 0.128%)
Notes:					
¹ Results are based on the number and percent of systems (and the corresponding population served by those systems) with estimated mean concentrations above the specified level of evaluation.					
² All percentages are shown to three significant figures. All system values are rounded to the nearest whole system. All population values are rounded to the nearest hundred.					
³ "Credible intervals" are generated to quantify the uncertainty around each estimated probability in the Bayesian analysis of the occurrence data. For further explanation of credible intervals and the Bayesian analysis, please see "Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Review of Existing National Primary Drinking Water Regulations" (USEPA, 2003d).					
⁴ Based on the change in the RfD and a 20 percent RSC.					
⁵ Based on the change in the RfD, a 20 percent RSC, and a risk management factor of 10.					
⁶ This value does not necessarily reflect the number of systems out of compliance with the current MCL, because these data were collected over the 1993-1997 time period, and because the value represents the estimated mean value over that time period, not the running quarterly average on which compliance is based.					

The results of the detailed occurrence and exposure analysis indicate that less than 0.02 percent of the 19,101 systems sampled in the 16-State cross-section, and less than 0.02 percent of the population served by those 19,101 systems might be affected if EPA were to consider levels as high as 0.03 mg/L to 0.3 mg/L. The current BATs and small system compliance technology for 1,1-dichloroethylene have other beneficial effects (e.g., reduction of other co-occurring contaminants, or other common impurities) in addition to 1,1-dichloroethylene removal.

Therefore, if EPA were to consider any of these higher levels, the Agency does not know how many of these public water systems that are currently treating to comply with the current MCL of 0.007 mg/L would be likely to discontinue treatment that is already in place (USEPA, 2002c; USEPA, 2003g).

c. Current Decision. Although there are new health effects data that might support calculation of a less stringent standard for 1,1-dichloroethylene, EPA does not believe a revision to the NPDWR for 1,1-dichloroethylene is appropriate at this time. In making this decision, the Agency considered whether any potential revision to the 1,1-dichloroethylene NPDWR is likely to provide a meaningful opportunity for cost-savings to public water systems and their customers. After consideration of this factor, EPA has decided that any revision to 1,1-dichloroethylene would be a low priority activity for the Agency, and, thus, is not appropriate to revise at this time because of:

- Competing workload priorities;
- The administrative costs associated with rulemaking; and
- The burden on States and the regulated community to implement any regulatory change that resulted.

8. Dichloromethane

One commenter stated that it may be difficult to lower the PQL for dichloromethane below the range of 0.001 to 0.002 mg/L since it is required in a number of EPA methods and therefore is a common laboratory contaminant. Because it is a common laboratory contaminant, the commenter stated that using the MDL for 524.2 and 502.2 does not constitute a reasonable basis for assuming that the PQL can be lower. The commenter stated that none of the existing WS studies had spike samples this low and, in addition, the occurrence data may have been compromised due to laboratory contamination.

EPA Response: The basis for EPA indicating that a lower PQL “may exist” was due to the fact that laboratories had greater than 95 percent laboratory

passing rates using a ± 40 percent acceptance window at “known” spike concentrations close to current MCL of 0.005 mg/L. If laboratory contamination due to dichloromethane were a problem, such high passing rates at this value would not be expected. The MDLs for 524.2 and 502.2 were only used with the 10 times MDL multiplier to estimate what the lower value could be. However, EPA does agree that, at this time, the Agency does not have sufficient data to recalculate the PQL for dichloromethane and for this reason, the Agency placed it in the data gap category.

Regarding the occurrence issue, EPA has no data to suggest that high occurrence values were due to false positives from laboratory contamination and the Agency is proceeding on the assumption that State data are accurate unless there is information to the contrary. If laboratory contamination due to dichloromethane does exist, laboratories should be able to identify and discern a contamination issue if they are running laboratory blanks.

9. Di(2-ethylhexyl)adipate (DEHA)

One commenter submitted detailed comments regarding di(2-ethylhexyl)adipate (DEHA). The commenter believed that EPA should consider removing the regulation for DEHA and provided the following reasons:

- The regulation of DEHA in drinking water does not provide any meaningful reduction in the health risk to humans because it is unlikely to cause adverse effects to humans, including reproductive effects, except at very high doses which cannot be attained in drinking water, due to the low water solubility of DEHA.
- The weight of evidence indicates that the peroxisome proliferation mechanism of DEHA rodent carcinogenicity is not relevant to humans. Thus, the MCLG for DEHA should not include an additional 10-fold risk management factor for possible carcinogenicity.

• The legislative history of the 1996 SDWA indicates that Congress envisioned circumstances where relaxation of an MCL would provide the same level of health protection as the existing regulation. Accordingly, if DEHA cannot be deregulated, the commenter believes the MCLG and MCL should be increased.

EPA Response: DEHA was regulated in 1992. Since that time, new studies have become available on the toxicity of DEHA and its metabolites. For this reason, EPA decided to initiate a new health risk assessment of DEHA (67 FR 1212, January 9, 2002 (USEPA, 2002a)).

The assessment will include examination of the studies on which the current NPDWR is based, as well as an evaluation of the data provided by this commenter and new studies that have become available since DEHA was regulated. This health risk assessment is planned for completion in the 2003–2004 time frame (68 FR 5870, February 5, 2003 (USEPA, 2003h)) and is expected to include development of an RfD for non-cancer health effects, as well as an assessment of potential carcinogenicity from oral exposure. At this time, it is premature to predict the outcome of the Agency’s assessment. Thus, as discussed in section IV.A.2.a of today’s action, the Agency believes that revision to the NPDWR for DEHA is not appropriate at this time. EPA will determine in the future if revision of the MCLG/MCL is warranted. Any revision to the MCLG/MCL will also take into consideration all the new information, including the water solubility of DEHA under various environmental conditions.

As stated by the commenter, the legislative history of the 1996 SDWA Amendments supports EPA’s interpretation that the Agency could increase an MCLG and MCL as long as the relaxed standard does not lessen the level of public health protection. However, EPA does not believe, at the present time, that it can demonstrate that deregulating DEHA would maintain the current level of public health protection (see section IV.A.1.c of today’s action).

10. Di(2-ethylhexyl)phthalate (DEHP)

The same commenter who submitted comments on DEHA also submitted detailed comments regarding di(2-ethylhexyl)phthalate (DEHP). The commenter felt that EPA should consider removing the regulation for DEHP for a variety of reasons, including the following:

- The regulation of DEHP in drinking water does not provide any meaningful reduction in the health risk to humans.
- The weight of the evidence indicates that the mode of action through which DEHP causes cancer in rodents is not relevant to humans and, thus, the MCLG for DEHP should not be zero. Any MCLG for DEHP should be based on a threshold endpoint and not on cancer. The commenter cited the February 2000 International Agency for Research on Cancer reclassification of DEHP from Group 2B (possibly carcinogenic to humans) to Group 3 (not classifiable as to its carcinogenicity to humans) as justification for recommending that EPA also reconsider its cancer classification.

- The solubility of DEHP in drinking water is well below any concentrations that would pose a risk to humans.

- If DEHP were to be considered for regulation under the statutory requirements of the 1996 SDWA, it would not be regulated.

- The legislative history of the 1996 SDWA indicates that Congress envisioned circumstances where relaxation of an MCL would provide the same level of health protection as the existing regulation. Accordingly, the commenter believes consideration should be given to increasing the MCLG for DEHP based on the new health effects data.

- Reproductive effects from DEHP as observed in rodents do not appear to be relevant for primates and the doses that are associated with effects in animals are well above those that would be experienced for humans exposed through drinking water because of solubility limitations. The commenter also highlighted the findings of the NTP Center for the Evaluation of Risk to Human Reproduction that there was "minimal concern for reproductive or developmental toxicity for the general population, based on estimates of total exposure to DEHP."

EPA Response: Revision of the NPDWR for DEHP is not appropriate at this time because an Agency health risk assessment is currently in process. The assessment is anticipated to be completed in the 2003–2004 time frame (68 FR 5870, February 5, 2003 (USEPA, 2003h)). Advances in understanding differences between the primate and rodent response to DEHP and the body of toxicological data that have become available in the past decade motivated the Agency's re-examination of DEHP and will be fully considered in the reassessment.

Once the Agency assessment is completed, EPA will consider the findings and will determine if there is a compelling reason to review the DEHP NPDWR prior to the next Six-Year Review cycle. As discussed in sections IV.A.1.b and IV.A.2.a of today's action, "revise" versus "not revise" decisions under the Six-Year Review take into consideration occurrence, advances in analytical methods, treatment technologies, available economic information, and other factors.

As stated by the commenter, the legislative history of the 1996 SDWA Amendments supports EPA's interpretation that the Agency could increase an MCLG and MCL as long as the relaxed standard does not lessen the level of public health protection. However, EPA does not believe, at the present time, that it can demonstrate

that deregulating DEHP would maintain the current level of public health protection (see section IV.A.1.c of today's action).

11. Fluoride

EPA received three comments on the Agency's decision to place fluoride in the data gap category while the National Academy of Sciences (NAS) examines the toxicological and RSC data published over the last decade. Two of the commenters supported EPA's decision. One of these requested that the NAS concentrate its review on all of the data on the toxicology of fluoride and not just data on the critical skeletal effects. A third commenter requested that EPA not lower the MCL for fluoride from 4 mg/L to 2 mg/L and supported the 1986 EPA decision that dental fluorosis is a cosmetic effect rather than an adverse health effect. The commenter stated that the Public Health Service (PHS) recommended fluoridation level to be used at schools is 3 mg/L. The commenter also stated that if EPA were to lower the MCL, then schools that are currently fluoridating might have a conflict with the PHS recommendations and the EPA MCL.

EPA Response: The National Research Council (NRC) of the NAS has agreed to review the toxicological data on fluoride that have been published since it completed the 1993 study of "Health Effects of Ingested Fluoride" (NRC, 1993), and to examine the data on relative fluoride exposure from drinking water compared to fluoride exposure from the diet and fluoride-containing dental products. Although the Agency indicated in the April 17, 2002, **Federal Register** that new data on bone effects were a reason for initiating the data review (because bone effects were the basis of the present MCLG), the NAS review will look at the new toxicological data for all endpoints. It is anticipated that the NAS review will take about two years to complete. Because of this pending review, revision of the NPDWR for fluoride is not appropriate at this time.

It is therefore premature to make any judgment regarding the NAS findings and whether or not they may lead to a consideration of a change in the MCL. However, PHS recommendations for school fluoridation programs are designed to provide the benefits of fluoridation without increasing the risk for dental fluorosis. The PHS recommends school water fluoridation only if:

- The school has its own source of water;
- The school is not connected to a community water system;

- More than 25 percent of students are not served by a public water system that provides water at levels adequate to protect against dental caries; and

- The students served are kindergarten age or greater.

12. Glyphosate

Two commenters made the statement that, despite continued use of glyphosate in pesticide applications, available data and the Agency's occurrence analysis, which includes a prediction of frequency of occurrence at levels below detection, indicate that glyphosate is not observed in compliance monitoring. One of these commenters stated that the occurrence appeared to be rare (less than 0.1 percent) at concentrations 1,000 times lower than the MCL. In addition, according to the commenters, the cost of analyzing for glyphosate is expensive, since it is a single analyte analysis. Accordingly, the commenters wanted EPA to reconsider the glyphosate standard taking costs and benefits into account. The commenters felt that the data may indicate that a glyphosate standard is inappropriate and does not result in any additional public health protection. Therefore, the commenters recommended EPA pursue data gaps that the Agency would need to fill in order to demonstrate that eliminating the glyphosate standard would not lower public health protection.

EPA Response: EPA is conducting an Agency risk assessment for glyphosate that will update the 1993 OPP assessment. As a part of this process, EPA is considering all the data that have been published or submitted to EPA since the completion of the RED in 1993 (USEPA, 1993). Accordingly, revision of the glyphosate NPDWR is not appropriate at this time due to the pending Agency assessment.

EPA recognizes that some utilities feel that the analysis of glyphosate in drinking water is expensive and that this should be taken into consideration with respect to cost and benefits. This will be considered when EPA evaluates glyphosate in the next review cycle (unless there is a compelling reason to evaluate glyphosate on an accelerated schedule). For the reasons stated in section IV.A.1.c of today's action, EPA does not believe it is appropriate to consider deregulation of glyphosate at this time.

13. Lead and Copper

a. Research Needs. Three commenters acknowledged the Agency's January 2000 revisions to the Lead and Copper Rule (LCR) but stated that the Agency should continue to consider how to

make the LCR easier to implement. In particular, they recommended that the following three LCR-related research areas be incorporated into EPA's overall research strategy:

1. How well LCR monitoring results correlate to actual exposure and the effectiveness of the rule in protecting public health.
2. Whether there is a correlation between water quality at indoor and outdoor taps.
3. What effect the ban on lead in fixtures has had on lead levels and whether changes need to be made based on this ban.

The commenters explained their rationale for recommending that the Agency determine if a correlation could be established between indoor and outdoor water quality. They stated that a major weakness of the LCR is that sample integrity may be compromised by allowing customers to collect water samples. If the Agency could establish such a correlation, the LCR could be revised to allow water system operators to collect samples from outdoor taps; thereby removing the need for customer-collected sampling.

EPA Response: EPA recognizes that the LCR is a challenging rule that requires difficult solutions to implement, 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. Since the Agency promulgated the revisions to the LCR in January 2000 (65 FR 1950, January 12, 2000 (USEPA, 2000)), the Agency has received no significant new information that would support a revision. 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. For this reason, EPA has revised its rationale for not revising the NPDWR for lead and placed it in the data gaps category. Although the Agency continues to believe that the NPDWR for copper belongs in the risk assessment in process category at the present time, EPA will also consider copper-related risk management and implementation issues as a part of any LCR-related research plans. The Agency is committed to working with stakeholders to support and coordinate identification and prioritization of LCR-related research needs. Until this research is completed, EPA believes it is premature to consider revisions to the LCR; as a result, revision of the LCR is not appropriate at this time.

The Agency believes that understanding the possible correlation

between monitoring results and actual rates of exposure and public health protection is a valid issue. However, EPA recognized during the initial regulatory development of the LCR that a significant effort would be necessary to provide a statistically valid number and frequency of samples for an exposure assessment. The Agency thus adopted an alternative approach which specified a monitoring scheme that sought to " * * * assure that systems are performing 'optimal corrosion control' in part by requiring systems to conduct comprehensive tap sampling at homes specifically targeted for their potential to contain elevated levels of lead and copper" (56 FR 26460 at 26514, June 7, 1991 (USEPA, 1991b)). One issue in assessing exposure reduction resulting from the LCR is a determination of an exposure baseline. EPA does not have a lot of data against which to measure changes in exposure that have occurred as a result of rule implementation. For these reasons, EPA believes that there is still insufficient information to change the basic monitoring approach adopted in the original rule, but recognizes that additional research may be useful.

Research on whether a correlation exists between the water quality at indoor taps and water quality at outdoor taps is a very complex issue. Several variables potentially affect whether a reliable correlation exists between indoor and outdoor taps. These variables include: standing time within the system; contact time with the building plumbing; and the content of the interior plumbing. These variables, coupled with the fact that lead levels from building-to-building can be highly site-specific, make a correlation between indoor and outdoor taps difficult to establish. EPA continues to believe that focusing on the point of delivery to the customer most closely links the data collected to the water quality consumed by the customer.

EPA recognizes the commenter's concerns regarding the integrity of samples collected by drinking water customers. To date, however, the Agency has not been able to identify an acceptable alternative to monitoring at the consumer's tap that can produce results equivalent to those obtained at the point of consumption in terms of ensuring adequate public health protection.

Regarding the commenter's third recommendation, EPA will consider this research need as part of the Agency's overall drinking water research planning process.

b. Relaxing the Monitoring Requirements. Three commenters recommended that water systems be

allowed to conduct water quality parameter (WQP) monitoring in lieu of continued lead and copper tap monitoring. One of these commenters added that this should be allowed once the system has demonstrated that it does not have a lead problem. This commenter also stated that the new requirements to use lead-free solder and plumbing fixtures should preclude problems with lead. Two commenters noted the difficulty that water systems are having maintaining their current sampling pool because homeowners no longer want to participate in the LCR monitoring program. One of these commenters recommended using WQP results to ensure corrosion control treatment is being adequately maintained and to stop lead and copper monitoring after three to five years. The commenter added that once the system ceases lead and copper monitoring, it can use public education to supplement continuing corrosion control, and can use coupons to demonstrate that corrosion rates meet accepted standards.

EPA Response: While EPA is sensitive to the difficulties associated with the monitoring requirements of the LCR, the Agency is also concerned about the implications of reduced or discontinued 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. Proper process control, including water quality and corrosion inhibitor residual concentration monitoring in the distribution system, is the key to making any corrosion control or other treatment work, and assure the continuation of proper water quality. However, EPA recognizes that some changes might be justified in the future based on new, scientifically valid, information and/or research. EPA is considering aspects such as the implications of simultaneous treatment modifications on water quality, including lead and copper control, in its research planning. EPA is not yet able to determine whether the outcome of such research will provide a basis for modifications to the LCR treatment or monitoring

requirements. As stated in the response in section IV.B.13.a. of today's action, EPA has placed the LCR in the data gaps category pending the completion of future research.

c. Corrosion Control Treatment Strategy. Two commenters noted concerns regarding the lead and copper corrosion control strategy. One commenter indicated that the LCR should be revised to allow systems to change corrosion control strategies. The commenter stated that considerable development of the corrosion control market has occurred since systems made their initial assessments and implemented corrosion control programs. The commenter felt that currently, the "LCR locks utilities into a given control strategy," when in some instances limited pilot work and ongoing WQP monitoring would allow a system to re-assess its treatment and implement an alternative corrosion control inhibitor.

The second commenter indicated that the current corrosion control strategies are marginally effective at preventing particulate lead and copper from entering the water supply. The commenter recommended that EPA consider methods for mitigating the release of insoluble components from plumbing fixtures.

EPA Response: The Agency disagrees that the LCR locks utilities into a given control strategy, but feels it is necessary to demonstrate a sound basis for re-assessing and implementing an alternative treatment strategy in the context of the existing regulation. EPA notes that the current regulation provides some flexibility to both States and water systems in the choice of a corrosion control strategy. For example, in response to its own initiative, a request by a water system or other interested party, a State may modify its determination of the optimal corrosion control treatment, among those listed in the Federal regulation, or may modify optimal WQPs if the State determines such changes are necessary to ensure that the system continues to optimize corrosion control treatment (40 CFR 141.82(h)).

The Agency believes that the existing requirements to notify the State when changing a corrosion control strategy remain necessary and appropriate. After they have optimized corrosion control, water systems must notify the State of any treatment changes⁷ within 60 days of the change (40 CFR 141.90(a)(3)). The

Agency encourages water systems to notify the State prior to making any changes thus allowing the Primacy Agency to review the changes to reduce the potential for detrimental side-effects. In the Agency's experience, changes in treatment, such as (but not restricted to) replacement of high pH treatment with corrosion inhibitor, changes in coagulant and coagulation conditions, changes in disinfection, installation of membrane processes, or introduction of chemically different waters into the distribution system provide potential for detrimental side-effects. Water treatment changes, therefore, should only be done with the greatest care and pilot investigations. While changes to treatment can be made under the existing regulation, systems should conduct additional monitoring (e.g., of lead, copper, and WQPs) until the new treatment is fully implemented and stabilized.

EPA also recognizes that the current LCR may limit flexibility to some extent, particularly in the adoption of new or emerging technologies. The original rule attempted to balance this concern with the need to provide strong public health protection by ensuring that only control strategies of proven effectiveness are adopted. The Agency does not have an adequate basis to revise the treatment requirements at this time but will continue to monitor new developments, including emerging technology. The Agency may consider revisions to the LCR prior to the end of the next Six-Year Review cycle if the Agency receives new, scientifically-valid, information that provides a basis for achieving significant improvement in public health protection or significant cost-savings to utilities and their customers while maintaining current public health protection.

EPA has always recognized 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.

d. Lead Levels in School Drinking Water. One commenter was concerned that the data on lead levels that was analyzed under the Six-Year Review of NPDWR standards may not indicate actual lead contamination of drinking water sources. As an example, the commenter noted that even though

Baltimore City is in compliance for lead levels, 1/3 of Baltimore schools are using alternative sources of drinking water due to lead contamination. The commenter expressed concern that since data obtained from schools, such as the data from Baltimore, was not considered in the evaluation of lead contamination in drinking water, the most vulnerable population may not be protected from exposure to lead. The commenter stated that it is time for the Agency to reassess how lead levels are evaluated.

EPA Response: 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 (USEPA, 1989). In 1994, the Agency updated and revised the guidance manual entitled "Lead in Drinking Water in Schools and Non-residential Buildings" (USEPA, 1994). 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.

14. Lindane (γ -hexachlorocyclohexane)

In the April 17, 2002, **Federal Register**, the Agency preliminarily placed lindane in the no revision category because a health risk assessment was pending at the time of publication. One commenter stated that

⁷ Treatment changes are categorized as changes to any water quality treatment process, including (but not restricted to) disinfection, disinfection by-product removal, and corrosion control.

the RED risk assessment for lindane, issued after publication of the April 17, 2002, **Federal Register**, should be considered in the Agency's review of the NPDWR and expressed concerns regarding the existing regulation. The commenter stated that the current NPDWR is based on an RfD developed in 1988 on the basis of adverse kidney effects and should be revised (USEPA, 1988). The kidney effects were determined to occur through a pathway that is not relevant to human health risk assessment. The commenter stated that the new OPP toxicological assessment has resulted in a significant change to the quantitative dose-response assessment for lindane and that there are no data gaps or uncertainties which would prevent a revision of the NPDWR for lindane at this time.

EPA Response: Since the publication of the April 17, 2002, **Federal Register** and receipt of the comment regarding lindane, the Agency has finalized the risk assessment for lindane and signed the RED on July 31, 2002. The remaining paragraphs in this section include a brief background discussion about the original promulgation of the lindane NPDWR, the results of the appropriate six-year technical reviews and the Agency's revise/not revise decision.

a. Background. EPA published the current NPDWR for lindane on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.0002 mg/L. The Agency based the MCLG on an RfD of 0.0003 mg/kg/day and a cancer classification of C, possible human carcinogen.

b. Technical Reviews. EPA updated the risk assessment on July 31, 2002 (USEPA, 2002h). The new risk assessment established an RfD of 0.0047 mg/kg/day. The Food Quality Protection Act (FQPA) of 1996 provides for an additional safety factor of up to 10-fold, if necessary, in assessing the risks to infants and children to take into account the potential for pre- and post-natal toxicity, and the completeness of the toxicity and exposure databases. This is referred to as the FQPA safety factor. The Agency concluded that an FQPA safety factor of three was required for lindane since there is evidence for increased susceptibility of the young demonstrated in a developmental neurotoxicity and two-generation reproductive toxicity study in rats. The rationale for using an FQPA safety factor of three is detailed in the RED.

In accordance with the 1999 EPA Draft "Guidelines for Carcinogen Risk Assessment" (USEPA, 1999a), the Agency classified lindane as "suggestive evidence of carcinogenicity, but not

sufficient to assess human carcinogenic potential." Based on the RfD for lindane of 0.0047 mg/kg/day, the application of the additional FQPA safety factor of three to this RfD, a 20 percent RSC, and a 10-fold risk management factor of suggested evidence of carcinogenicity, EPA used 0.001 mg/L as a level for evaluating the occurrence data.

Analytical or treatment feasibility do not pose any limitations for the current MCL and would not be a limiting factor at the 0.001 mg/L level (USEPA, 2003a; USEPA 2003g). The Agency's review of possible "other regulatory revisions" did not identify any issues that are specific to lindane (USEPA, 2003b).

EPA evaluated the results of the occurrence and exposure analyses for lindane to determine whether possible changes to the standard would be likely to result in a meaningful opportunity for cost-savings to public water systems and their customers (USEPA, 2003d). Table IV-2 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for concentrations of 0.0002 mg/L (the current MCL), and for 0.001 mg/L. Based on the detailed analysis, it appears that lindane is unlikely to occur at concentrations above 0.0002 mg/L in the States used for the cross-section.

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Table IV-2: Lindane Occurrence ¹				
Systems ²				
Level (in mg/L)	16-State Cross- Section - Total Systems with Data	Estimated # of Systems > Level Evaluated (credible intervals) ^{3,4}	Estimated % of Systems > Level Evaluated (credible intervals) ³	
Level Evaluated 0.001	16,098	0 (0-0)	0.000% (0.000% - 0.000%)	
Current MCL 0.0002	16,098	0 (0-0)	0.000% (0.000% - 0.000%)	
Population Served by Systems ²				
Level (in mg/L)	16-State Cross- Section - Total Population Served by Systems with Data	Estimated Population Served by Systems > Level Evaluated (credible intervals) ³	Estimated % of Population Served by Systems > Level Evaluated (credible intervals) ³	
Level Evaluated 0.001	99,942,600	0 (0-0)	0.000% (0.000% - 0.000%)	
Current MCL 0.0002	99,942,600	0 (0-0)	0.000% (0.000% - 0.000%)	

Notes:

¹ Results are based on the number and percent of systems (and the corresponding population served by those systems) with estimated mean concentrations above the specified level of evaluation.

² All percentages are shown to three significant figures. All system values are rounded to the nearest whole system. All population values are rounded to the nearest hundred.

³ "Credible intervals" are generated to quantify the uncertainty around each estimated probability in the Bayesian analysis of the occurrence data. For further explanation of credible intervals and the Bayesian analysis, please see "Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Review of Existing National Primary Drinking Water Regulations" (USEPA, 2003d).

⁴ This value does not necessarily reflect the number of systems out of compliance with the current MCL, because these data were collected over the 1993-1997 time period, and because the value represents the estimated mean value over that time period, not the running quarterly average on which compliance is based.

The results of the detailed occurrence and exposure analysis indicate that few, if any, of the 16,098 systems sampled in the 16-State cross-section might be affected if EPA were to consider levels as high as 0.001 mg/L. The current BATs and small system compliance technology for lindane have other beneficial effects (e.g., reduction of other co-occurring contaminants, or other common impurities) in addition to lindane removal. Therefore, if EPA were to consider a higher level, the Agency does not know how many of these public water systems that are currently treating to comply with the current MCL of 0.0002 mg/L would be likely to discontinue any treatment that is already in place (USEPA, 2002c; USEPA, 2003g).

c. Current Decision. Although there are new health effects data that might support calculation of a less stringent standard for lindane, EPA does not believe a revision to the NPDWR for lindane is appropriate at this time. In making this decision, the Agency considered whether any potential revision to the lindane NPDWR is likely to provide a meaningful opportunity for cost-savings to public water systems and their customers. After consideration of this factor, EPA has decided that any revision to lindane would be a low priority activity for the Agency, and, thus, is not appropriate to revise at this time because of:

- Competing workload priorities;
- The administrative costs associated with rulemaking; and
- The burden on States and the regulated community to implement any regulatory change that resulted.

15. Simazine

One commenter agreed that simazine should be addressed after the risk assessment is completed in 2003 or 2004. The commenter requested that the Office of Water (OW) work closely with the OPP on the risk assessment at that time. The commenter also recommended that OW address the revision of the existing simazine NPDWR before the next review cycle year, scheduled for 2008. The commenter believes the extensive mammalian toxicology database, submitted as part of the Triazine Special Review, can be used in this process.

EPA Response: OW has been coordinating with OPP for the revision of the atrazine and simazine risk assessments. Once the simazine risk assessment is completed, EPA will determine whether a compelling reason exists to consider review of the simazine NPDWR on an accelerated schedule.

C. What Comments Did EPA Receive Regarding the Review of Implementation-Related Issues for Chemical NPDWRs?

Several commenters recommended that EPA ensure consistent application of rules by making rules more consistent with respect to monitoring frequency, triggers for increased monitoring, criteria for returning to routine monitoring, and criteria for reducing sample requirements. In addition, commenters suggested that the Agency review possible ways for reducing the reporting burden on States, which could free up State resources currently used to implement rules.

One commenter was concerned about monitoring and reporting issues in conjunction with CMR. The commenter felt that EPA should not miss an opportunity to relieve some of the unnecessary confusion that the monitoring requirements of Phase II and V have created. This confusion includes issues such as, what a detection is and what the monitoring requirements are for systems in States without a waiver program. EPA was encouraged to provide this consistency as much as possible, including using the standard monitoring framework to allow States and water systems to more easily understand rule requirements and reduce the need for States to update their data management systems.

One commenter said EPA should ensure consistent application of rules by determining whether or not chronic contaminants should be regulated at non-transient non-community water systems (NTNCWSs), and review existing NPDWRs to ensure that rules are applied consistently. Another commenter recommended that the compliance language for the synthetic organic chemicals (SOCs) and volatile organic chemicals (VOCs) in the Final Arsenic Rule (66 FR 6975, January 22, 2001 (USEPA, 2001)) be adopted for the inorganic chemicals (IOCs), and that systems not be considered in violation of the MCL until it has completed one year of quarterly samples.

EPA 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 for CMR (62 FR 36100, July 3, 1997 (USEPA, 1997a)), EPA considered some of the issues raised by the commenters. 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 a standardized monitoring framework 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 standardized monitoring framework. The Agency made special efforts to ensure that the reduced monitoring periods are in line with the 3-year compliance periods in the standardized monitoring framework.

To assist States with understanding rule requirements, the Agency conducted a series of Phase II/V training in 2001. The training provided information to help States make informed decisions about reducing quarterly monitoring requirements. With respect to reduced monitoring, States currently have the flexibility to reduce the frequency of monitoring and/or to waive 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.

NTNCWSs are traditionally regulated for chronic contaminants. However, through an alternative mechanism, 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.

EPA intends to consistently implement compliance determination provisions for IOCs, SOCs, and VOCs for all NTNCWSs and community water systems, as described in the preamble to the Final Arsenic Rule (66 FR 6975 at 6990, January 22, 2001 (USEPA, 2001)). The rule makes compliance determinations 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 sample 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.

D. What Comments Did EPA Receive on the Total Coliform Rule?

Several commenters addressed the TCR. Several commenters raised several issues relating to monitoring. Some contended that routine monitoring should be focused on critical locations in the distribution system, rather than on the current requirement to monitor all parts of the distribution system. They also urged EPA to allow the use of dedicated sampling taps. Some commenters argued for allowing a finished water storage reservoir as a routine monitoring site. Two commenters urged EPA to focus on *E. coli* as the measure of water quality in the distribution system, rather than on total coliforms. In addition to routine monitoring, a few commenters addressed the topic of repeat samples after a total coliform-positive sample. One commenter, for example, urged EPA to eliminate the requirement to take upstream and downstream repeat samples after a total coliform-positive sample. Environmental groups urged EPA to strengthen the TCR and other rules that protect against pathogens, and exhorted EPA not to ease the TCR burden such that public health is compromised.

EPA Response: EPA's announcement in the April 17, 2002, **Federal Register** was only intended to discuss the Agency's intent to begin the process for revising the TCR. EPA will consider the commenters' suggestions as part of the revision process. As stated in the April 17, 2002, **Federal Register**, the Agency plans to consider revisions to the TCR with new requirements for ensuring the integrity of distribution systems. The Agency remains committed to obtaining input from stakeholders as part of the rule development process. EPA agrees with the comment that public health should not be compromised, and will consider only those revisions that will assure public health protection.

E. What Comments Did EPA Receive on Research Needs?

Commenters found that EPA's information on potential research resulting from the review of NPDWRs would be better represented by a summary of research needs that were identified by the Agency. Commenters felt that this summary is important to inform future regulatory decisions. Commenters also suggested additional research needs that had not been

identified by EPA in its preliminary review.

EPA Response: EPA agrees that the identification of research needs is an important component of the review of NPDWRs. Research findings may support future reviews and/or revisions to NPDWRs.

The Agency is considering research needs that it identified as part of the review as well as those suggested by commenters. EPA will continue to identify areas where data are lacking. Dialogue with industry and other groups, including those that sponsor or conduct research on priority areas, would be beneficial to the drinking water program. Collaboration in sponsoring studies can provide multiple benefits.

There are two research needs associated with the Six-Year Review that are being addressed through mechanisms external to EPA. The National Research Council of the National Academy of Sciences is conducting an assessment of recent data on fluoride health effects. In addition, the National Toxicology Program is conducting a study on chromium VI toxicity. Both of these research efforts are discussed in the April 17, 2002, **Federal Register** announcement of EPA's preliminary revise/not revise decisions. The current review identified several general and specific areas of potential research related to treatment. The treatment-related research areas are briefly discussed in the Treatment Feasibility Document (USEPA, 2003g).

EPA is currently in the process of examining whether specific research needs exist within each of the Six-Year Review areas of regulatory consideration (*i.e.*, health effects, analytical methods, treatment, implementation, and occurrence/exposure). Some of the research needs identified during the Six-Year Review effort will be discussed in the context of the Multi-Year Plan (MYP) for drinking water. The MYP describes the EPA Office of Research and Development's fiscal year 2003 to 2010 research program to support the regulatory development activities of the EPA Office of Water. EPA plans to make this document available to the public in 2003.

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