



# Federal Register

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**Wednesday,  
April 17, 2002**

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**Part III**

## **Environmental Protection Agency**

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**40 CFR Part 141**

**National Primary Drinking Water  
Regulations; Announcement of the Results  
of EPA's Review of Existing Drinking  
Water Standards and Request for Public  
Comment; Proposed Rule**

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 141**

[FRL-7167-9]

RIN 2040-AD67

**National Primary Drinking Water Regulations; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Review of regulations; request for comments.

**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 is requesting public comment on the results of 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 is to identify those NPDWRs for which current health risk assessments, changes in technology, and/or other factors, provide a health or technical basis to support a regulatory revision that will improve or strengthen public health protection. Based on its review, and pending an evaluation of public comments, the Agency preliminarily believes that the 68 chemical NPDWRs remain appropriate at this time, and that the TCR should be revised.

**DATES:** EPA must receive public comments on this action by June 17, 2002.

**ADDRESSES:** Please send your comments to the W-01-14 Comments Clerk. Submit electronic comments to: *ow-docket@epa.gov*. Written comments should be mailed to: Water Docket (MC-4101), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460. Hand deliveries should be delivered to EPA's Water Docket at East Tower Basement (EB Room 57), Waterside Mall, 401 M Street, SW., Washington, DC, 20460. You may contact the docket at (202) 260-3027 between 9 a.m. and 3:30 p.m. Eastern Time, Monday through Friday. Comments may be submitted electronically. See **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing and docket review.

**FOR FURTHER INFORMATION CONTACT:** For technical inquiries contact: Judy

Lebowich, (202) 564-4884, e-mail: *lebowich.judy@epa.gov*, or Wynne Miller, (202) 564-4887, e-mail: *miller.wynne@epa.gov*. For general information about, and copies of, this document or information about the existing NPDWRs discussed in this action, contact the Safe Drinking Water Hotline. Callers within the United States may reach the Hotline at (800) 426-4791. The Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. Eastern Time.

**SUPPLEMENTARY INFORMATION:****How Should I Submit Comments on This Action?**

EPA will accept written or electronic comments (please do not send both). EPA prefers electronic comments. Commenters should use a separate paragraph for each issue discussed. No facsimiles (faxes) will be accepted. Commenters who want EPA to acknowledge receipt of their comments should also send a self-addressed, stamped envelope. If you submit written comments, please submit an original and three copies of your comments and enclosures (including references).

Electronic comments must be submitted in WordPerfect 8 (or an older version) or ASCII file format. Compressed or zipped files will not be accepted. You may file electronic comments on this action online at many Federal Depository Libraries.

The Agency's response-to-comments document for the final decision will address the comments received on this action, and the response-to-comments document will be made available in the docket.

**How Can I Obtain Materials in the Docket?**

The docket is available for inspection from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays, at the Water Docket, East Tower Basement (EB Room 57), Waterside Mall, USEPA, 401 M Street, SW; Washington, DC. For access to docket (Docket Number W-01-14) materials, please call (202) 260-3027 between 9:00 a.m. and 3:30 p.m., Eastern Time, Monday through Friday, to schedule an appointment.

**Does This Action Apply to My Public Water System?**

This action itself does not impose any requirements on anyone. Instead, it notifies interested parties of EPA's preliminary revise/not revise decisions for 69 NPDWRs.

**Abbreviations and Acronyms Used in This Action**

>—greater than  
 2,4-D—2,4-dichlorophenoxyacetic acid  
 AA—activated alumina  
 AI—adequate intake  
 ASDWA—Association of State Drinking Water Administrators  
 ATSDR—Agency for Toxic Substances and Disease Registry  
 AWWA—American Water Works Association  
 BAT—best available technology  
 BMD—benchmark dose  
 bw—body weight  
 CCL—Contaminant Candidate List  
 CFR—Code of Federal Regulations  
 CMR—Chemical Monitoring Reform  
 CWS—community water system  
 DBCP—1,2-dibromo-3-chloropropane  
 DBPR—Disinfectants and Disinfection Byproducts Rule  
 DEHA—di(2-ethylhexyl)adipate  
 DEHP—di(2-ethylhexyl)phthalate  
 DRI—dietary reference intake  
 DWEL—drinking water equivalent level  
 EDB—ethylene dibromide  
 EPA—U.S. Environmental Protection Agency  
 EPTDS—entry points to a distribution system  
 FR—Federal Register  
 GAC—granular activated carbon  
 GC/MS—gas chromatography/mass spectrometry  
 HHS—Department of Health and Human Services  
 HPC—heterotrophic plate count  
 I—daily drinking water intake  
 IESWTR—Interim Enhanced Surface Water Treatment Rule  
 IRIS—Integrated Risk Information System  
 LCR—Lead and Copper Rule  
 LOAEL—lowest-observed-adverse-effect level  
 LT1ESWTR—Long-Term 1 Enhanced Surface Water Treatment Rule  
 LT2ESWTR—Long-Term 2 Enhanced Surface Water Treatment Rule  
 MCL—maximum contaminant level  
 MCLG—maximum contaminant level goal  
 M/DBP—Microbial/Disinfection Byproducts  
 MDL—method detection limit  
 MF—modifying factor  
 MFL—million fibers per liter  
 mg/kg/day—milligrams per kilogram of body weight per day  
 mg/L—milligrams per liter  
 MSRC—Mercury Study Report to Congress  
 MTD—maximum tolerated dose  
 N—nitrogen  
 NAS—National Academy of Sciences  
 NCOD—National Drinking Water Contaminant Occurrence Database

NDWAC—National Drinking Water Advisory Council  
 NIPDWR—National Interim Primary Drinking Water Regulation  
 NOAEL—no-observed-adverse-effect level  
 NPDWR—National Primary Drinking Water Regulation  
 NRC—National Research Council  
 NTNCWS—non-transient, non-community water system  
 NTP—National Toxicology Program  
 NWIS—National Water Information System  
 OGWDW—Office of Ground Water and Drinking Water  
 OPP—Office of Pesticide Programs  
 OW—Office of Water  
 PAC—powdered activated carbon  
 PCBs—polychlorinated biphenyls  
 POU—point-of-use  
 ppm—part per million  
 PQL—practical quantitation level  
 PTA—packed tower aeration  
 PWS—public water system  
 RDA—recommended dietary allowance  
 RfD—reference dose  
 RO—reverse osmosis  
 RSC—relative source contribution  
 SAB—Science Advisory Board  
 SDWA—Safe Drinking Water Act  
 SDWIS—Safe Drinking Water Information System  
 SMCL—secondary maximum contaminant level  
 SOC—synthetic organic chemical  
 SWTR—Surface Water Treatment Rule  
 TCR—Total Coliform Rule  
 TNCWS—transient, non-community water system  
 TT—treatment technique  
 TTHM—total trihalomethanes  
 UF—uncertainty factor  
 UL—tolerable upper intake level  
 URCIS—Unregulated Contaminant Information System  
 VOC—volatile organic chemical  
 WS—water supply

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## I. Background and Summary of Today's Action

### A. What Are the Statutory Requirements for the Six-Year Review?

Under the 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.

Pursuant to the SDWA 1996 Amendments, EPA developed a systematic approach, or protocol, for the review of NPDWRs discussed in today's action. EPA has applied the protocol discussed in section IV of today's action to the Agency's initial Six-Year Review of NPDWRs for total coliforms and 68 inorganic and organic chemicals, published prior to the SDWA 1996 Amendments (i.e., pre-1997 NPDWRs). Section III of today's action identifies these NPDWRs and section V of today's action contains a summary of the review findings for each of these 69 NPDWRs (see Table III-1).

While the Agency expects that modifications to the protocol will be made in subsequent six-year reviews to address changing circumstances, the Agency expects to use the framework developed for the current review as the starting point. EPA, therefore, is seeking public comment on the protocol that has been applied to the current review.

### B. What Is the Schedule for Reviewing Existing NPDWRs?

EPA plans to publish its final findings with respect to the initial review of these 69 NPDWRs in the **Federal Register** (FR) in the August 2002 time frame.

In addition to these 69 NPDWRs, there are additional pre-1997 NPDWRs, which are being or have been reviewed separately from today's action. Section III explains how the Agency plans to satisfy the Six-Year Review requirement for those regulations. In most cases, EPA has performed or is performing the review in conjunction with recent or ongoing rulemakings. NPDWRs published after the 1996 SDWA Amendments will be reviewed as a part of the 2002-2008 review cycle.

## II. Stakeholder Involvement in the Six-Year Review Process

### A. How Have Stakeholders Been Involved in the Review Process?

Stakeholders include:

- The general public;
- Congress;
- Other Federal agencies;
- State, Tribal, and local officials;
- Public health/health care providers;
- Public interest groups;
- Public water suppliers;
- National trade associations;
- Environmental groups;
- Manufacturers; and
- Agricultural producers.

EPA involved stakeholders by: holding a stakeholder meeting; participating in national meetings, workshops, and technical forums; meeting informally with associations and technical experts; posting information on the Office of Ground Water and Drinking Water's (OGWDW's) web page ([www.epa.gov/safewater/](http://www.epa.gov/safewater/)); and publishing this FR notice on the Six-Year Review.

EPA invited representatives from State and Tribal communities, public water systems (PWSs), public health organizations, academia, environmental and public interest groups, engineering firms, and other stakeholders to a stakeholder meeting in Washington, DC, in November 1999 (64 FR 55711, October 14, 1999 (USEPA, 1999c)). Approximately 50 participants attended, including representatives from the invited groups. EPA discussed its preliminary strategy for the Six-Year Review and invited stakeholder comment. Stakeholders generally agreed that EPA had identified the appropriate key elements for the review; however, in some cases, stakeholders suggested that EPA needed to be more proactive in seeking out new information that might affect the regulatory decision (USEPA, 1999e). For more detailed information about this stakeholder meeting, the docket for this action (Docket Number W-01-14) contains the stakeholder meeting discussion papers, the agenda, the participant list, presentation materials, and an executive meeting summary which includes the specific comments and questions posed by stakeholders. The executive meeting summary is also available on EPA's drinking water web page, <http://www.epa.gov/safewater/ccl/novmtg.html>.

In the Spring of 2000, the National Drinking Water Advisory Council (NDWAC) formed a working group to develop recommendations regarding the process the Agency should apply to conduct a periodic and systematic

review of existing NPDWRs. The Working Group held two meetings and a conference call during June through September 2000 (USEPA, 2000b; USEPA, 2000c; USEPA, 2000d). The NDWAC approved the Working Group's recommendations in November 2000 and formally provided them to EPA in December 2000 (NDWAC, 2000). The NDWAC recommended that EPA's review include consideration of five key elements, as appropriate: health effects, analytical and treatment feasibility, implementation-related issues, occurrence and exposure, and economic impacts. The NDWAC suggested that the Agency conduct an initial screening review of each NPDWR to identify potential candidates for an in-depth analysis. As discussed in more detail in section IV of today's action, EPA has followed the general protocol recommended by the NDWAC.

In addition to the November 1999 stakeholder meeting and consultation with the NDWAC, EPA representatives have delivered presentations at a variety of meetings held by other organizations, including: two American Water Works Association (AWWA) Technical Advisory Workgroup meetings, one held in February 2001 in Washington, DC, and one held in February 2002 in San Diego, CA; a meeting held by the Association of State Drinking Water Administrators (ASDWA) in March 2001 in Alexandria, VA; and the annual AWWA meeting held in Washington, DC in June 2001. At each of these meetings, stakeholders were given the opportunity to comment on the protocol by which EPA was planning to perform the review of existing NPDWRs. EPA received valuable input from stakeholders on the planned protocol.

### B. How Does EPA Plan To Involve the Science Advisory Board (SAB)?

EPA plans to consult with the SAB Drinking Water Committee on today's action. The Agency will request their review and comment on whether the protocol EPA developed based on the NDWAC recommendations was consistently applied and appropriately documented.

## III. Regulations Included in the Six-Year Review

Table III-1 lists the pre-1997 NPDWRs covered by today's action and the rulemaking by which they were originally promulgated. Table III-2 lists the NPDWRs not covered by today's action. These include the remaining pre-1997 NPDWRs which are being or have already been reviewed in separate actions and the NPDWRs promulgated after the 1996 SDWA Amendments. The

NPDWRs listed in Table III-2 will be included in the 2002-2008 review

round. Section V of today's action summarizes the results of the review of

68 pre-1997 chemical NPDWRs and the NPDWR for total coliforms.

**BILLING CODE 6560-50-P**

Table III-1: Pre-1997 NPDWRs Included in Today's Action

Contaminant	Corresponding NPDWR	Contaminant	Corresponding NPDWR
<b>Chemical Contaminants</b>		<b>Chemical Contaminants (continued)</b>	
Acrylamide	Phase II Rule	Endrin	Phase V Rule
Alachlor	Phase II Rule	Epichlorohydrin	Phase II Rule
Antimony	Phase V Rule	Ethylbenzene	Phase II Rule
Asbestos	Phase II Rule	Ethylene dibromide (EDB)	Phase II Rule
Atrazine	Phase II Rule	Fluoride	Fluoride Rule; Phase II Rule revised monitoring requirements
Barium	Phase IIB Rule	Glyphosate	Phase V Rule
Benzene	Phase I Rule	Heptachlor	Phase II Rule
Benzo[a]pyrene	Phase V Rule	Heptachlor epoxide	Phase II Rule
Beryllium	Phase V Rule	Hexachlorobenzene	Phase V Rule
Cadmium	Phase II Rule	Hexachlorocyclopentadiene	Phase V Rule
Carbofuran	Phase II Rule	Lead	LCR
Carbon tetrachloride	Phase I Rule	Lindane	Phase II Rule
Chlordane	Phase II Rule	Mercury (Inorganic)	Phase II Rule
Chromium (total)	Phase II Rule	Methoxychlor	Phase II Rule
Copper	Lead and Copper Rule (LCR)	Monochlorobenzene (Chlorobenzene)	Phase II Rule
Cyanide	Phase V Rule	Nitrate (as N)	Phase II Rule
2,4-D	Phase II Rule	Nitrite (as N)	Phase II Rule
Dalapon	Phase V Rule	Oxamyl (Vydate)	Phase V Rule
1,2-Dibromo-3-chloropropane (DBCP)	Phase II Rule	Pentachlorophenol	Phase IIB Rule
1,2-Dichlorobenzene ( <i>o</i> -Dichlorobenzene)	Phase II Rule	Picloram	Phase V Rule
1,4-Dichlorobenzene ( <i>p</i> -Dichlorobenzene)	Phase I Rule	Polychlorinated biphenyls (PCBs)	Phase II Rule
1,2-Dichloroethane (Ethylene dichloride)	Phase I Rule	Selenium	Phase II Rule
1,1-Dichloroethylene	Phase I Rule	Simazine	Phase V Rule
cis-1,2-Dichloroethylene	Phase II Rule	Styrene	Phase II Rule
trans-1,2-Dichloroethylene	Phase II Rule	2,3,7,8-TCDD (Dioxin)	Phase V Rule
Dichloromethane (Methylene chloride)	Phase V Rule	Tetrachloroethylene	Phase II Rule
1,2-Dichloropropane	Phase II Rule	Thallium	Phase V Rule
Di(2-ethylhexyl)adipate (DEHA)	Phase V Rule	Toluene	Phase II Rule
Di(2-ethylhexyl)phthalate (DEHP)	Phase V Rule	Toxaphene	Phase II Rule
Dinoseb	Phase V Rule	2,4,5-TP (Silvex)	Phase II Rule
Diquat	Phase V Rule	1,2,4-Trichlorobenzene	Phase V Rule
Endothall	Phase V Rule	1,1,1-Trichloroethane	Phase I Rule

**Table III-1: Pre-1997 NPDWRs Included in Today's Action**

Contaminant	Corresponding NPDWR	Contaminant	Corresponding NPDWR
<b>Chemical Contaminants (continued)</b>		<b>Microorganisms</b>	
Trichloroethylene	Phase I Rule	Total coliforms (including fecal coliform and <i>E. coli</i> )	Total Coliform Rule (TCR)
Vinyl chloride	Phase I Rule		
Xylenes (total)	Phase II Rule		
1,1,2-Trichloroethane	Phase V Rule		
Dates of original promulgation are as follows:			
- Phase II Rule: 56 <i>FR</i> 3526, January 30, 1991 (USEPA, 1991a)		- ICR: 56 <i>FR</i> 26460, June 7, 1991 (USEPA, 1991b)	
- Phase V Rule: 57 <i>FR</i> 31776, July 17, 1992 (USEPA, 1992)		- Fluoride Rule: 51 <i>FR</i> 11396, April 2, 1986 (USEPA, 1986a)	
- Phase IIB Rule: 56 <i>FR</i> 30266, July 1, 1991 (USEPA, 1991c)		- TCR: 54 <i>FR</i> 27544, June 29, 1989 (USEPA, 1989c)	
- Phase I Rule: 52 <i>FR</i> 25690, July 8, 1987 (USEPA, 1987)			

<b>Table III-2: NPDWRs Not Included in Today's Action</b>		
<b>Contaminant/Indicator</b>	<b>Corresponding NPDWR<sup>1</sup></b>	<b>Reason Not Included</b>
<i>Chemical Contaminants</i>		
Arsenic	Pre-1986 National Interim Primary Drinking Water Regulation (NIPDWR)	Reviewed/revise under January 22, 2001 Arsenic Rule <sup>2,3</sup>
<i>Radionuclides</i>		
Beta particles and photon emitters	Pre-1986 NIPDWR	Reviewed/revise under December 7, 2000 Radionuclides Rule <sup>2</sup>
Gross alpha particle activity		
Radium-226/228 (combined)		
Uranium	2000 Radionuclides Rule	Promulgated after 1996. NPDWR established in the December 7, 2000 Radionuclides Rule <sup>2</sup>
<i>Microorganisms</i>		
<i>Cryptosporidium</i>	Interim Enhanced Surface Water Treatment Rule (IESWTR) Long-Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR)	Subject of ongoing rulemaking activity - Long-Term 2 ESWTR (LT2ESWTR) (November 2003) <sup>4</sup>
<i>Giardia lamblia</i>	Surface Water Treatment Rule (SWTR); IESWTR; LT1ESWTR	
Heterotrophic plate count (HPC)	SWTR	
<i>Legionella</i>	SWTR	
Turbidity	SWTR; IESWTR; LT1ESWTR	
Viruses	SWTR; IESWTR; LT1ESWTR	
<i>Disinfection Byproducts</i>		
Bromate ion	Stage 1 Disinfectants and Disinfection Byproducts Rule Stage I (DBPR)	Revised rule promulgated after 1996 and additional revisions to be considered under Stage 2 DBPR (July 2003) <sup>4</sup>
Chlorite ion		
Haloacetic acids: Monobromoacetic acid; Dibromoacetic acid; Monochloroacetic acid; Dichloroacetic acid; and Trichloroacetic acid		
Total Trihalomethanes (TTHMs): Chloroform; Bromodichloromethane; Dibromochloromethane; and Bromoform	TTHM Rule; Requirements revised under Stage 1 DBPR	Revised rule promulgated after 1996 and additional revisions to be considered under Stage 2 DBPR (July 2003) <sup>4</sup>
<i>Disinfectant Residuals</i>		
Chlorine	Stage 1 DBPR	Revised rule promulgated after 1996
Chloramines		
Chlorine dioxide		



**Table III-2: NPDWRs Not Included in Today's Action**

Contaminant/Indicator	Corresponding NPDWR <sup>1</sup>	Reason Not Included
<sup>1</sup> Dates of original promulgation are as follows:		
<ul style="list-style-type: none"> <li>– Arsenic Rule: 40 FR 59566, December 24, 1975 (USEPA, 1975)</li> </ul>		
<ul style="list-style-type: none"> <li>– Radionuclides Rule: 41 FR 28402, July 9, 1976 (USEPA, 1976)</li> </ul>		
<ul style="list-style-type: none"> <li>– IESWTR: 63 FR 69478, December 16, 1998 (USEPA, 1998c)</li> </ul>		
<ul style="list-style-type: none"> <li>– LTIESWTR: 67 FR 1811, January 14, 2002 (USEPA, 2002b)</li> </ul>		
<ul style="list-style-type: none"> <li>– SWTR: 54 FR 27486, June 29, 1989 (USEPA, 1989c)</li> </ul>		
<ul style="list-style-type: none"> <li>– Stage 1 DBPR Rule: 63 FR 69389, December 16, 1998 (USEPA, 1998b)</li> </ul>		
<ul style="list-style-type: none"> <li>– TTHM Rule: 44 FR 68624, November 29, 1979 (USEPA, 1979)</li> </ul>		
<sup>2</sup> Indicates date of rule revision.		
<ul style="list-style-type: none"> <li>– Arsenic Rule: 66 FR 6976, January 22, 2001 (USEPA, 2001a)</li> </ul>		
<ul style="list-style-type: none"> <li>– Radionuclides Rule: 65 FR 76707, December 7, 2000 (USEPA, 2000g)</li> </ul>		
<sup>3</sup> After promulgation of the revised arsenic NPDWR on January 22, 2001, EPA initiated a review of the new maximum contaminant level (MCL), and postponed the effective date of the rule until February 22, 2002. EPA requested independent expert panel reviews of the science, cost and benefits analyses for the January 2001 rule, and in July 2001, sought additional public comment on a range of MCLs. Following receipt of the final expert panel reports in the Fall of 2001, EPA requested comment on the reports. EPA will continue to evaluate the expert panel reports, the voluminous comments received during these comment periods, and other relevant information and comments as they become available as part of the next six-year review; EPA expects to make a final decision on whether to revise the January 2001 rule as part of that six-year review, which is due in August 2008. In the meantime, as announced by the Administrator on October 31, 2001, EPA will not further postpone the January 2001 rule, and EPA also does not expect to take any other additional action relative to the July 2001 proposal in the interim. The revised arsenic MCL became effective on February 22, 2002. The date for compliance with the MCL remains January 23, 2006.		
<sup>4</sup> Indicates anticipated date of promulgation.		

## BILLING CODE 6560-50-C

**IV. EPA's Protocol for Reviewing the NPDWRs Included in Today's Action****A. What Was EPA's Review Process?**

The document, "EPA Protocol for the Review of Existing National Primary Drinking Water Regulations" (USEPA, 2002f), contains a detailed description of the process the Agency used to review the 69 NPDWRs discussed in today's action. EPA's primary goal was to identify and prioritize candidates for regulatory revision in order to target those revisions that are most likely to result in an increased level of public health protection and/or result in substantial cost savings while maintaining the level of public health protection. This section provides an overview of the review process. Sections IV.B and IV.C of today's action provide a more detailed description of how EPA applied the process to the review of 68 chemical NPDWRs and the TCR, respectively.

EPA applied the following basic principles to the review process:

- Health effects, analytical feasibility, treatment data, and analyses underlying existing regulations remain adequate and relevant, except in those instances

where reliable, peer-reviewed, new data are available that indicate a need to re-evaluate an NPDWR (e.g., where a change in health risk assessment has occurred).

- If new data were available, EPA determined whether changes in existing standards were warranted. For example, in determining whether there was a change in analytical feasibility, the Agency applied the current policy and procedures for calculating the practical quantitation level for drinking water contaminants.<sup>1</sup>

- EPA was unable to complete evaluation of certain new data within the time available for the review. For example, if a new health risk assessment for a contaminant was not completed during the review cycle, EPA generally made a "not revise" decision on the rationale that it was not appropriate to revise the regulation while the assessment was ongoing. When an updated assessment is completed, EPA will review the update and any new conclusions or additional information associated with the contaminant during the next review cycle. The Agency may

make a determination to revise a particular NPDWR before August 2008 where justified by new public health risk information.

- During the review, EPA identified areas where information is inadequate or unavailable (data gaps) and is needed before an NPDWR may be considered as a candidate for revision. Where the Agency has been unable to fill such gaps during the review process, today's action provides information about the data gaps so that further research and data collection can be considered as part of the second review cycle. For example, the review may identify a need to better understand new treatment technologies. Such an information gap will need to be considered in the context of EPA's overall OGWDW research strategy.

- During the review process, the Agency did not consider potential regulatory revisions that were already the subject of other rulemaking activities.

- EPA applied the Agency's peer review policy (USEPA, 2000i) where appropriate, to any new analyses.

Figure 1 provides an overview of the review process. To most efficiently utilize limited resources and assure

<sup>1</sup> See: 50 FR 46880, November 13, 1985 (USEPA, 1985); 52 FR 25690, July 8, 1987 (USEPA, 1987); 54 FR 22062, May 22, 1989 (USEPA, 1989a).

continued public health protection, the Agency conducted the review in two phases: (1) an initial technical review of all 69 NPDWRs discussed in today's action; and (2) an in-depth technical evaluation of those NPDWRs identified during the initial review as potential candidates for revision.

#### 1. Initial Technical Review

The initial review phase included these three screening and general evaluation steps:

- *Health effects review.* Identify NPDWRs for which the Agency has revised health risk assessments that indicate possible changes to the maximum contaminant level goal (MCLG) and perhaps to the maximum contaminant level (MCL);
- *Current technology review.* Identify NPDWRs where improvements in analytical measurement or treatment feasibility might allow the MCL to be established closer to the MCLG, or where adjustments in treatment technique (TT) requirements might be appropriate; and/or
- *Other regulatory revisions review.* Identify NPDWRs where adjustments to system monitoring and reporting requirements might be appropriate and where such changes are not already

being considered as a part of another activity.

EPA generally determined that an NPDWR was not a candidate for revision after the initial review if a health risk assessment was in process or was initiated as a result of the review, since the Agency does not believe it is appropriate to revise the NPDWR while a health risk assessment is underway. The Agency also determined that an NPDWR was not a candidate for revision after the initial screening if none of the initial screening analyses identified a health or technological basis for a regulatory revision.

#### 2. In-Depth Technical Review

The Agency subjected the remaining NPDWRs to more in-depth technical analyses. If the initial review indicated a possible revision to the MCLG/MCL, EPA further considered health and technology factors that might affect the development of a revised MCLG/MCL or revised MCLG/TT requirements. The Agency also estimated potential occurrence and exposure at PWSs at concentrations of regulatory interest for the chemical NPDWRs and conducted a qualitative evaluation of economic impacts. EPA based the qualitative economic evaluation primarily on available occurrence and exposure data,

to determine whether the possible revision was likely to present an opportunity for significant gains in public health protection and/or significant cost savings that could be realized without lessening the level of public health protection.

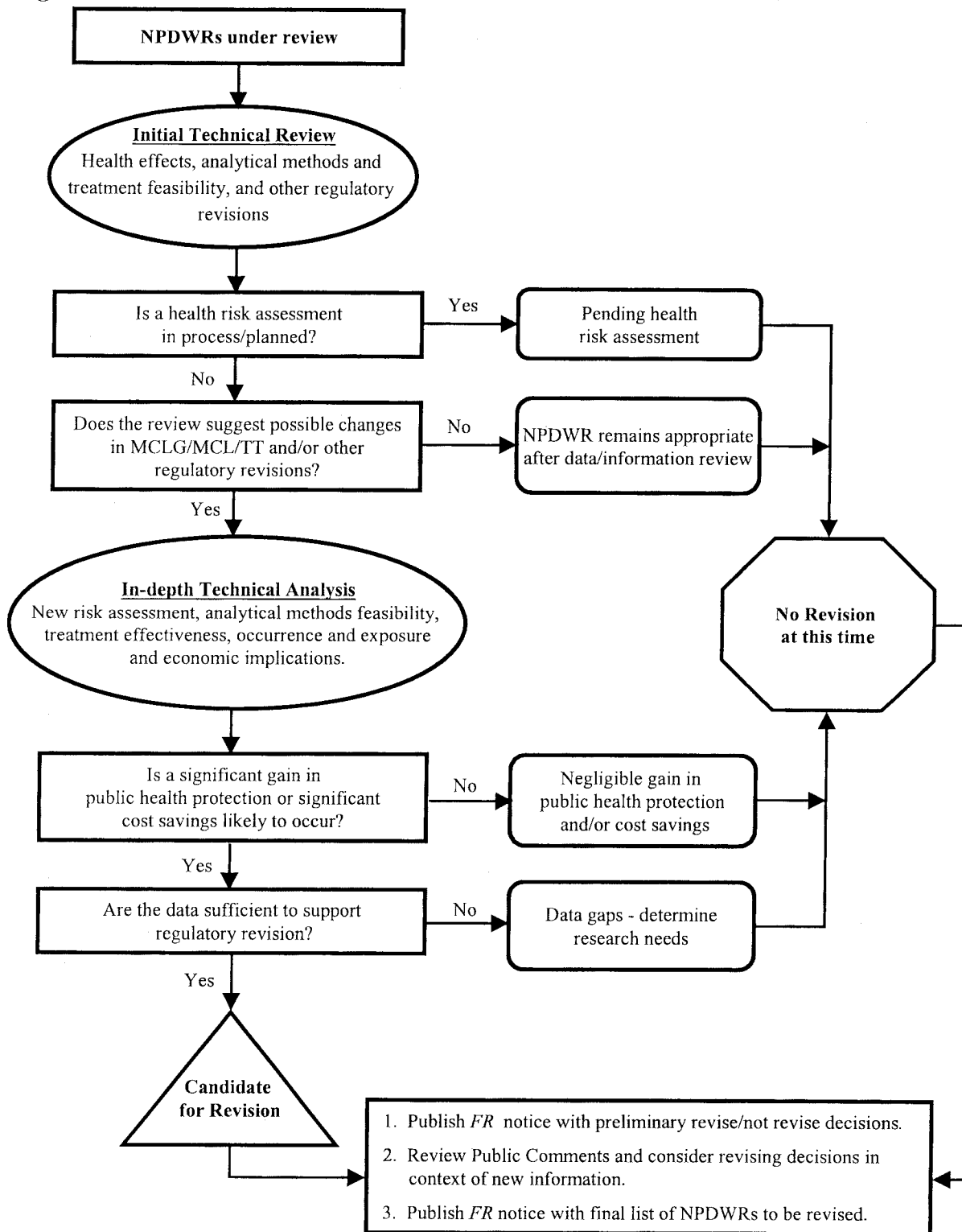
In the case of three contaminants, EPA identified data gaps that could not be filled during the current review cycle. Figure 1 shows the identification of data gaps as the final step in the review; however, in some instances, data gaps were identified during earlier steps in the process. Where this occurred, EPA did not conduct some or all of the remaining analyses. If the Agency identified data gaps, EPA determined not to revise the NPDWR.

After completing these comprehensive analyses, EPA identified those NPDWRs that remain appropriate at this time, and those NPDWRs that may be appropriate for revision.

Today's action discusses the Agency's preliminary determinations and seeks public comment on them. After considering the public comments received and any new peer-reviewed data that may become available to the Agency, EPA will publish its final decision in the FR.

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**Figure 1: Overview of the Protocol for the Revise/Not Revise Decision**



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**B. How Did EPA Review the Chemical NPDWRs?**

This section describes the specific technical reviews that EPA conducted for the chemical NPDWRs.

**1. Health Effects**

The document, “Six-Year Review—Chemical Contaminants—Health Effects Technical Support Document” (USEPA, 2002i), describes how EPA reviewed the chemical contaminants discussed in

today’s action and provides the results of the health effects technical review. The principal objective of the health effects review was to identify each contaminant for which a new health risk assessment indicated that a change in MCLG might be appropriate. For most of

the chemical NPDWRs discussed in today's action, the MCLG is derived from the cancer classification and/or the reference dose (RfD), as described in Appendix A. Therefore, the health effects technical review focused on whether there has been a change to these values. The Agency reviewed the results of health risk assessments completed under the following programs to determine if there had been a change in critical effect or dose-response pattern that indicates the possible need for an MCLG revision.

- EPA Integrated Risk Information System (IRIS);
- EPA Office of Pesticide Programs (OPP);
- Agency for Toxic Substances and Disease Registry (ATSDR); and
- National Academy of Sciences (NAS).

Table IV-1 reflects the outcome of the health effects review for the 68 chemical NPDWRs discussed in today's action. EPA placed each contaminant into one of the following categories.

- *New risk assessment 1997 or later.* An IRIS, OPP, ATSDR, and/or NAS assessment has been completed in 1997 or later. These assessments have considered developmental and reproductive toxicity as a part of the assessment. The Agency considers these assessments to be recent enough that it is not necessary to conduct a literature search to identify any additional relevant studies that have become available on the toxicological effects of these contaminants. In cases where the health risk assessment resulted in a change in the critical effect, or the dose-response pattern for a regulated contaminant, and where that change could result in a change in the MCLG, EPA subjected the NPDWR to more in-depth analysis as a part of the review

process. Where recent assessments were conducted by an agency other than EPA and new developmental and reproductive data were identified, EPA initiated an update of its assessment.

- *New risk assessment since promulgation, but prior to 1997.* An IRIS, OPP, ATSDR, and/or NAS assessment has been completed since the NPDWR was promulgated but prior to 1997. None of these assessments reflected a change in RfD or cancer classification. However, since these assessments may not have specifically considered developmental and reproductive health effects, EPA conducted a full literature search, including developmental and reproductive toxicity, for those NPDWRs with non-zero MCLGs to identify any relevant studies that might affect the MCLGs of these contaminants. EPA did not identify any chemicals for which developmental or reproductive effects might now be the critical effect.<sup>2</sup>

- *Agency risk assessment in process and not completed as of February 2002.* The Agency currently is conducting a health risk assessment for the contaminant. That assessment will consider all relevant studies that have become available on the toxicology of the contaminant, including developmental and reproductive toxicity. EPA does not believe it is appropriate to revise the MCLG for these contaminants at this time.

- *Original NPDWR risk assessment.* No health risk assessment has been

<sup>2</sup> A zero MCLG is already considered protective of public health and new information on developmental and reproductive effects would not affect the MCLG. However, for those NPDWRs with a zero MCLG, EPA reviewed available information to inquire whether data show a nonlinearity of the dose-response; EPA did not find any data to support such a mode of action (USEPA, 2002i).

conducted since promulgation of the NPDWR. The Agency conducted a full toxicological literature search, including developmental and reproductive toxicity, for each of these contaminants with non-zero MCLGs (see footnote 2) to identify new toxicological studies that might have an impact on the MCLGs. In a few instances, the results of the literature search indicate that it might be appropriate to revise the RfD and/or cancer classification. EPA initiated updates to the risk assessments for these chemicals, and established a schedule for their completion. EPA does not believe it is appropriate to revise the MCLG at this time.

Thus, only contaminants in the first category might be potential candidates for an MCLG revision at this time.

The initial health effects review identified beryllium, oxamyl, and picloram as potential candidates for an MCLG revision, depending on the outcome of the more in-depth health effects review and on the other technical analyses (e.g., analytical feasibility, treatment, occurrence, etc.). The initial health effects review also identified changes in the RfD for chromium as well as data gaps with respect to its potential carcinogenicity via oral ingestion. EPA also identified health effects-related data gaps for fluoride. Contaminants in any of the categories except the third (risk assessment in process) may be candidates for a new assessment if the initial health effects review identified new studies that may affect the contaminant's RfD or cancer classification. EPA has initiated a new assessment for cyanide, di(2-ethylhexyl)adipate, and thallium as a result of the health effects technical review.

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**Table IV-1: Summary of the Outcome of the Six-Year Health Effects Review for Chemical NPDWRs**

Risk Assessment Timing		Literature Search Status/Results		Outcome of Health Effects Review	Contaminants
		<i>Reproductive/ developmental endpoints only</i>	<i>Other toxicological endpoints</i>		
New risk assessment 1997 or later		Already considered in the assessment, so literature search not necessary	Already considered in the assessment, so literature search not necessary	Change in assessment	<b>4 Total</b> - Beryllium; Chromium; Oxamyl; Picloram
				Change in assessment but negligible gain in health protection	<b>1 Total</b> - Hexachlorocyclopentadiene
				No change in assessment	<b>8 Total</b> - Barium; Benzene; Chlordane; Dichloromethane; Lead; Mercury (inorganic); Selenium; Vinyl chloride
				New assessment initiated or planned	<b>2 Total</b> - Cyanide, Fluoride <sup>1</sup>
New risk assessment since promulgation but prior to 1997	Zero MCLG	Literature not reviewed since zero MCLG is protective	Zero MCLG remains appropriate	Zero MCLG retained	<b>5 Total</b> - 1,2-Dibromo-3-chloropropane; Heptachlor; Heptachlor epoxide; Hexachlorobenzene; Toxaphene
	Non-zero MCLG	New information does not support a need to revise the RfD or cancer classification	New information does not support a need to revise the RfD or cancer classification	No revisions to MCLG	<b>5 Total</b> - cis-1,2-Dichloroethylene; trans-1,2-Dichloroethylene; Endrin; Nitrate; Nitrite
Agency risk assessment in process and not completed as of February 2002		Literature search addressed as part of ongoing assessment	Literature search addressed as part of ongoing assessment	Not appropriate to revise MCLG at this time	<b>33 Total</b> <sup>2</sup> - Acrylamide; Alachlor; Antimony; Asbestos; Atrazine; Benzo[a]pyrene; Cadmium; Carbofuran; Carbon tetrachloride; Copper; 2,4-D; 1,2-Dichlorobenzene; 1,4-Dichlorobenzene; 1,2-Dichloroethane; 1,1-Dichloroethylene; Di(2-ethylhexyl)phthalate; Diquat; Endothal; Ethylbenzene; Ethylene dibromide; Glyphosate; Lindane; Methoxychlor; Pentachlorophenol; Polychlorinated biphenyls; Simazine; Styrene; 2,3,7,8-TCDD (Dioxin); Tetrachloroethylene; Toluene; 1,1,1-Trichloroethane; Trichloroethylene; Xylenes (total)
Original NPDWR risk assessment	Zero MCLG	Literature not reviewed since zero MCLG is protective	Zero MCLG remains appropriate	Zero MCLG retained	<b>2 Total</b> - 1,2-Dichloropropane; Epichlorohydrin
	Non-zero MCLG	New information	Literature not reviewed - to be considered in new assessment	Initiated new assessment as a result of health effects review	<b>2 Total</b> - Di(2-ethylhexyl)adipate; Thallium
		New information does not support a need to revise the RfD or cancer classification	New information does not support a need to revise the RfD or cancer classification	No revisions to MCLG	<b>6 Total</b> - Dalapon; Dinoseb; Monochlorobenzene; 2,4,5-TP (Silvex); 1,2,4-Trichlorobenzene; 1,1,2-Trichloroethane

<sup>1</sup> See contaminant specific discussion for fluoride in section V.A.37.

<sup>2</sup> These 33 contaminants do not include risk assessments initiated as a result of the Six-Year Review. For copper, NAS recommended retaining the MCLG.

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#### 2. Analytical Feasibility

Since EPA has a process in place to approve new analytical methods for drinking water contaminants, the actual review and approval of potential new methods are outside the scope of the

Six-Year Review protocol. EPA recognizes that the approval and addition of new and/or improved analytical methods (since the promulgation of the NPDWRs under this review) may enhance the ability of laboratories to quantify contaminants at

lower levels. For this reason, EPA evaluated whether there have been changes in analytical feasibility for a subset of the 68 chemical NPDWRs discussed in today's action. The document, "Analytical Feasibility Support Document for the Six-Year

Review of Existing National Primary Drinking Water Regulations (Reassessment of Feasibility for Chemical Contaminants)" (USEPA, 2002d), describes the process EPA used to evaluate possible changes in analytical feasibility and provides the results of the analytical feasibility analyses. The purpose of these analyses is to determine whether changes in the practical quantitation level (PQL) are possible in those instances where the MCL is limited, or might be limited, by analytical feasibility. EPA uses the PQL to estimate the level at which laboratories can routinely measure a chemical contaminant in drinking water. Historically, EPA has used two main approaches to determine a PQL for SDWA analytes: (1) data from water supply (WS) studies, the preferred alternative when sufficient WS data are available; or (2) a multiplier method, in which the PQL is calculated by multiplying the EPA-derived method detection limit (MDL) by a factor of 5 or 10 (50 FR 46880, November 13, 1985 (USEPA, 1985); 52 FR 25690, July 8, 1987 (USEPA, 1987); 54 FR 22062, May 22, 1989 (USEPA, 1989a)).

EPA performed the analytical feasibility analyses under two circumstances. First, for those contaminants where the MCL is currently limited by analytical feasibility (i.e., the MCL is set at the PQL) and the MCLG is still appropriate, EPA evaluated the currently approved methods for those contaminants and available WS data to determine whether it might be possible to lower the PQL and hence set an MCL that is closer to

the MCLG. Section V of today's action provides the results of the analytical feasibility review of 11 contaminants that are not currently undergoing a health risk assessment and for which the MCL was limited by analytical feasibility. These 11 contaminants include 10 with zero MCLGs<sup>3</sup> and 1 with a non-zero MCLG. Of these 11, EPA identified 10 where the data indicate it might be possible to set a lower PQL (see Table IV-2). Although the data are indicative of a lower PQL for these 10, they are not definitive and considered to be insufficient to support an actual recalculation at this time. To determine whether it was worthwhile to gather more definitive data for PQL recalculation, EPA estimated what the potentially lower PQL could be for these 10 analytes and used these values in the occurrence and exposure analyses.<sup>4</sup> As

<sup>3</sup> Although they have a zero MCLG, EPA excluded lead and epichlorohydrin from the analytical feasibility review since they are TT rules and do not have an MCL.

<sup>4</sup> Using WS data to derive the PQL for chemical NPDWRs involves determining the concentration of an analyte at which 75 percent of EPA Regional and State laboratories achieve results within a specified acceptance window (see 54 FR 22062 at 22100, May 22, 1989 (USEPA, 1989a)). In re-evaluating more recent WS data for the Six-Year Review, sufficient data were not available around the 75 percent criterion to actually recalculate the PQL. However, if the passing rates for the EPA Regional and State laboratories exceeded 80 to 85 percent at spike concentrations close to the current PQL, this information was considered to be indicative of a possible change in the PQL. If data indicated a possible change in the PQL, EPA then evaluated the distribution of the analytical methods used to analyze the spike samples in the WS studies. Evaluation of the method usage over time allowed EPA to determine the analytical methods that appear to be the most widely used for the analysis

discussed for specific contaminants in section V of today's action, EPA believes that a negligible gain in public health exists at the possibly lower PQL for 9 of these 10 NPDWRs. The results of the occurrence and exposure analysis for dichloromethane, using the possibly lower PQL as a concentration value, indicate that it may be appropriate to consider gathering data to recalculate a more definitive PQL for this analyte.

The second circumstance under which EPA re-evaluated the PQL was for three of the four contaminants identified under the health effects technical review as potential candidates for revision (see Table IV-2). These three contaminants were evaluated to determine if any potential MCL revision would be limited by analytical feasibility. Based on this review, EPA believes that analytical feasibility may be a limiting factor for revising the MCL for oxamyl (see section V.A.50 of today's action for a more detailed discussion). The Agency believes that analytical feasibility would not be a limiting factor for the remaining two contaminants identified by the health effects review as having potential changes in their MCLG (i.e., beryllium and chromium).

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of a particular contaminants. Knowledge of which analytical methods are the most widely used, along with the MDL for these methods, and a 10 times MDL multiplier allowed EPA to estimate where the potential lower limit of quantitation may lie today. This estimated PQL was used as a value in the occurrence analysis to help the Agency determine if there may be a significant gain in public health protection if EPA were to consider gathering the information needed to recalculate the PQL.

<b>Table IV-2: Chemical NPDWRs Included in the Analytical Feasibility Reassessment and the Result of that Assessment</b>			
<b>SDWA Chemical Contaminant</b>		<b>Current PQL (mg/L)<sup>1</sup> (PQL at the time of the original promulgation)</b>	<b>Result of the Six-Year Analytical Feasibility Reassessment</b>
<b>Eleven NPDWRs Limited by Analytical Feasibility<sup>2</sup> (MCL set at the PQL)</b>			
1	Benzene	0.005	WS data indicate possible change
2	Chlordane	0.002	WS data indicate possible change
3	1,2-Dibromo-3-chloropropane (DBCP)	0.0002	WS data indicate possible change
4	Dichloromethane	0.005	WS data indicate possible change
5	1,2-Dichloropropane	0.005	WS data indicate possible change
6	Heptachlor	0.0004	WS data indicate possible change
7	Heptachlor epoxide	0.0002	WS data indicate possible change
8	Hexachlorobenzene	0.001	WS data indicate possible change
9	Toxaphene	0.003	WS data indicate possible change
10	1,1,2-Trichloroethane (Non-zero MCLG = 0.003 mg/L)	0.005	WS data indicate possible change
11	Vinyl chloride	0.002	Current PQL still appropriate
<b>Three of the Four NPDWRs Identified Under the Health Effects Review as Potential Candidates for Revision<sup>3</sup></b>			
1	Beryllium	0.001	Current PQL not a limiting factor
2	Chromium (total - Cr III and VI)	0.01	Current PQL not a limiting factor
3	Oxamyl (Vydate)	0.02	Current PQL may be a limiting factor
<sup>1</sup> Milligrams per liter (mg/L). <sup>2</sup> Although 23 NPDWRs have MCLs that were set due to the limits of analytical feasibility, EPA is only discussing the results of the analytical feasibility analysis for these 11, since the remaining 12 are undergoing or scheduled for a health risk reassessment. <sup>3</sup> Since the health effects review for picloram indicates a potential increase in the MCLG, it is not necessary to evaluate analytical feasibility for this analyte.			

**BILLING CODE 6560-50-C****3. Treatment Feasibility**

An NPDWR either identifies the Best Available Technology (BAT) for meeting an MCL, or establishes enforceable treatment technique (TT) requirements. Currently, for all the chemical NPDWRs covered in today's action that include an MCL, the MCL is set equal to either the MCLG or the PQL. None of these MCLs are currently limited by treatment feasibility. Thus, as a part of the Six-Year Review process, EPA only needed to review available information on treatment technologies if either of the following conditions apply:

- The health effects technical review identified a potential change to the MCLG/MCL (applied to 4 NPDWRs); or

- A health risk assessment is not in process for the contaminant and one of the following two conditions apply:

(1) the analytical feasibility review identified a possible change to the PQL

and thus to the MCL (applied to 10 NPDWRs); or

(2) the NPDWR is a TT-type rule (applied to 3 NPDWRs).

The draft EPA document, "Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In Support of EPA Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2002k), describes the process EPA used to evaluate treatment feasibility, where appropriate, for the chemical NPDWRs discussed in today's action and provides the results of these analyses. As a part of this review, EPA utilized the same sources that have been the primary resources in development of EPA regulations and guidance, including published EPA treatment reports, peer-reviewed journals, and other technology sources, as well as information received from EPA stakeholders.

a. *MCL-type Rules.* EPA evaluated existing treatment technology information for 14 MCL-type NPDWRs

(see Table IV-3) to determine whether treatment feasibility would be a limiting factor if EPA were to lower the MCL. In addition and where appropriate, EPA evaluated the likelihood that systems would discontinue existing treatment if EPA were to raise the MCL.

Based upon this preliminary evaluation, the Agency believes that treatment capabilities would be adequate to support a lower MCL value, if EPA were to revise the MCL for any of the contaminants for which a lower MCL may be appropriate (USEPA, 2002k). Treatment technologies specified as BAT within the current NPDWR, and small system compliance technologies which were specified by EPA in 1998 (USEPA, 1998a) are considered to be efficient and practical for implementation at PWSs. However, if EPA were to determine that it is appropriate to revise any of these NPDWRs, it would undertake a more thorough review of treatment feasibility, including a consideration of costs, to

determine whether treatment feasibility would be a constraint or not. In a few instances, the Agency identified some potential treatment effectiveness research needs that will be considered in the context of the overall drinking water research strategy.<sup>5</sup> The revise/not revise decisions discussed in section V of today's action do not depend on EPA addressing these research needs.

In two instances (beryllium<sup>6</sup> and picloram), the outcome of the health effects technical review indicated it might be appropriate to raise the MCLG/MCL. For these two contaminants, BATs specified in the NPDWR are also BATs for several other contaminants (USEPA, 2002k). Available data are insufficient for EPA to determine how many PWSs are specifically treating for either of these contaminants using the same

treatment for co-occurring contaminants and/or for secondary benefits. The Agency thus cannot determine whether these water systems would discontinue existing treatment if the MCL were to be raised (USEPA, 2002c; USEPA, 2002k). However, in both cases, relatively few systems would be affected so there would be little potential for significant cost savings at a national level.

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**Table IV-3: Chemical NPDWRs Included in the Treatment Feasibility Analysis**

Ten Contaminants Where Analytical Feasibility Assessments Indicate Potential for an MCL Change			
1	Benzene	6	Heptachlor
2	Chlordane	7	Heptachlor Epoxide
3	1,2-Dibromo-3-chloropropane (DBCP)	8	Hexachlorobenzene
4	Dichloromethane	9	Toxaphene
5	1,2-Dichloropropane	10	1,1,2-Trichloroethane
Four Contaminants Where Health Effects Assessments Indicate Potential for an MCLG/MCL Change			
1	Beryllium	3	Oxamyl
2	Chromium	4	Picloram

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*b. Treatment Technique-type Rules.*

EPA reviewed three of the four chemical NPDWRs for which a TT is set in lieu of an MCL (copper, epichlorohydrin, and lead). A health risk assessment is in process for the fourth TT-type NPDWR, acrylamide.

The Agency found no new information relating to new treatment or other technology which would support a revision to the TT for epichlorohydrin at this time. EPA also reviewed issues relating to current TT requirements for copper and lead that were identified by EPA and/or stakeholders. Sections V.A.15 and V.A.43 of today's action summarize these issues for copper and lead, respectively. EPA believes these TT requirements remain appropriate at this time; however, EPA has identified a few potential treatment effectiveness research needs and will consider them in the context of the overall drinking water research strategy (USEPA, 2002k).

**4. Other Regulatory Revisions**

In addition to possible revisions to MCLGs, MCLs, and TTs, EPA considered other regulatory revisions, such as monitoring and system

reporting requirements, as a part of the Six-Year Review process. EPA focused this review on issues that are not already being addressed, or have not been addressed, through alternative mechanisms (e.g., as part of a recent or ongoing rulemaking, in conjunction with possible chemical monitoring reform, etc.). Where appropriate alternative mechanisms do not exist, EPA considered these implementation-related concerns if the potential revision met the following criteria:

- It indicated a potential change in the 40 Code of Federal Regulations (CFR) 141 requirements;
- It was "ready" for rulemaking—that is, the problem to be resolved has been clearly identified and specific option(s) have been formulated to address the problem; and
- It met at least one of the following conditions:
  - Clearly improved the level of public health protection; and/or
  - Represented a significant cost savings while maintaining or improving the public health protection.

The document, "Consideration of Other Regulatory Revisions for

Chemical Contaminants in Support of the Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2002e) summarizes the specific issues identified during the review process. Some of these issues (e.g., the need to specifically define new system/new source monitoring requirements for chemical contaminants) have already been addressed in the recently published arsenic and radionuclides NPDWRs (66 FR 6975, January 22, 2001 (USEPA, 2001a); 65 FR 76707, December 7, 2000 (USEPA, 2000g)). Additional issues are contaminant-specific, and are discussed in conjunction with the review of the NPDWR in section V of today's action.

**5. Occurrence and Exposure Analysis**

EPA's goal in evaluating contaminant occurrence was to estimate the number of PWSs at which contaminants occur at levels of regulatory interest in drinking water, and to evaluate the number of people exposed to these levels. For its occurrence analysis, EPA used drinking water compliance monitoring data from 16 States, collected in the 1993 to 1997 time frame, and statistically analyzed the data to estimate occurrence. The

<sup>5</sup> Refer to the document, "Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In Support of EPA Six-Year Review of National Primary Drinking Water

Regulations" (USEPA, 2002k) for a description of these research needs.

<sup>6</sup> As discussed in section V.A.9.b of today's action, the outcome of the health effects technical

review indicates it might be possible to either lower or raise the MCLG/MCL.



support document "Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Regulatory Review" describes in detail the development of the data set and the statistical methodology for analysis (USEPA, 2002g). This section presents a summary of the data and analysis.

a. *Development of the 16-State Contaminant Occurrence Data Set.* For the current Six-Year Review, EPA used PWS contaminant monitoring results, voluntarily provided by 16 States, as the primary source of information. EPA selected these States based on their geographic diversity and on their agricultural and industrial pollution potential. EPA also used data from a number of additional sources for comparative purposes. These secondary sources include the Safe Drinking Water Information System (SDWIS), the U.S. Geological Survey's National Water Information System (NWIS), EPA's Unregulated Contaminant Information System (URCIS), and other privately- and publicly-available data sources (USEPA, 2002g). In future reviews rounds, EPA plans to use the National Drinking Water Contaminant Occurrence Database (NCOD) as the primary data source when conducting the occurrence and exposure analyses as a part of the Six-Year Review process. EPA is in the process of populating the NCOD, however, sufficient data from the NCOD are not yet available.

EPA developed the 16-State contaminant occurrence data set in two stages. In the first stage, EPA developed an 8-State cross-section to support occurrence analyses for its Chemical Monitoring Reform (CMR) evaluation. The Agency selected the eight States for use in a national analysis because they provided the best data quality and completeness, and formed a balanced national cross-section of occurrence

data based on the States' geographic distribution and relative rankings in pollution potential, as described later in this section. The methodology for selecting the State data sets is described in an EPA report, "A Review of Contaminant Occurrence in Public Water Systems" (USEPA, 1999d). EPA had this report externally peer reviewed and also received public comment from stakeholders. In the second stage, for the current Six-Year Review, EPA augmented the data from the CMR 8-State data set with data from 8 additional States. The resulting data set includes 13 million analytical results, from approximately 41,000 PWSs in 16 States. For the 14 contaminants that EPA identified for detailed occurrence analysis, i.e., those with either new health effects information or a potential change in the PQL (see Table IV-3 of today's action), the number of analytical results per contaminant varies from about 34,000 to greater than 200,000; the number of PWSs with data varies from about 8,000 to 23,000; and the number of States providing relevant data varies from 13 to 16.

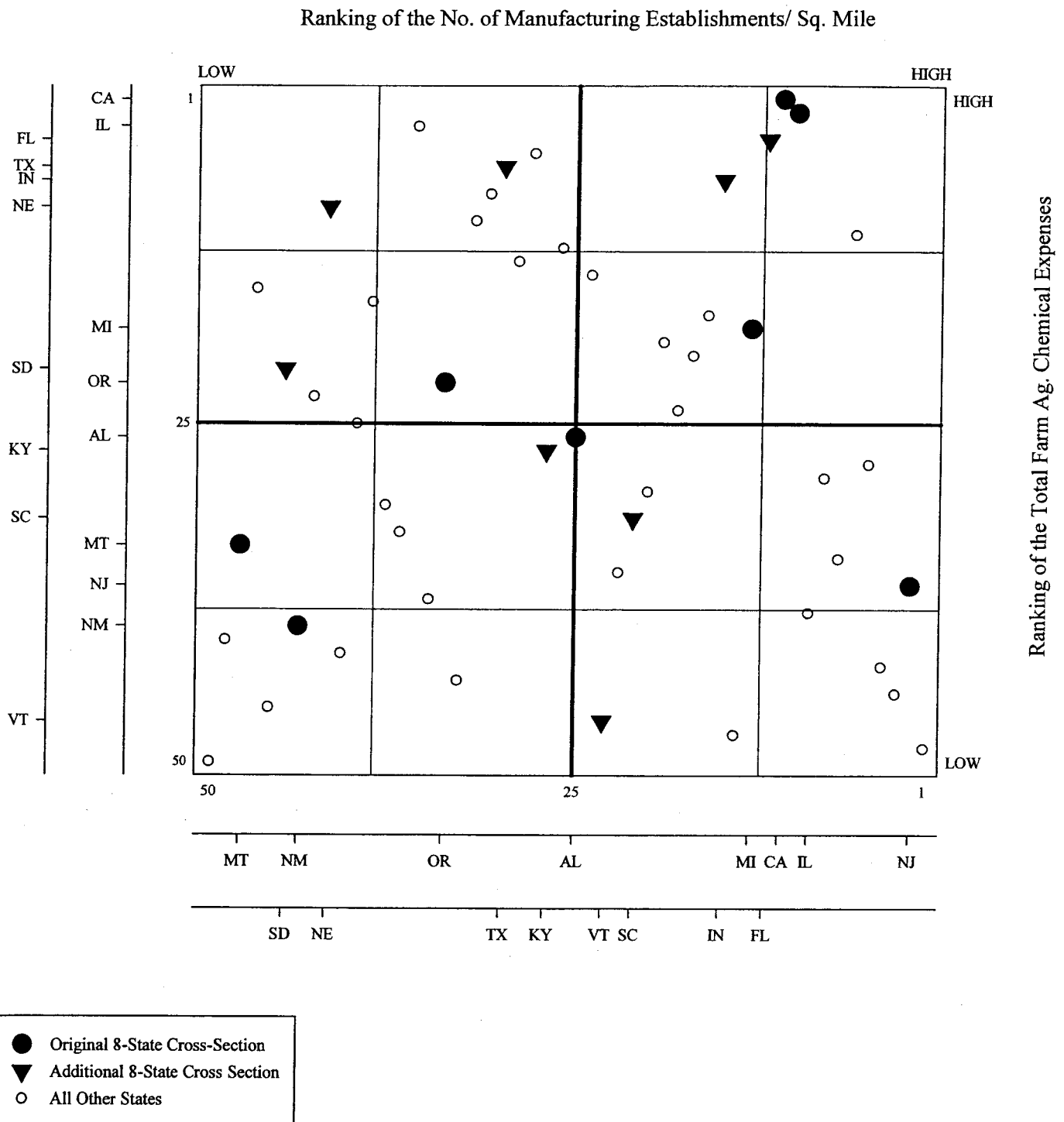
All samples in the 16-State data set were standard SDWA compliance samples. Data were limited to those with confirmed water source and sampling type information. "Special" samples, "investigation" samples (investigating a contaminant problem, that would likely bias the results), or samples of unknown type were excluded from further analysis. EPA conducted various quality control and review checks of the results, including follow-up questions to the States providing the data to clarify potential reporting inconsistencies, records with invalid codes, or use of analytical units. The Agency then compiled State data sets into a single database with a unified format.

In selecting a cross-section of State data sets that is generally representative of the U.S., EPA considered two broad factors: geographic or spatial diversity, and pollution potential. Geographic diversity in the data set helps to ensure that contaminant occurrence data come from areas representing the range of climatic and hydrologic conditions across the U.S. A range of agricultural and industrial pollution potential helps to ensure that the data represent the range of likely contaminant occurrence across the United States.

As indicators of States' pollution potential, EPA used two primary measures: the number of manufacturing facilities per square mile (to reflect the potential for VOC occurrence), and the total expenditures on farm agricultural chemicals (to reflect the potential for synthetic organic chemical (SOC) occurrence). In order to construct a cross-section with a balance of pollution potential, EPA divided the 50 States into high and low pollution potential groups based on their rank orderings with respect to the two primary pollution potential indicators. For each of the two pollution potential indicators, EPA ranked the 50 States from 1 to 50 (1 being the highest and 50 being the lowest). The States were then plotted on a two-dimensional scatter plot (see Figure 2), with the x- and y-axes representing the manufacturing and agricultural ranking, respectively, of each State. The amount spent on agricultural chemicals per State increases along the y-axis from bottom to top. The number of manufacturing establishments per square mile per State increases along the x-axis from left to right. EPA then reviewed the rankings and selected a subset of 16 States (the "cross-section States") in order to give approximate balance across the range of pollution indicators.

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**Figure 2: Distribution of State Rankings: Manufacturing Establishments per Square Mile vs. Total Farm Agricultural Chemical Expenses**



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The bold cross in the center of Figure 2 separates the plot into four quadrants. The upper right-hand quadrant contains

the States with the most manufacturing establishments per square mile and the greatest amount of farm agricultural chemical expenses. These States,

therefore, have the greatest amount of pollution potential based on these manufacturing and agricultural indicators. The lower left-hand quadrant

contains the States with the least amount of manufacturing establishments per square mile and the least amount of farm agricultural chemical expenses. This quadrant, therefore, contains the States with the least amount of pollution potential, based on these indicators. To identify the location of each of the 16 States within the quadrants, find the intersection of the State name from the x- and the y-axes. This intersection should be represented by either a filled-in circle (one of the original 8 States), or a filled-in triangle (one of the additional 8 States).

The Agency performed analyses to verify the validity of this approach. The results of these analyses support the applicability of these indicators relative to pollution potential. The mean

concentration values for select contaminants were estimated for groups of top quartile and bottom quartile States. The cross-section development approach presumes that the top quartile States have a higher pollution potential than the bottom quartile States, and, therefore, the estimated mean concentrations for the top quartile States should be greater than those for the bottom quartile States. The estimated mean concentration values for the top quartile States were always higher than the mean concentration for the bottom quartile States with the lone exception of heptachlor (a very low occurrence SOC).

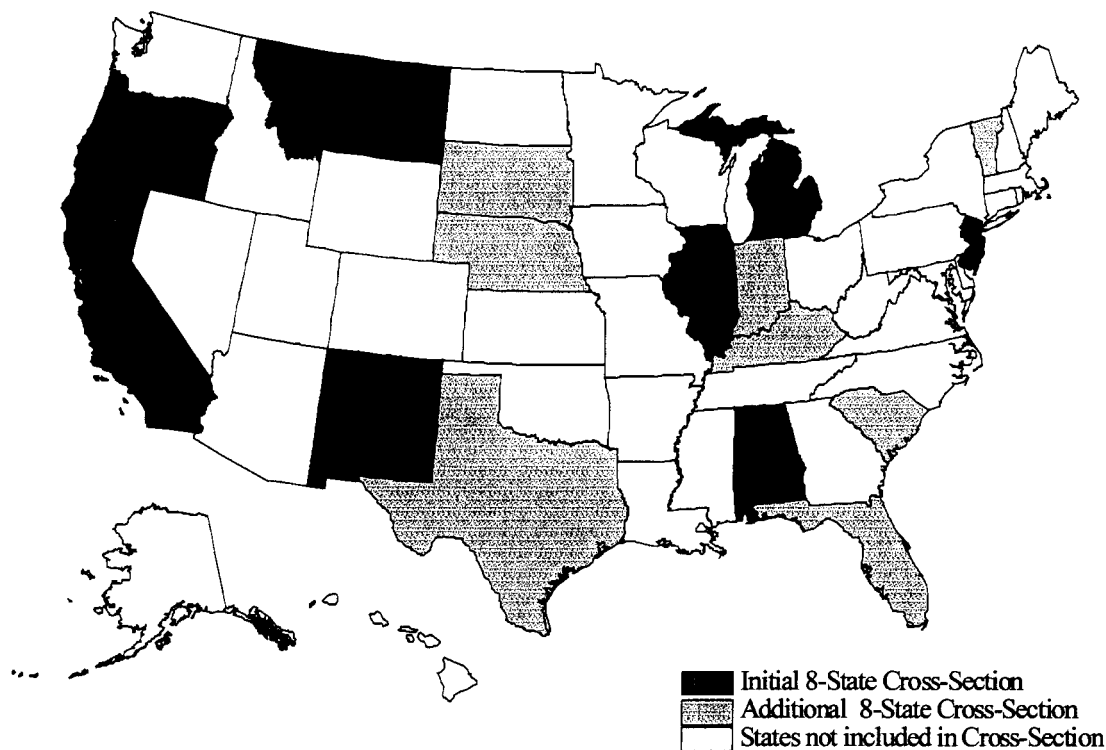
EPA believes the distribution of the 16 selected States is representative of the national distribution of States with respect to these pollution indicators.

Eight of the selected States comprised EPA's original 8-State cross-section that was used for the CMR analyses; EPA solicited occurrence data from the remaining eight. The geographic distribution of the resulting 16-State cross-section is shown in Figure 3. Other, secondary pollution potential indicators were also considered in order to help ensure that the data were representative of the range of pollution potential across the U.S.

While this cross-section does not represent a statistical random sample of States, and thus, does not capture all local variations in occurrence, EPA, nonetheless, believes that the data set provides a reliable picture of overall distribution of contaminant occurrence in the U.S.

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**Figure 3: Geographic Distribution of the 16-State Cross-Section Used for Occurrence Analysis**



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b. *Analysis of Contaminant Occurrence.* Statistical analysis of contaminant occurrence was focused at the water system level. The goal was to estimate the fraction of PWSs with contaminant occurrence above levels of regulatory interest, and the

corresponding fraction of people exposed to those levels.

Occurrence analysis proceeded in two stages. For the initial, or "Stage 1" analysis, EPA computed simple occurrence measures which are more straightforward and conservative than a full probabilistic analysis. In this stage of analysis, EPA estimated the percent

of PWSs and total population served by PWSs with at least one analytical result exceeding concentrations equal to specified contaminant levels. EPA considered three specified contaminant levels: The lower limit of detection reported by the States, one-half the current MCL, and the current MCL. Of the 68 chemicals discussed in today's

action, 60 were analyzed in this way. The exceptions were:

- The two contaminants for which not enough data were available (dioxin and asbestos);
- The four contaminants for which the NPDWR specifies a TT-type requirement instead of an MCL (acrylamide, copper, epichlorohydrin, and lead); and
- The two contaminants for which EPA did not request data, since the Agency determined there was no health or technological basis for revising, and because these data would have required extra effort for States to transmit (nitrate and nitrite).

Because of the simple and conservative nature of Stage 1 estimates, EPA used them only as preliminary indicators of contaminant occurrence, to guide further analysis. The occurrence support document (USEPA, 2002g) includes the details of the Stage 1 analyses.

Following the initial occurrence analysis, EPA performed a more detailed, "Stage 2" statistical analysis of occurrence for the 14 contaminants identified as potential candidates by the health effects and analytical feasibility technical reviews. This analysis used a statistical model, known as a Bayesian hierarchical model, to estimate the number of systems (and the corresponding affected populations) with mean contaminant concentrations above the levels of regulatory interest. Statistical modeling is usually required in order to estimate mean contaminant concentrations, because many sample concentrations are non-detects, meaning that the true concentration is unknown and may range anywhere from zero to the detection limit of the analytical method. In the hierarchical model, individual samples are assumed to be log-normally distributed within entry points to a distribution system (EPTDS) (e.g., wells or treatment plants); EPTDS means are assumed to be log-normally distributed within each water system; and system means are assumed to be log-normally distributed nationwide. This model can be applied to estimate the number of systems with mean concentrations above levels of interest, and also the amount of variability between sources within a system. Population exposure can also be estimated at the same time, by using information from EPA's SDWIS database about the population served by each system in the database. The hierarchical model has important advantages:

- It provides a unified model for estimating occurrence, both between and within systems;
- It uses information about non-detected concentrations; and

- It provides uncertainty intervals around each estimate, taking into account both sampling variability over time and across systems, and uncertainty due to non-detected concentrations.

Details of the hierarchical model, and its application to estimating mean contaminant concentrations, are provided in the occurrence support document (USEPA, 2002g).

The results of the Stage 2 analyses for each of the 14 contaminants listed in Table IV-3 are presented in section V.A of today's action. These results represent only the systems in EPA's 16-State database. EPA considered this the most straightforward and accurate way to present the data that were available for the review process. As indicated in the preceding discussion of the development of the analysis of contaminant occurrence, EPA developed the more refined Stage 2 analysis based on the preliminary evaluation using the results of the Stage 1 analysis. A detailed explanation of this process is provided in EPA's occurrence support document and is available for review and comment (USEPA, 2002g).

For those contaminants where occurrence was evaluated with respect to the revise/not revise decision, EPA used the Stage 2 occurrence analysis for the 16 States to determine the percentage of PWSs that could be impacted, and the percentage of the exposed population served by these systems. Section V contains a discussion of the incremental percentage of systems and the incremental percentage of the population served by these systems. That is, EPA considered the difference between levels of occurrence and exposure above the current MCL and the occurrence and exposure at the potentially revised level(s).

#### 6. Economic Considerations

While SDWA provides the Agency with broad discretion to consider economics in the context of the Six-Year Review, the statute precludes EPA from using economics as the sole basis for a revision that would provide less health protection than the current standard (i.e., anti-backsliding). However, if new peer-reviewed scientific health effects research indicates that an MCLG could be raised while maintaining public health protection, then such a change is permitted. For NPDWRs published after the 1996 SDWA Amendments, Congress added specific requirements for economic and cost-benefit analyses in their development. Where EPA decides to revise an NPDWR based on health

effects or other technical reasons, economic factors, including feasibility and an assessment of costs and benefits in accordance with Section 1412(b)(6) of the SDWA, must then be taken into consideration. EPA considered likely economic impacts, based primarily on available occurrence and exposure data, to qualitatively evaluate whether the potential revisions identified by the health and technology reviews may present a significant opportunity for improved or strengthened public health standards and/or a significant cost savings while maintaining public health protection (USEPA, 2002c).

#### C. How Is EPA Reviewing the Total Coliform Rule?

The memorandum, "Six-Year Review of the Total Coliform Rule—Comments Received" (USEPA, 2002j), describes the process EPA applied to the review of the TCR. Where appropriate, EPA applied the same approach to reviewing the TCR as it did to the review of the chemical NPDWRs discussed in today's action. However, because of the nature of the TCR and the pathogens it controls, the Agency focused its review on the implementation-related requirements. As discussed in section V.B of today's action, these analyses indicate that a rulemaking to initiate possible revisions to the TCR is appropriate at this time.

#### D. How Did EPA Factor Children's Health Concerns Into the Review?

The 1996 amendments to SDWA require special consideration of all sensitive populations (infants, children, pregnant women, elderly, and immunocompromised) in the development of drinking water regulations (Section 1412(b)(3)(C)(V) of SDWA, as amended in 1996). Over the past decade, the amount of available data on the impact of chemical contaminants on conception and early developmental life stages has increased dramatically. Accordingly, as a part of the Six-Year Review process, EPA completed a literature search covering developmental and reproductive endpoints (fertility, embryo survival, developmental delays, birth defects, endocrine effects, etc.) for regulated chemicals that have a non-zero MCLG and have not been the subject of an updated 1997 or later risk assessment (see section IV.B.1 of today's action). EPA reviewed the output from the literature searches to identify any studies that might have an influence on the present MCLG. Three chemicals were identified with potential developmental/reproductive endpoints of concern: cyanide, di(2-ethylhexyl)adipate (DEHA), and

thallium (see sections V.A.16, V.A.28, and V.A.59 of today's action). In each case, where the literature search indicated a need to consider recent studies of developmental or reproductive toxicity, EPA has initiated the process to update the Agency risk assessment. Assessments conducted by EPA, ATSDR, and NAS in 1997 or later thoroughly considered the potential for reproductive and developmental toxicity; thus, literature searches for chemicals with such recent assessments were not necessary.

Young children, especially infants, are generally at greater health risk from infections caused by waterborne pathogens. Any revision to the TCR will maintain or improve the control of waterborne pathogens and, therefore, the protection afforded to children.

#### **V. EPA's Preliminary Decisions Based on its Review of NPDWRs Included in Today's Action**

Table V-1 lists EPA's preliminary revise/not revise decision for each of the

69 NPDWRs discussed in today's action along with the principal rationale for the decision. If EPA has decided it is not appropriate to revise an NPDWR at this time, that decision is based on one of the following reasons.

- *Health risk assessment is in process:* 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, the Agency does not believe it is appropriate to make a "revise decision" at this time. In these cases, today's action does not include a discussion of the review of other key elements (e.g., technology, "other regulatory revisions", and occurrence/exposure analyses). EPA will consider the results of the updated health risk assessment during the 2002-2008 review cycle. However, if the results of the health risk assessment indicate a compelling need to reconsider the 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 recommended because:*

- Negligible gain in public health protection:* Any resulting changes to the NPDWR would not significantly improve the level of public health protection or result in a major cost savings.

- 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 V-1: Preliminary Revise/Not Revise Decisions for the 68 Chemical NPDWRs and TCR**

<b>Not Appropriate for Revision at this Time</b>	Risk assessment in process: chemical currently undergoing an EPA health risk assessment; includes the three initiated as a result of this review <sup>1</sup> (36 NPDWRs)		Acrylamide (TT) <sup>2</sup> (2004 / 2005) Alachlor (2002 / 2003) Antimony (2002 / 2003) Asbestos (2004 / 2005) Atrazine (2002) Benzo[a]pyrene (2002 / 2003) Cadmium (2002 / 2003) Carbofuran (2002 / 2003) Carbon tetrachloride (2002 / 2003) Copper (TT) <sup>2</sup> (2002 / 2003) Cyanide (2004 / 2005) <sup>1</sup> 2,4-D (2003 / 2004) 1,2-Dichlorobenzene (2002 / 2003) 1,4-Dichlorobenzene (2002 / 2003) 1,2-Dichloroethane (2002 / 2003) 1,1-Dichloroethylene (2002 / 2003) Di(2-ethylhexyl)adipate (2003 / 2004) <sup>1</sup> Di(2-ethylhexyl)phthalate (2002 / 2003)	Diquat (2002) Endothall (2003 / 2004) Ethylbenzene (2002 / 2003) Ethylene dibromide (2002 / 2003) Glyphosate (2002 / 2003) Lindane (2003 / 2004) Methoxychlor (2002 / 2003) Pentachlorophenol (2002 / 2003) Polychlorinated biphenyls (2002 / 2003) Simazine (2003 / 2004) Styrene (2002 / 2003) 2,3,7,8-TCDD (Dioxin) (2002 / 2003) Tetrachloroethylene (2002 / 2003) Thallium (2004 / 2005) <sup>1</sup> Toluene (2002 / 2003) 1,1,1-Trichloroethane (2003 / 2004) Trichloroethylene (2002 / 2003) Xylenes (2002 / 2003)
	NPDWR remains appropriate after data/information review (17 NPDWRs)		Barium Dalapon cis-1,2-Dichloroethylene trans-1,2-Dichloroethylene Dinoseb Endrin Epichlorohydrin (TT) <sup>2</sup> Hexachlorocyclopentadiene Lead (TT) <sup>2</sup>	Mercury Monochlorobenzene Nitrate Nitrite Selenium 2,4,5-TP (Silvex) 1,2,4-Trichlorobenzene Vinyl chloride
	New information, but no revision recommended because:	<i>Negligible gain in health protection (12 NPDWRs)</i>	Benzene Beryllium Chlordane 1,2-Dibromo-3-chloropropane 1,2-Dichloropropane Heptachlor	Heptachlor epoxide Hexachlorobenzene Oxamyl Picloram Toxaphene 1,1,2-Trichloroethane
		<i>Information gaps (3 NPDWRs)</i>	Chromium Dichloromethane <sup>3</sup>	Fluoride <sup>4</sup>
<b>Candidates for Revision</b>	Based on other regulatory revisions (1 NPDWR)		Total Coliform Rule (TCR)	
<p><sup>1</sup> New information was identified for cyanide, di(2-ethylhexyl)adipate, and thallium as a result of the six-year health effects review. The Agency has initiated new risk assessments for these three contaminants.</p> <p><sup>2</sup> TT designates treatment-technique rules (i.e., those NPDWRs for which a treatment technique has been set in place of an MCL).</p> <p><sup>3</sup> Preliminary analysis indicates that there may be an opportunity for improvement in public health protection if the PQL/MCL were lowered. Additional data are needed to support such a change.</p> <p><sup>4</sup> EPA plans to ask NAS to update the risk assessment for fluoride.</p>				

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**A. What Preliminary Decisions Has EPA Made Regarding the Chemical NPDWRs?**

1. Acrylamide

a. *Background.* EPA published the current NPDWR for acrylamide on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an

MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR imposes a TT requirement that limits the allowable monomer levels in products used during drinking water treatment, storage, and distribution to 0.05 percent acrylamide in polyacrylamide coagulant aids dosed at 1 part per million (ppm). Each water system is required to certify, in writing,

to the State (using third-party or manufacturer's certification) that the product used meets these residual monomers and use-level specifications.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to acrylamide. The revised risk assessment will consider relevant studies that have become available on the toxicity of

acrylamide including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2004 or 2005 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for acrylamide is appropriate at this time because a reassessment of the health risks resulting from exposure to acrylamide is ongoing.

## 2. Alachlor

a. *Background.* EPA published the current NPDWR for alachlor on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.002 milligrams per liter (mg/L) based on analytical feasibility.

b. *Technical Reviews.* The Agency updated the health risk assessment for alachlor in 1998 as a part of the pesticides reregistration process (USEPA, 2002i). However, the Agency has initiated another update to the alachlor health risk assessment. The revised risk assessment will consider relevant studies that have become available on the toxicity of alachlor including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame.

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for alachlor is appropriate at this time because a reassessment of the health risks resulting from exposure to alachlor is ongoing.

## 3. Antimony

a. *Background.* EPA published the current NPDWR for antimony on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.006 mg/L. EPA based the MCLG on an RfD of 0.0004 milligrams per kilogram of body weight per day (mg/kg/day) and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to antimony. The revised risk assessment will consider relevant studies that have become available on the toxicity of antimony including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for antimony is appropriate at this time because a reassessment of the health risks resulting from exposure to antimony is ongoing.

## 4. Asbestos

a. *Background.* EPA published the current NPDWR for asbestos on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 7 million fibers per liter (MFL) for asbestos fibers exceeding 10 micrometers in length. EPA evaluated asbestos as a Category II<sup>7</sup> contaminant (equivalent to Group C, possible human carcinogen) by the oral route of exposure (see Appendix A of today's action for discussion of cancer classifications).

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to asbestos. The new risk assessment will consider relevant studies that have become available on the toxicity of asbestos, including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2004 or 2005 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for asbestos is appropriate at this time because a reassessment of the health risks resulting from exposure to asbestos is ongoing.

## 5. Atrazine

a. *Background.* EPA published the current NPDWR for atrazine on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.003 mg/L. EPA based the MCLG on an RfD of 0.005 mg/kg/day and a cancer classification of Group C, possible human carcinogen, based on limited evidence of carcinogenicity in animals in the absence of human data. EPA published an FR notice in February 1999, in which EPA responded to recommendations by the Children's Health Advisory Committee, by committing to re-evaluate the MCL for atrazine after the Agency has finalized

<sup>7</sup>Category II contaminants include those contaminants for which EPA has determined there is limited evidence of carcinogenicity from drinking water considering weight of evidence, pharmacokinetics, potency, and exposure. For Category II contaminants, EPA has used two approaches to set the MCLG: Either (1) setting the MCLG based upon noncarcinogenic endpoints of toxicity (the RfD) then applying an additional risk management factor of 1 to 10; or (2) setting the MCLG based upon a theoretical lifetime excess cancer risk range of  $10^{-5}$  to  $10^{-6}$  using a conservative mathematical extrapolation model.

its risk assessment (64 FR 5277, February 3, 1999 (USEPA, 1999a)).

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to atrazine. The revised risk assessment will consider relevant studies that have become available on the toxicity of atrazine including its potential developmental and neuroendocrine effects. The Agency expects the new risk assessment to be completed in the 2002 time frame. EPA is in the process of conducting an occurrence and exposure analysis.

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for atrazine is appropriate at this time because a reassessment of the health risks resulting from exposure to atrazine is ongoing. EPA has committed to revisiting the NPDWR for atrazine if a revision is appropriate once the results of the revised risk assessment become available. Therefore, EPA will revisit this "not revise" decision once the new risk assessment is completed.

## 6. Barium

a. *Background.* EPA published the current NPDWR for barium on July 1, 1991 (56 FR 30266 (USEPA, 1991c)). The NPDWR established an MCLG and an MCL of 2 mg/L. EPA based the MCLG on an RfD of 0.07 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency updated the health risk assessment for barium in 1998 and retained the RfD and cancer classification on which the 1991 MCLG is based (USEPA, 1999f). As a part of the 1998 assessment, EPA considered all relevant data on the toxicity of barium including developmental and reproductive toxicity.

A review of analytical or treatment feasibility is not necessary for barium because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any barium-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the barium NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for barium remains appropriate and thus, it is not subject to revision at this time.

## 7. Benzene

a. *Background.* EPA published the current NPDWR for benzene on July 8, 1987 (52 FR 25690 (USEPA, 1987)). The NPDWR established an MCLG of zero based on a cancer classification of A, known human carcinogen. The NPDWR also established an MCL of 0.005 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency updated the health risk assessment for benzene in 2000 and retained the cancer classification on which the 1987 zero MCLG is based (USEPA, 2000j; USEPA, 2002i). The revised risk assessment considered relevant studies on the toxicity of benzene including developmental and reproductive toxicity.

The current MCL for benzene is based on a PQL of 0.005 mg/L. As a part of the Six-Year Review, EPA analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. The analysis of the WS data indicates that an improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State

laboratories exhibit greater than 95 percent laboratory passing rates at concentrations around the current PQL of 0.005 mg/L. Because most of the laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL corresponding to the 75 percent passing rate might exist for benzene. While this information is indicative of a possibly lower PQL, the WS data are insufficient at this time to actually recalculate what the lower PQL for benzene might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of benzene in the more recent WS studies, laboratories predominantly used EPA Method 524.2 (Gas Chromatography/Mass Spectrometry or GC/MS), which has an upper limit MDL of 0.00004 mg/L. A 10 times MDL multiplier predicts that the PQL could lie around 0.0004 mg/L. The 0.0004 mg/L value is used as a threshold in the occurrence analysis, which is discussed in this section.

Since the analytical feasibility analysis indicates that the PQL for

benzene (and therefore the MCL) could possibly be lower if EPA had more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BATs for benzene are packed tower aeration (PTA) and granular activated carbon (GAC). Small system compliance technologies for benzene include GAC and several aeration technologies. EPA believes these BATs are still practical and would not pose any limitations for benzene at a possibly lower MCL.

The results of EPA's review of possible "other regulatory revisions" did not identify any benzene-specific issues (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for benzene to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if the PQL were recalculated (USEPA, 2002g; USEPA 2002h). Table V-2 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for the current MCL (0.005 mg/L) and the possible PQL/MCL based on the analytical feasibility analysis (0.0004 mg/L).

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Table V-2: Benzene Occurrence <sup>1</sup>				
Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3, 5</sup>	Estimated % Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.005	23,266	7 (4 - 12)	0.0313% (0.0172% - 0.0516%)	
Possible PQL/MCL <sup>4</sup> 0.0004	23,266	80 (57 - 106)	0.343% (0.245% - 0.456%)	
Population Served by Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3, 5</sup>	Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.005	110,866,600	10,500 (2,100 - 33,200)	0.00947% (0.00188% - 0.0300%)	
Possible PQL/MCL <sup>4</sup> 0.0004	110,866,600	342,500 (234,200 - 570,100)	0.309% (0.211% - 0.514%)	
Notes:				
<sup>1</sup> 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 threshold.				
<sup>2</sup> 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.				
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).				
<sup>4</sup> The "possible PQL/MCL" is the possibly lower PQL/MCL as estimated by the analytical feasibility analysis.				
<sup>5</sup> 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 to 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.				

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The results of the detailed occurrence and exposure analysis indicate that approximately 0.3 percent of the 23,266 systems sampled in the 16 cross-section States and approximately 0.3 percent of the population served by those systems, might be affected if EPA were to gather information to recalculate the PQL (to a lower PQL of around 0.0004 mg/L) and revise the MCL accordingly.

*c. Preliminary Decision.* Although there are new data that support consideration of a possibly lower PQL (and therefore a possibly lower MCL), EPA does not believe a revision to the NPDWR for benzene is appropriate at this time. The Agency does not have sufficient data at this time on which to base a PQL recalculation and hence an MCL revision. In addition, because the occurrence of benzene appears to be minimal between the current MCL and any likely PQL/MCL revision, the Agency believes that any potential revisions to the benzene NPDWR are

unlikely to significantly improve the level of public health protection.

**8. Benzo[a]pyrene**

*a. Background.* EPA published the current NPDWR for benzo[a]pyrene on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.0002 mg/L based on analytical method feasibility.

*b. Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to benzo[a]pyrene. The revised risk assessment will consider relevant studies that have become available on the toxicity of benzo[a]pyrene including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for benzo[a]pyrene is appropriate at this time because a reassessment of the health risks resulting from exposure to benzo[a]pyrene is ongoing.

**9. Beryllium**

*a. Background.* EPA published the current NPDWR for beryllium on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.004 mg/L. EPA classified beryllium in Group B2, probable human carcinogen, based on clear evidence of its carcinogenicity via inhalation or injection in several animal species. However, EPA also placed beryllium in drinking water Category II for regulation, based on the weight of evidence for carcinogenicity via ingestion, and the potency, exposure and pharmacokinetics of this chemical. EPA derived the MCLG by applying an additional risk management factor of 10

to the RfD of 0.005 mg/kg/day (57 FR 31776 at 31785, July 17, 1992 (USEPA, 1992)).

b. *Technical Reviews.* The Agency updated the health risk assessment of beryllium in 1998. The 1998 reassessment established a new RfD of 0.002 mg/kg/day and also considered relevant studies on the toxicity of beryllium including its developmental and reproductive toxicity. The 1998 assessment classified inhaled beryllium as a B1, probable human carcinogen, using the 1986 cancer guidelines (51 FR 33992, September 24, 1986 (USEPA, 1986b)). Using the 1996 Proposed Guidelines for Carcinogen Risk Assessment, the 1998 assessment characterized inhaled beryllium as a "likely" carcinogen in humans and concluded that the human carcinogenic potential of ingested beryllium could not be determined (61 FR 17960, April 23, 1996 (USEPA, 1996; USEPA, 1998d)). On this basis, EPA will re-examine the application of the additional risk management factor of 10 to account for potential carcinogenicity of beryllium via ingestion that was used when deriving the current MCLG, if the Agency determines that an MCLG revision is appropriate.

EPA believes that any likely revision to the MCLG for beryllium could range

from 0.01 mg/L to 0.001 mg/L, based on the change in the RfD in the 1998 assessment, the inclusion or non-inclusion of the risk management factor, and using a 20 percent relative source contribution (RSC).<sup>8</sup> Whereas the 0.01 mg/L value assumes no adjustment for potential carcinogenicity via oral ingestion (i.e., no 10-fold risk management factor), the 0.001 mg/L value retains the current risk management factor of 10.

Because of changes in the health risk assessment for beryllium, EPA considered whether analytical feasibility is likely to be a limitation if the Agency were to lower the MCLG/MCL. The results of the analytical feasibility analyses indicate that the current PQL of 0.001 mg/L for beryllium is still appropriate and is unlikely to change. Therefore, the Agency believes the PQL is unlikely to be a limiting factor if EPA decides to lower the MCLG/MCL (USEPA, 2002d).

EPA also considered whether treatment feasibility is likely to pose any limitations if EPA were to lower the MCLG/MCL. The current BATs for beryllium include activated alumina

<sup>8</sup>This is the RSC used for the current MCLG and also the default value. EPA has no reason to believe that the RSC for beryllium would change. See Appendix A for a further discussion of the RSC.

(AA), ion exchange, lime softening, coagulation/filtration, and reverse osmosis (RO) with removal efficiencies ranging from 80 to 99 percent. Small system compliance technologies also include point-of-use (POU) RO and POU ion exchange. The Agency believes these BATs are still practical and would not pose any limitations if the Agency were to lower the MCLG/MCL (USEPA, 2002k).

The results of EPA's review of possible "other regulatory revisions" did not identify any issues which are specific to beryllium (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for beryllium to determine whether possible changes to the MCLG/MCL would be likely to result in additional public health protection or an opportunity for significant cost savings to PWSs and their customers (USEPA, 2002g; USEPA, 2002h). Table V-3 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section at the current MCL (0.004 mg/L), the possible lower level of any MCLG/MCL value (0.001 mg/L), and the possible upper level of any MCLG/MCL value (0.01 mg/L).

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Table V-3: Beryllium Occurrence <sup>1</sup>			
Systems <sup>2</sup>			
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3, 5</sup>	Estimated % Systems > Threshold (credible intervals) <sup>3</sup>
Possible upper level of any MCLG/MCL value <sup>4</sup> 0.01	18,933	2 (0 - 4)	0.00809% (0.000% - 0.0211%)
Current MCL 0.004	18,933	15 (7 - 24)	0.0781% (0.0370% - 0.127%)
Possible lower level of any MCLG/MCL value <sup>4</sup> 0.001	18,933	203 (167 - 237)	1.07% (0.882% - 1.25%)
Population Served by Systems <sup>2</sup>			
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3, 5</sup>	Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>
Possible upper level of any MCLG/MCL value <sup>4</sup> 0.01	104,573,700	2,000 (0 - 13,400)	0.00190% (0.000% - 0.0128%)
Current MCL 0.004	104,573,700	21,800 (2,900 - 81,700)	0.0208% (0.00278% - 0.0781%)
Possible lower level of any MCLG/MCL value <sup>4</sup> 0.001	104,573,700	731,300 (372,400 - 1,237,100)	0.699% (0.356% - 1.18%)
<p><sup>1</sup> 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 threshold.</p> <p><sup>2</sup> 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.</p> <p><sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).</p> <p><sup>4</sup> These are possible upper and lower MCLG/MCL values based on the change in the RfD, using a 20 percent RSC and whether or not to consider the risk management factor of 10. The upper level MCLG/MCL value was calculated without applying the 10-fold risk management factor, whereas the lower level was calculated using the 10-fold risk management factor.</p> <p><sup>5</sup> 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 to 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.</p>			

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The results of the detailed occurrence and exposure analysis indicate that approximately 0.07 percent of the 18,933 systems sampled in the 16 cross-section States, and approximately 0.02 percent of the population served by those systems, might be affected if EPA were to raise the MCLG/MCL. The current BATs and small system compliance technology for beryllium also apply to other contaminants. In

addition to the removal of beryllium, these treatment technologies have other beneficial effects (e.g., reduction of hardness or other common impurities) (USEPA, 2002k). Therefore, if EPA were to raise the MCLG/MCL, the Agency does not know how many of these PWSs currently treating to comply with the current MCL of 0.004 mg/L would discontinue any treatment that is already in place. If, on the other hand,

EPA were to retain the risk management factor and lower the MCLG/MCL, less than 1 percent of the 18,933 systems sampled in the 16 cross-section States and less than 0.7 percent of the population served by those systems might be affected.

c. *Preliminary Decision.* Although there are new data indicating that it might be possible to revise the MCLG/MCL for beryllium, EPA does not

believe a revision to the NPDWR for beryllium, either higher or lower, is appropriate at this time. The Agency believes that any change in the MCLG/MCL would be unlikely to significantly improve the level of public health protection (if EPA were to lower the MCLG/MCL) or provide an opportunity for significant cost savings to PWSs (if EPA were to raise the MCLG/MCL).

#### 10. Cadmium

a. *Background.* EPA published the current NPDWR for cadmium on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.005 mg/L. Because of inadequate dose-response data to characterize the presence or lack of a carcinogenic hazard from oral exposure, the Agency regulated cadmium as a Group D carcinogen, not classifiable as to human carcinogenicity by the oral route of exposure. Therefore, EPA developed the MCLG for cadmium based on the RfD of 0.0005 mg/kg/day.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to cadmium. The revised risk assessment will consider relevant studies that have become available on the toxicity of cadmium including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for cadmium is appropriate at this time because a reassessment of the health risks resulting from exposure to cadmium is ongoing.

#### 11. Carbofuran

a. *Background.* EPA published the current NPDWR for carbofuran on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.04 mg/L. EPA based the MCLG on an RfD of 0.005 mg/kg/day and a cancer classification of E, evidence of non-carcinogenicity for humans.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to carbofuran. The revised risk assessment will consider relevant studies on the toxicity of carbofuran including recent data on neurotoxicity and potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the

NPDWR for carbofuran is appropriate at this time because a reassessment of the health risks resulting from exposure to carbofuran is ongoing.

#### 12. Carbon Tetrachloride

a. *Background.* EPA published the current MCLG for carbon tetrachloride on July 8, 1987 (52 FR 25690 (USEPA, 1987)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.005 mg/L based on analytical feasibility.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to carbon tetrachloride. The revised risk assessment will consider relevant studies that have become available on the toxicity of carbon tetrachloride including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for carbon tetrachloride is appropriate at this time because a reassessment of the health risks resulting from exposure to carbon tetrachloride is ongoing.

#### 13. Chlordane

a. *Background.* EPA published the current NPDWR for chlordane on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.002 mg/L based on analytical feasibility.

b. *Technical Reviews.* EPA updated its risk assessment for chlordane in 1998 (USEPA, 1998e). That assessment included an evaluation of developmental and reproductive endpoints. The assessment also retained the B2 cancer classification, concluding that chlordane is a probable human carcinogen using the 1986 EPA Guidelines for Carcinogen Risk Assessment (51 FR 33992, September 24, 1986 (USEPA, 1986b)). Under the 1996 Proposed Guidelines for Carcinogen Risk Assessment (61 FR 17960, April 23, 1996 (USEPA, 1996)), chlordane is characterized as a likely carcinogen by all routes of exposure and, at the present time, would require quantification using a linear dose response, thus, the MCLG of zero remains appropriate.

EPA based the current MCL for chlordane on a PQL of 0.002 mg/L. As a part of the Six-Year Review, EPA

analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. The results of these analyses indicate that only a slight improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State laboratories exhibit greater than 85 percent laboratory passing rates at concentrations around the current PQL of 0.002 mg/L. Because most of the laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL corresponding to the 75 percent passing rate might exist for chlordane. While this information is indicative of a possibly lower PQL, the WS data are insufficient at this time to actually recalculate what the lower PQL for chlordane might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of chlordane in the more recent WS studies, laboratories predominantly used EPA Methods 505 (Gas Chromatography with microextraction) and 508 (Gas Chromatography with Electron Capture Detector), which have MDLs of 0.00014 mg/L and 0.000041 mg/L, respectively. A 10 times MDL multiplier predicts that the PQL could range from 0.0014 mg/L to 0.00041 mg/L. EPA averaged these two values, rounded up to 0.001 mg/L, and used this value as a threshold in the occurrence analysis discussed in this section.

Since the analytical feasibility analysis indicates that the PQL for chlordane (and therefore the MCL) could possibly be lower if EPA had more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BAT for chlordane is GAC. Small system compliance technologies for chlordane include GAC, POU GAC, and powdered activated carbon (PAC). Because chlordane is a moderately adsorbed pesticide, EPA believes that GAC is still a practical treatment and would not pose any limitations for chlordane at a possibly lower MCL.

The results of EPA's review of possible "other regulatory revisions" did not identify any issues which are specific to chlordane (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for chlordane to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if

the PQL were recalculated (USEPA, 2002g; USEPA, 2002h). Table V-4 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for the current MCL (0.002 mg/L) and the

possible PQL/MCL based on the analytical feasibility analysis (0.001 mg/L).

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Table V-4: Chlordane Occurrence <sup>1</sup>				
Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.002	13,184	0 (0 - 0)	0.000% (0.000% - 0.000%)	
Possible PQL/MCL <sup>4</sup> 0.001	13,184	0 (0 - 0)	0.0000910% (0.000% - 0.000%)	
Population Served by Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.002	97,459,900	0 (0 - 0)	0.000% (0.000% - 0.000%)	
Possible PQL/MCL <sup>4</sup> 0.001	97,459,900	0 (0 - 0)	0.00000146% (0.000% - 0.000%)	
Notes:				
<sup>1</sup> 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 threshold.				
<sup>2</sup> 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.				
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).				
<sup>4</sup> The "possible PQL/MCL" is the possibly lower PQL/MCL as estimated by the analytical feasibility analysis.				

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The detailed occurrence and exposure analysis indicates that chlordane is unlikely to occur at the current MCL or any potential MCL revision for the States used in the cross-section. Since chlordane uses were canceled in the United States in 1988 and since it is subject to the United Nations Prior Informed Consent procedure (USEPA, 2002g; USEPA, 2002h), EPA expects the occurrence of chlordane in PWSs to be rare.

c. *Preliminary Decision.* Although there are new data that support consideration of a slightly lower PQL (and therefore a possibly lower MCL), EPA does not believe a revision to the NPDWR for chlordane is appropriate at this time. The Agency does not have sufficient data at this time on which to base a PQL recalculation and hence an

MCL revision. Also, the Agency believes that any change in the PQL would be minimal and unlikely to significantly improve the level of public health protection because chlordane appears to occur infrequently at concentrations at or below the current MCL.

#### 14. Chromium

a. *Background.* EPA published the current NPDWR for total chromium on January 31, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and MCL of 0.1 mg/L. Although the NPDWR regulates total chromium, the adverse health effects associated with hexavalent chromium (chromium VI) are the basis of the current MCLG since that is the more toxic species (56 FR 3526, January 31, 1991 (USEPA, 1991a)). EPA based the MCLG on an RfD of 0.005 mg/kg/day and an assumed

RSC from water of 70 percent for total chromium (refer to Appendix A for a description of the RSC). EPA regulated chromium as a Group D carcinogen, not classifiable as to human carcinogenicity by the oral route of exposure.

b. *Technical Reviews.* The Agency updated the risk assessment for chromium in 1998 (USEPA, 1998f). The revised risk assessment considered relevant studies that were available on the toxicity of chromium including potential developmental and reproductive toxicity. Based on the revised risk assessment, EPA has identified changes in the health risk assessment that support consideration of whether it may be appropriate to revise the MCLG and MCL (USEPA, 2002i). The 1998 assessment revised the RfD for hexavalent chromium (chromium VI) from 0.005 mg/kg/day to

0.003 mg/kg/day based on a modification to the original uncertainty factor and the addition of a modifying factor because of data on the potential for gastrointestinal effects in humans as a result of oral exposures. The critical study used as the basis for the RfD did not change.

The 1998 assessment of chromium VI made no change to the cancer classification of Group D for oral exposures and determined that the carcinogenicity of chromium VI cannot be determined because of a lack of sufficient epidemiological or toxicological studies under the 1996 Proposed Guidelines for Carcinogen Risk Assessment. Chromium VI is a Group A known human carcinogen by the inhalation route of exposure.

Public concern over the adverse health effects of chromium VI has increased in recent years. One issue is whether chromium VI is a human carcinogen through oral ingestion. In 2001, the State of California convened a Blue Ribbon Panel to evaluate the available data on this issue. The Panel issued its report in August 2001 (Flegal *et al.*, 2001) and found no basis in either the epidemiological or animal data published in the literature for concluding that orally ingested chromium VI is a carcinogen. The National Toxicology Program (NTP) has agreed to study the chronic toxicity and carcinogenicity of chromium VI after

oral exposure. That effort will include shorter-term toxicity studies, two-year rodent toxicity and carcinogenicity studies as well as bioavailability, distribution, and mechanistic studies. NTP expects the results to be available in the next three to five years (NTP, 2001).

The availability of new data on the contribution of dietary chromium to total chromium exposure supports a re-evaluation of the RSC (NAS, 2001). The Agency applied an RSC of 70 percent in determining the current MCLG. Using the new Agency RfD of 0.003 mg/kg/day along with the application of 20 percent, 50 percent, or 70 percent as RSC values, the Agency believes that any likely revisions to the MCLG could range from 0.02 mg/L to 0.07 mg/L. A general evaluation of the data indicates that a revised RSC would likely fall within the 20 percent to 50 percent range.

Because the results of the health effects review support consideration of whether it may be appropriate to revise the NPDWR for chromium based on changes in the RfD and possible changes in the RSC assumptions, EPA considered whether analytical feasibility is likely to be a limitation. The results of the analytical feasibility analyses indicate that the current PQL of 0.01 mg/L for chromium is still appropriate and is unlikely to change. Therefore, the Agency believes the PQL is unlikely to be a limiting factor if EPA

decides to revise the MCLG/MCL (USEPA, 2002d).

EPA also considered whether treatment feasibility is likely to pose any limitations if EPA were to revise the MCLG/MCL. The current BATs for chromium include ion exchange, lime softening, coagulation/filtration, and RO. Small system compliance technologies also include POU RO and POU ion exchange. At the present time, EPA believes these BATs are still practical and would not pose any limitations if the Agency were to revise the MCLG/MCL (USEPA, 2002k).

The results of EPA's review of possible "other regulatory revisions" did not identify any issues which are specific to chromium (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for chromium to determine whether a revised MCLG/MCL would be likely to result in additional public health protection (USEPA, 2002g; USEPA, 2002h). Table V-5 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for the current MCLG/MCL (0.1 mg/L), the possible MCLG/MCL value retaining the 70 percent RSC (0.07 mg/L), the possible MCLG/MCL value using a 50 percent RSC (0.05 mg/L), and the possible MCLG/MCL value using a 20 percent RSC (0.02 mg/L).

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<b>Table V-5: Chromium Occurrence<sup>1</sup></b>					
<b>Systems<sup>2</sup></b>					
<b>Threshold (in mg/L)</b>	<b>16 Cross-Section States - Total Systems with Data</b>	<b>Estimated # Systems &gt; Threshold (credible intervals)<sup>3,5</sup></b>		<b>Estimated % Systems &gt; Threshold (credible intervals)<sup>3</sup></b>	
Current MCL 0.1	19,695	1	(0 - 3)	0.00424%	(0.000% - 0.0152%)
Possible MCLG/MCL value retaining the 70% RSC <sup>4</sup>	19,695	3	(0 - 7)	0.0133%	(0.000% - 0.0355%)
Possible MCLG/MCL value using a 50% RSC <sup>4</sup>	19,695	7	(3 - 13)	0.0366%	(0.0152% - 0.0660%)
Possible MCLG/MCL value using a 20% RSC <sup>4</sup>	19,695	73	(54 - 92)	0.371%	(0.274% - 0.467%)
<b>Population Served by Systems<sup>2</sup></b>					
<b>Threshold (in mg/L)</b>	<b>16 Cross-Section States - Total Population Served by Systems with Data</b>	<b>Estimated Population Served by Systems &gt; Threshold (credible intervals)<sup>3,5</sup></b>		<b>Estimated % Population Served by Systems &gt; Threshold (credible intervals)<sup>3</sup></b>	
Current MCL 0.1	105,380,000	1,500	(0 - 8,400)	0.00139%	(0.000% - 0.00793%)
Possible MCLG/MCL value retaining the 70% RSC <sup>4</sup>	105,380,000	4,500	(0 - 50,600)	0.00427%	(0.000% - 0.0481%)
Possible MCLG/MCL value using a 50% RSC <sup>4</sup>	105,380,000	11,300	(600 - 58,900)	0.0108%	(0.000580% - 0.0559%)
Possible MCLG/MCL value using a 20% RSC <sup>4</sup>	105,380,000	106,600	(47,100 - 167,700)	0.101%	(0.0447% - 0.159%)
Notes:					
<sup>1</sup> 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 threshold.					
<sup>2</sup> 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.					
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).					
<sup>4</sup> These are possible MCLG/MCL values based on changes in the RfD and using RSC values of 70, 50, and 20 percent.					
<sup>5</sup> 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 to 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 detailed occurrence and exposure analysis indicate that less than 0.4 percent of the 19,695 systems sampled in the 16 cross-section States and approximately 0.1 percent of the population served by those systems, might be affected if EPA were to lower the MCL to 0.02 mg/L.

c. *Preliminary Decision.* Although EPA has identified a change to the RfD on which the current MCLG for chromium is based, the Agency believes that a decision to revise the chromium NPDWR at this time is premature in light of the ongoing NTP studies on the toxicology and carcinogenicity of hexavalent chromium. The Agency is aware of considerable public controversy on the subject of the appropriate level for chromium in drinking water and realizes there are differing views regarding the severity of the health effects of chromium in water, the relative importance of drinking water as a source of chromium as compared with other sources, and the chemical form that should serve as the basis for regulating chromium (total versus hexavalent chromium). Because the NTP studies will not be available in time for the final revise/not revise decision, EPA is placing chromium in the “not revise—data gap” category. When completed, the NTP results will be considered either in the next review round or sooner, if the Agency deems it appropriate.

#### 15. Copper

a. *Background.* EPA published the current NPDWR for copper on June 7, 1991 (56 FR 26460 (USEPA, 1991b)). The NPDWR established a MCLG of 1.3 mg/L, based on a lowest-observed-adverse-effect level (LOAEL) of 5.3 mg/day<sup>9</sup>, and an action level of 1.3 mg/L for first-draw samples at the 90th percentile of taps tested. The NPDWR requires water systems to monitor for copper at the tap. Water systems must optimize corrosion control. This requires water systems serving more than 50,000 persons and those smaller size systems that exceed the copper action level to install corrosion control treatment and to monitor for specified water quality control parameters. The regulation also requires any size system that exceeds the copper action level to monitor for copper in source water and, if appropriate, to install source water treatment. EPA published revisions to the copper NPDWR on January 12, 2000 (65 FR 1950 (USEPA, 2000a)). These

revisions made changes to monitoring and reporting requirements but did not affect the copper MCLG, action level, or basic TT requirements.

b. *Technical Reviews.* In 1999, EPA requested that the National Research Council (NRC) of the NAS examine the available nutritional and toxicological data for copper and provide a recommendation regarding the levels in drinking water that are associated with adverse effects. The NRC concluded that copper in drinking water could produce adverse gastrointestinal effects in some individuals at concentrations of about 3 mg/L or greater. In addition, the NRC advised that individuals who carry a recessive gene for Wilson’s disease could accumulate excess copper in their livers at these same concentrations. Accordingly, the NAS recommended that EPA retain the MCLG of 1.3 mg/L while additional data are collected on the risk to the carriers of the Wilson’s Disease gene and other populations that may accumulate copper in their livers (NAS, 2000a).

EPA has initiated an assessment of health risks resulting from exposure to copper that will include the findings of NAS as well as more recently published data (USEPA, 2002i). This assessment will consider relevant studies on the toxicity of copper including its effects on genetically and developmentally sensitive populations. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

EPA has received comments on the copper NPDWR suggesting that EPA discontinue copper as a regulated contaminant or change it to a secondary standard (USEPA, 2002e). EPA is not aware of any new information that would warrant such a revision.

EPA has identified several potential research needs which may be considered in the context of an overall drinking water research strategy. These research needs are described in the “Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In Support of EPA Six-Year Review of National Primary Drinking Water Regulations” (USEPA, 2002k).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for copper is appropriate at this time because a reassessment of the health risks resulting from exposure to copper is ongoing. Several potential research needs were identified for copper. The NAS review of copper in drinking water concluded that there was a need to conduct research that would characterize copper-sensitive populations (both population size and

the factors leading to sensitivity) and further define the contribution of copper from drinking water to total copper intake (NAS, 2000a). Treatment-related research needs for copper are described in the Six-Year Review treatment feasibility support document (USEPA, 2002k).

#### 16. Cyanide

a. *Background.* EPA published the current NPDWR for cyanide on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established a MCLG and MCL of 0.2 mg/L. The MCLG was developed based on an RfD of 0.02 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The results of the health effects technical review identified some information on reproductive effects from the ATSDR toxicological profile that indicate the need to update the Agency’s risk assessment for cyanide (USEPA, 2002i). In light of this information, EPA has initiated a reassessment of the health risks resulting from exposure to cyanide and has already solicited scientific information from the public for consideration (67 FR 1212, January 9, 2002 (USEPA, 2002a)). The new risk assessment will consider relevant data on the toxicity of cyanide including its potential developmental and reproductive toxicity. Because the new assessment is not expected to be completed until the 2004 or 2005 time frame, EPA does not believe it is appropriate to revise the MCLG at this time.

A review of analytical or treatment feasibility is not necessary for cyanide because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. EPA’s review of “other regulatory revisions” identified a potential revision relating to an error in the BAT specified for cyanide in the CFR (USEPA, 2002e). The CFR currently specifies “chlorine” as a BAT for cyanide for compliance with the MCL and with variance and exemption requirements (40 CFR 141.62 and 142.62, respectively); however, the CFR should specify “alkaline chlorination”, as BAT. EPA plans to correct this error through a technical amendment to the cyanide NPDWR in the near future. In the meantime, water systems and States should continue to be guided by the “Public Water System Warning: Cyanide” (USEPA, 1994a) that EPA distributed through its regional offices. The warning includes information on the use of chlorination (non-alkaline) and the potential for formation of harmful cyanogen chloride due to reaction of chlorine with cyanide

<sup>9</sup>In June 1994, EPA published a technical amendment that provided additional information on the basis of the copper MCLG (59 FR 33860, June 30, 1994 (USEPA, 1994b)).



in water under those conditions. The PWS Warning explains this process in detail and outlines treatment practice, including contact times, required chlorine concentrations, and compensation for temperature effects. The July 25, 1990 proposed regulation for cyanide discusses the effectiveness of oxidation of cyanide at high pH levels (55 FR 30370 at 30419 (USEPA, 1990)) and the PWS Warning discusses mitigation of the formation of cyanogen chloride. This information is also summarized in the six-year review treatment technology support document (USEPA, 2002k).

Since the potential regulatory revision identified by these analyses does not affect the MCLG or the MCL, EPA does not believe it is necessary to conduct a detailed occurrence and exposure analysis for cyanide.

c. *Preliminary Decision.* Other than the technical amendment to correct the BAT, EPA does not believe a revision to the NPDWR for cyanide is appropriate at this time. A reassessment of the health risks has been initiated and the Agency does not believe it is appropriate to revise the NPDWR while that effort is in process.

#### 17. 2,4-D (2,4-Dichlorophenoxyacetic Acid)

a. *Background.* EPA published the NPDWR for 2,4-D on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.07 mg/L. EPA developed the MCLG based on a RfD of 0.01 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to 2,4-D. The revised risk assessment will consider relevant studies that have become available on the toxicity of 2,4-D including its potential developmental and reproductive toxicity. EPA expects the new risk assessment to be completed in the 2003 or 2004 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for 2,4-D is appropriate at this time because a reassessment of the health risks resulting from exposure to 2,4-D is ongoing.

#### 18. Dalapon (2,2-Dichloropropionic Acid)

a. *Background.* EPA published the current NPDWR for dalapon on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.2 mg/L. EPA developed the MCLG based on an RfD of 0.03 mg/kg/

day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for dalapon since the NPDWR was published. Therefore, as part of the Six-Year Review process, EPA conducted a literature search for relevant data on the toxicology of dalapon, including its potential developmental and reproductive toxicity. The literature search did not identify any studies that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

A review of analytical or treatment feasibility is not necessary for dalapon because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any dalapon-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the dalapon NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for dalapon remains appropriate and thus, it is not subject to revision at this time.

#### 19. 1,2-Dibromo-3-chloropropane (DBCP)

a. *Background.* EPA published the current NPDWR for DBCP on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.0002 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for DBCP since the NPDWR was published; however, ATSDR completed a toxicological profile for DBCP in 1992 (ATSDR, 1992). This assessment and other recent information do not warrant a review of the cancer classification because there are inadequate data to support a nonlinear dose response relationship (USEPA, 2002i). Accordingly, the MCLG remains at zero and the Agency believes that a further review of the health effects of DBCP is not warranted at this time.

EPA based the current MCL for DBCP on a PQL of 0.0002 mg/L. As a part of the Six-Year Review, EPA analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide

number of laboratories. The results of these analyses indicate that a slight improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State laboratories exhibit greater than 85 percent laboratory passing rates at concentrations around the current PQL of 0.0002 mg/L. Because most of the laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL corresponding to the 75 percent passing rate might exist for DBCP. While this information is indicative of a possibly lower PQL, the WS data are insufficient at this time to actually recalculate what the lower PQL for DBCP might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of DBCP in the more recent WS studies, laboratories predominantly used EPA Method 504.1 (Gas Chromatography with microextraction), which has an MDL of 0.00001 mg/L. A 10 times MDL multiplier predicts that the PQL may be around 0.0001 mg/L (also one-half the current MCL). The 0.0001 mg/L value is used as a threshold in the occurrence analysis, which is discussed in this section.

Since the analytical feasibility analysis indicates that the PQL for DBCP (and therefore the MCL) could possibly be lower if EPA had more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The BATs for DBCP include aeration and GAC. Small system compliance technologies for DBCP include GAC, POU GAC, PAC, and several aeration technologies. Since the Henry's Law coefficient for DBCP is relatively low (i.e., DBCP is "less strippable" than other contaminants), GAC may in some cases be the preferred treatment. Considering that only a slight improvement in analytical feasibility may exist, EPA believes that these BATs are still practical and would not pose any limitations for DBCP at a possibly lower MCL.

The results of EPA's review of possible "other regulatory revisions" did not identify any issues which are specific to DBCP (USEPA, 2002e).

EPA evaluated the results of the detailed occurrence and exposure analyses for DBCP to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if

the PQL were recalculated (USEPA, 2002g; USEPA, 2002h). Table V-6 shows the results of the detailed occurrence and exposure analysis based

on the 16-State cross-section at the current MCL (0.0002 mg/L) and the possible PQL/MCL based on the

analytical feasibility analysis (0.0001 mg/L).

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Table V-6: 1,2-Dibromo-3-chloropropane Occurrence <sup>1</sup>					
Systems <sup>2</sup>					
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3,5</sup>		Estimated % Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.0002	14,042	199	(171 - 231)	1.41%	(1.22% - 1.65%)
Possible PQL/MCL <sup>4</sup> 0.0001	14,042	273	(238 - 310)	1.94%	(1.70% - 2.21%)
Population Served by Systems <sup>2</sup>					
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3</sup>		Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.0002	87,727,200	2,278,300	(1,853,700 - 3,307,300)	2.60%	(2.11% - 3.77%)
Possible PQL/MCL <sup>4</sup> 0.0001	87,727,200	2,828,300	(2,182,700 - 4,353,900)	3.22%	(2.49% - 4.96%)
Notes:					
<sup>1</sup> 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 threshold.					
<sup>2</sup> 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.					
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).					
<sup>4</sup> The "possible PQL/MCL" is the possibly lower PQL/MCL as estimated by the analytical feasibility analysis.					
<sup>5</sup> 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 to 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.					

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The results of detailed occurrence and exposure analysis indicate that approximately 0.5 percent of the 14,042 systems sampled in the 16 cross-section States and approximately 0.6 percent of the population served by those systems, might be affected if EPA were to gather the information to recalculate the PQL (estimated to be around 0.0001 mg/L) and to revise the MCL accordingly.

*c. Preliminary Decision.* Although there are new data that support consideration of a slightly lower PQL (and therefore a possibly lower MCL), EPA does not believe a revision to the NPDWR for DBCP is appropriate at this time. The Agency does not have sufficient data at this time on which to base a PQL recalculation and hence an

MCL revision. In addition, because the occurrence of DBCP appears to be minimal between the current MCL and any likely PQL/MCL revision, the Agency believes that any potential revisions to the DBCP NPDWR are unlikely to significantly improve the level of public health protection.

20. 1,2-Dichlorobenzene (o-Dichlorobenzene)

*a. Background.* EPA published the current NPDWR for 1,2-dichlorobenzene on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.6 mg/L. EPA developed the MCLG based on an RfD of 0.09 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

*b. Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to 1,2-dichlorobenzene. The revised risk assessment will consider relevant studies on the toxicity of 1,2-dichlorobenzene including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for 1,2-dichlorobenzene is appropriate at this time because a reassessment of the health risks resulting from exposure to 1,2-dichlorobenzene is ongoing.

21. 1,4-Dichlorobenzene (p-Dichlorobenzene)

a. *Background.* EPA published the current NPDWR for 1,4-dichlorobenzene on July 8, 1987 (52 FR 25690 (USEPA, 1987)). The NPDWR established an MCLG and an MCL of 0.075 mg/L. EPA developed the MCLG based on an RfD of 0.1 mg/kg/day and a cancer classification of C, possible human carcinogen.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to 1,4-dichlorobenzene. The revised risk assessment will consider relevant studies on the toxicity of 1,4-dichlorobenzene including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for 1,4-dichlorobenzene is appropriate at this time because a reassessment of the health risks resulting from exposure to 1,4-dichlorobenzene is ongoing.

22. 1,2-Dichloroethane (Ethylene Dichloride)

a. *Background.* EPA published the current NPDWR for 1,2-dichloroethane on July 8, 1987 (52 FR 25690 (USEPA, 1987)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.005 mg/L based on analytical feasibility.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to 1,2-dichloroethane. The revised risk assessment will consider relevant studies that have become available on the toxicity of 1,2-dichloroethane including potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for 1,2-dichloroethane is appropriate at this time because a reassessment of the health risks resulting from exposure to 1,2-dichloroethane is ongoing.

23. 1,1-Dichloroethylene

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 developed the MCLG based on an RfD of 0.009 mg/kg/day and a cancer classification of C, possible human carcinogen.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to 1,1-dichloroethylene. The revised risk assessment will consider relevant studies on the toxicity of 1,1-dichloroethylene including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for 1,1-dichloroethylene is appropriate at this time because a reassessment of the health risks resulting from exposure to 1,1-dichloroethylene is ongoing.

24. cis-1,2-Dichloroethylene

a. *Background.* EPA published the current NPDWR for cis-1,2-dichloroethylene on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and MCL of 0.07 mg/L. The Agency developed the MCLG based on an RfD of 0.01 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for cis-1,2-dichloroethylene since the NPDWR was published; however, ATSDR completed a toxicological profile for cis-1,2-dichloroethylene in 1996 (ATSDR, 1996a). This review did not find data that would warrant a review of the RfD or cancer classification. As part of the Six-Year Review process, EPA conducted a literature search for relevant data on the toxicology of cis-1,2-dichloroethylene, including its potential developmental and reproductive toxicity. The literature search did not identify any studies that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

A review of analytical or treatment feasibility is not necessary for cis-1,2-dichloroethylene because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any issues that were specific to cis-1,2-dichloroethylene (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the cis-1,2-dichloroethylene NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent

technical analyses, the Agency believes the NPDWR for cis-1,2-dichloroethylene remains appropriate and thus, it is not subject to revision at this time.

25. trans-1,2-Dichloroethylene

a. *Background.* EPA published the current NPDWR for trans-1,2-dichloroethylene on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.1 mg/L. The Agency developed the MCLG based on an RfD of 0.02 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for trans-1,2-dichloroethylene since the NPDWR was published; however, ATSDR completed a toxicological profile for trans-1,2-dichloroethylene in 1996 (ATSDR, 1996a). This review did not find data that would warrant a review of the RfD or cancer classification. As part of the Six-Year Review process, EPA conducted a literature search for relevant data on the toxicology of trans-1,2-dichloroethylene, including its potential developmental and reproductive toxicity. The literature search did not identify any studies that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

A review of analytical or treatment feasibility is not necessary for trans-1,2-dichloroethylene because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any issues that were specific to trans-1,2-dichloroethylene (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the trans-1,2-dichloroethylene NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for trans-1,2-dichloroethylene remains appropriate and thus, it is not subject to revision at this time.

26. Dichloromethane (Methylene Chloride)

a. *Background.* EPA published the NPDWR for dichloromethane on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.005 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for dichloromethane since the NPDWR was published; however, ATSDR completed a toxicological profile for dichloromethane in 2000 (USEPA, 2002i). This review did not find any data that would warrant a change in the cancer classification on which the 1992 zero MCLG is based. The ATSDR toxicological profile considered relevant studies on the toxicity of dichloromethane including developmental and reproductive toxicity.

The current MCL for dichloromethane is based on a PQL of 0.005 mg/L. As a part of the Six-Year Review, EPA analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. The analysis of the WS data indicates that a slight improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State laboratories exhibit greater than 90 percent laboratory passing rates at concentrations around the current PQL of 0.005 mg/L. Because most of the

laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL corresponding to the 75 percent passing rate might exist for dichloromethane. While this information is indicative of a possibly lower PQL, the WS data are insufficient at this time to actually recalculate what the lower PQL for dichloromethane might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of dichloromethane in the more recent WS studies, laboratories predominantly used EPA Methods 524.2 (GC/MS) and 502.2 (Purge and Trap Gas Chromatography), which have MDLs of 0.00003 mg/L and 0.00002 mg/L, respectively. A 10 times MDL multiplier predicts that the PQL may be around 0.0003 to 0.0002 mg/L. The Agency used the average of these two values (0.00025 mg/L) as a threshold (i.e., possible PQL) in the occurrence analysis discussed in this section.

Since the analytical feasibility analysis indicates that the PQL for

dichloromethane (and therefore the MCL) could possibly be lower if EPA had more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BAT for dichloromethane is PTA. EPA believes this BAT is still practical and would not pose any limitations for dichloromethane at a possibly lower MCL.

The results of EPA's review of possible "other regulatory revisions" did not identify any dichloromethane-specific issues (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for dichloromethane to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if the PQL were recalculated (USEPA, 2002g; USEPA, 2002h). Table V-7 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for the current MCL (0.005 mg/L) and the possible PQL/MCL based on the analytical feasibility analysis (0.00025 mg/L).

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Table V-7: Dichloromethane Occurrence <sup>1</sup>				
Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3, 5</sup>		Estimated % Systems > Threshold (credible intervals) <sup>3</sup>
Current MCL 0.005	21,530	3	(1 - 6)	0.0131% (0.00465% - 0.0279%)
Possible PQL/MCL <sup>4</sup> 0.00025	21,530	1,067	(977 - 1,157)	4.96% (4.54% - 5.37%)
Population Served by Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3, 5</sup>		Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>
Current MCL 0.005	110,146,100	131,200	(200 - 275,300)	0.119% (0.000159% - 0.250%)
Possible PQL/MCL <sup>4</sup> 0.00025	110,146,100	10,350,400	(9,383,400 - 11,642,400)	9.40% (8.52% - 10.6%)
Notes:				
<sup>1</sup> 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 threshold.				
<sup>2</sup> 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.				
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).				
<sup>4</sup> The "possible PQL/MCL" is the possibly lower PQL/MCL as estimated by the analytical feasibility analysis.				
<sup>5</sup> 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 to 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.				

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The results of the detailed occurrence and exposure analysis indicate that less than 5 percent of the 21,530 systems sampled in the 16 cross-section States and slightly more than 9 percent of the population served by those systems, might be affected if EPA were to gather information to recalculate the PQL (to a lower PQL of around 0.00025 mg/L) and revise the MCL accordingly.

c. *Preliminary Decision.* EPA does not believe it is appropriate to revise the NPDWR for dichloromethane at this time because the data indicating the possibility of a PQL/MCL revision are not sufficient to support a regulatory revision at this time. However, EPA believes there may be an opportunity for improvement in the level of public health protection if the Agency had sufficient data to recalculate the PQL. The Agency therefore solicits comment on whether to gather better data on which to recalculate the PQL. Any such effort is unlikely to be completed in

time to inform the revise/not revise decision for the final notice but may provide new information for consideration during the next six-year review cycle.

#### 27. 1,2-Dichloropropane

a. *Background.* EPA published the current NPDWR for 1,2-dichloropropane on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.005 mg/L based on analytical feasibility.

b. *Technical Reviews.* EPA has not identified any new information that indicates that it is appropriate to revise the cancer classification for 1,2-dichloropropane at this time (USEPA, 2002i). Because the MCLG remains at zero, the Agency believes that a further review of the health effects of 1,2-dichloropropane is not warranted at this time.

The current MCL for 1,2-dichloropropane is based on a PQL of 0.005 mg/L. As a part of the Six-Year Review, EPA analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. The results of these analyses indicate that some improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State laboratories exhibit greater than 95 percent laboratory passing rates at concentrations around the current PQL of 0.005 mg/L. Because most of the laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL corresponding to the 75 percent passing rate might exist for 1,2-dichloropropane. While this information is indicative of

a possibly lower PQL, the WS data are insufficient at this time to actually recalculate what the lower PQL for 1,2-dichloropropane might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of 1,2-dichloropropane in the more recent WS studies, laboratories predominantly used EPA Methods 524.2 (GC/MS) and 502.2 (Purge and Trap Gas Chromatography), which have MDLs of 0.00004 mg/L and 0.00003 mg/L, respectively. A 10 times MDL multiplier predicts that the PQL may be around 0.0004 to 0.0003 mg/L. EPA used the 0.0004 mg/L value as a threshold in the

occurrence analysis discussed in this section.

Since the analytical feasibility analysis indicates that the PQL for 1,2-dichloropropane (and therefore the MCL) could possibly be lower if EPA had more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BATs for 1,2-dichloropropane are GAC and PTA. Small system compliance technologies for 1,2-dichloropropane include GAC, PTA, and several other aeration technologies. EPA believes that these BATs are still practical and would not pose any limitations for 1,2-dichloropropane at a possibly lower MCL.

The results of EPA's review of possible "other regulatory revisions"

did not identify any issues that are specific to 1,2-dichloropropane (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for 1,2-dichloropropane to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if the PQL were recalculated (USEPA, 2002g; USEPA, 2002h). Table V-8 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for the current MCL (0.005 mg/L) and the possible PQL/MCL based on the analytical feasibility analysis (0.0004 mg/L).

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**Table V-8: 1,2-Dichloropropane Occurrence<sup>1</sup>**

<b>Systems<sup>2</sup></b>			
<b>Threshold (in mg/L)</b>	<b>16 Cross-Section States - Total Systems with Data</b>	<b>Estimated # Systems &gt; Threshold (credible intervals)<sup>3,5</sup></b>	<b>Estimated % Systems &gt; Threshold (credible intervals)<sup>3</sup></b>
Current MCL 0.005	21,988	1 (0 - 2)	0.00358% (0.000% - 0.00910%)
Possible PQL/MCL <sup>4</sup> 0.0004	21,988	11 (7 - 16)	0.0506% (0.0318% - 0.0728%)
<b>Population Served by Systems<sup>2</sup></b>			
<b>Threshold (in mg/L)</b>	<b>16 Cross-Section States - Total Population Served by Systems with Data</b>	<b>Estimated Population Served by Systems &gt; Threshold (credible intervals)<sup>3,5</sup></b>	<b>Estimated % Population Served by Systems &gt; Threshold (credible intervals)<sup>3</sup></b>
Current MCL 0.005	110,450,100	39,500 (0 - 142,000)	0.0358% (0.000% - 0.129%)
Possible PQL/MCL <sup>4</sup> 0.0004	110,450,100	165,700 (145,000 - 197,400)	0.150% (0.131% - 0.179%)
Notes:			
<sup>1</sup> 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 threshold.			
<sup>2</sup> 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.			
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).			
<sup>4</sup> The "possible PQL/MCL" is the possibly lower PQL/MCL as estimated by the analytical feasibility analysis.			
<sup>5</sup> 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 to 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.			

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The results of the detailed occurrence and exposure analysis indicate that less

than 0.05 percent of the 21,988 systems sampled in the 16 cross-section States and approximately 0.1 percent of the

population served by those systems, might be affected if EPA were to gather the information to recalculate the PQL

(to a lower PQL of around 0.0004 mg/L) and revise the MCL accordingly.

c. *Preliminary Decision.* Although there are new data that support consideration of a possibly lower PQL (and therefore a possibly lower MCL), EPA does not believe a revision to the NPDWR for 1,2-dichloropropane is appropriate at this time. The Agency does not have sufficient data at this time on which to base a PQL recalculation and hence an MCL revision. In addition, because the occurrence of 1,2-dichloropropane appears to be minimal between the current MCL and any likely PQL/MCL revision, the Agency believes that any potential revisions to the 1,2-dichloropropane NPDWR are unlikely to significantly improve the level of public health protection.

#### 28. Di(2-ethylhexyl)adipate (DEHA)

a. *Background.* EPA published the NPDWR for DEHA on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.4 mg/L. The Agency developed the MCLG based on an RfD of 0.6 mg/kg/day and a cancer classification of C, possible human carcinogen.

b. *Technical Reviews.* The Agency has identified data that indicate it may be appropriate to update the risk assessment for DEHA (USEPA, 2002i). The literature search on reproductive and developmental toxicity identified differences in the evaluation of the critical study on which the MCLG is based. Therefore, EPA believes it is appropriate to update the risk assessment and evaluate relevant new studies that have become available on the toxicity of DEHA and its metabolites including its potential developmental and reproductive toxicity. In light of this information, EPA has initiated a reassessment of the health risks resulting from exposure to DEHA and has already solicited scientific information from the public for consideration (67 FR 1212, January 9, 2002 (USEPA, 2002a)). Because the new assessment is not expected to be completed until the 2003 or 2004 time frame, EPA does not believe it is appropriate to revise the MCLG at this time.

The current MCL is not limited by the analytical or treatment feasibility. Review of these capabilities is not necessary since no changes to the MCL are warranted at this time. The results of EPA's review of possible "other regulatory revisions" did not identify any issues that are specific to DEHA (USEPA, 2002e). Because none of these analyses indicate a change to the DEHA regulation, it is not necessary to conduct

a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for DEHA is appropriate at this time. A reassessment of the health risks has been initiated and the Agency does not believe it is appropriate to revise the NPDWR while that effort is in process.

#### 29. Di(2-ethylhexyl)phthalate (DEHP)

a. *Background.* EPA published the current NPDWR for DEHP on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen, and an MCL of 0.006 based on analytical feasibility.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to DEHP. Many studies on DEHP and its metabolites have become available over the past decade and are being evaluated as part of the Agency's ongoing assessment. The new assessment will evaluate cancer and noncancer endpoints, including potential developmental and reproductive endpoints. EPA expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for DEHP is appropriate at this time because a reassessment of the health risks resulting from exposure to DEHP is ongoing.

#### 30. Dinoseb

a. *Background.* EPA published the current NPDWR for dinoseb on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.007 mg/L. The Agency developed the MCLG based on an RfD of 0.001 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for dinoseb since the NPDWR was published. Therefore, as part of the Six-Year Review process, EPA conducted a literature search for relevant data on the toxicology of dinoseb, including its potential developmental and reproductive toxicity. The literature search did not identify any studies that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

A review of analytical or treatment feasibility is not necessary for dinoseb because changes to the MCLG are not warranted at this time, and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not

identify any dinoseb-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the dinoseb NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for dinoseb remains appropriate and thus, it is not subject to revision at this time.

#### 31. Diquat

a. *Background.* EPA published the current NPDWR for diquat on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.02 mg/L. The Agency developed the MCLG based on an RfD of 0.002 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks from exposure to diquat. The revised risk assessment will consider relevant studies that have become available on the toxicity of diquat, including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for diquat is appropriate at this time because a reassessment of the health risks resulting from exposure to diquat is ongoing.

#### 32. Endothall

a. *Background.* EPA published the current NPDWR for endothall on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.1 mg/L. The Agency developed the MCLG based on an RfD of 0.02 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to endothall. The revised risk assessment will consider relevant studies on the toxicity of endothall including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2003 or 2004 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for endothall is appropriate at this time because a reassessment of the health risks resulting from exposure to endothall is ongoing.

## 33. Endrin

a. *Background.* EPA published the current NPDWR for endrin on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.002 mg/L. The Agency developed the MCLG based on an RfD of 0.0003 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for endrin since the NPDWR was published; however, ATSDR completed a toxicological profile for endrin in 1996 (ATSDR, 1996b). This review did not find data that would warrant a review of the RfD or cancer classification. As part of the Six-Year Review process, EPA conducted a literature search for relevant data on the toxicology of endrin, including its potential developmental and reproductive toxicity. The literature search did not identify any studies that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

A review of analytical or treatment feasibility is not necessary for endrin because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any endrin-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the endrin NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis. (Note: Endrin uses were canceled in 1986 except for use on bird perches, which was canceled in 1991 (USDA, 1998)).

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for endrin remains appropriate and thus, it is not subject to revision at this time.

## 34. Epichlorohydrin

a. *Background.* EPA published the current NPDWR for epichlorohydrin on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR imposes a TT requirement that limits the allowable level of epichlorohydrin monomer in the polymer that is added to drinking water as a flocculent to remove particulates. Each water system is required to certify, in writing, to the State (using third-party or manufacturer's certification) that the combination (or product) of dose and monomer level does not exceed the

following level: 0.01 percent residual epichlorohydrin monomer in polymer products used during water treatment and dosed at 20 ppm.

b. *Technical Reviews.* EPA has not identified any new information that indicate that it is appropriate to revise the cancer classification for epichlorohydrin at this time. Because the MCLG remains at zero, the Agency believes that a further review of the health effects of epichlorohydrin is not warranted at this time (USEPA, 2002i).

There are no standardized methods available for epichlorohydrin at low levels in drinking water (56 FR 3526 at 3558, July 1, 1991 (USEPA, 1991a)). Therefore, no analysis of analytical feasibility is appropriate for this contaminant. EPA has no new information that indicates it is appropriate to revise the TT requirement for epichlorohydrin at this time (USEPA, 2002k). The results of EPA's review of possible "other regulatory revisions" did not identify any issues which are specific to epichlorohydrin (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the epichlorohydrin NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for epichlorohydrin remains appropriate and thus, it is not subject to revision at this time.

## 35. Ethylbenzene

a. *Background.* EPA published the current NPDWR for ethylbenzene on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.7 mg/L. The Agency developed the MCLG based on an RfD of 0.1 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to ethylbenzene. The revised risk assessment will consider relevant studies that have become available on the toxicity of ethylbenzene, including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for ethylbenzene is appropriate at this time because a reassessment of the health risks resulting from exposure to ethylbenzene is ongoing.

## 36. Ethylene Dibromide (EDB; 1,2-Dibromoethane)

a. *Background.* EPA published the current NPDWR for EDB on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.00005 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to EDB. The revised risk assessment will consider relevant studies that have become available on the toxicity of EDB, including its developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for EDB is appropriate at this time because a reassessment of the health risks resulting from exposure to EDB is ongoing.

## 37. Fluoride

a. *Background.* EPA published the current NPDWR for fluoride on April 2, 1986 (51 FR 11396 (USEPA, 1986a)). The NPDWR established an MCLG and an MCL of 4.0 mg/L. The MCLG was developed from a lowest effect level for crippling skeletal fluorosis of 20 mg/day with continuous exposures over a 20-year or longer period. The LOAEL was divided by an uncertainty factor of 2.5 and a drinking water intake of 2 liters/day (L/day) to obtain the MCLG. Drinking water was considered to be the only source of exposure for the calculation. At the same time, EPA published a secondary maximum contaminant level (SMCL) for fluoride of 2.0 mg/L to protect against dental fluorosis, which is considered to be an adverse cosmetic effect. PWSs exceeding the fluoride SMCL must provide public notification to their customers.

Fluoride is unique as a drinking water contaminant because of its beneficial effects at low level exposures, and because it is voluntarily added to some drinking water systems as a public health measure for reducing the incidence of cavities among the treated population. The amount of fluoride added to drinking water for fluoridation ranges from 0.7 to 1.2 mg/L, depending on ambient air temperatures. The decision to fluoridate a water supply is made by the State or local municipality, and is not mandated by EPA or any other Federal entity.



b. *Technical Reviews.* In 1997, NAS established Dietary Reference Intakes (DRI) for fluoride as a nutrient. As a component of the DRI, NAS established age and gender specific tolerable upper intake levels (UL) to reflect the highest average daily nutrient intake level likely to pose no risk of adverse effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases. The NAS set the UL for fluoride at 0.10 mg/kg/day for infants, toddlers, and children through eight years of age, to protect them from moderate enamel fluorosis (NAS, 1997). A UL of 10 mg/day was established for adults and for children older than eight years, based on protection against skeletal fluorosis. The NAS UL evaluation of fluoride does not have an effect on the MCLG/MCL because a 2 liter drinking water intake of 4 mg/L equals 8mg/day for adults, which is less than 10 mg/day and allows for fluoride in food and dental products.

In addition, the NAS established age and gender specific Adequate Intake (AI) values for fluoride. AI values are set when the data do not permit determination of the more precise and better known Recommended Dietary Allowance (RDA). The NAS (1997) AI for infants, 0 through 6 months, is 0.01 mg/day and for infants, 7 through 12 months, is 0.5 mg/day. Values for children range from 0.7 mg/day to 3 mg/day increasing with age. For adults, the NAS (1997) AI is 3 mg/day for females, and 4 mg/day for males.

There are new studies regarding the effects of fluoride on bone that have been published since EPA established the MCLG/MCL. EPA believes that it is important to review these new data, since effects on bone are the basis of the present MCLG and MCL. The Agency has conducted a literature search to identify reports of the clinical and epidemiological data on fluoride and the skeletal system. The results of that search indicate that a review of the new data is justified as part of the regulatory review process. EPA plans to request NAS to conduct a review of these data. In light of this planned assessment, EPA does not believe it is appropriate to revise the MCLG at this time.

As part of the continuing review of the new toxicological data for fluoride, EPA also intends to examine the RSC used in the 1986 regulation. At that time, a 100 percent RSC was applied in setting the regulation. The increased use of fluoride in dental products, the tendency for children to swallow these dental products, and the potential for increased exposure from foods support

a re-evaluation of the RSC as a component of the fluoride review.

As a part of the review of possible "other regulatory revisions," EPA identified one issue pertaining to the public notification requirement associated with exceedance of the SMCL and the timing of the notification. Currently, PWSs that exceed the SMCL of 2.0 mg/L are required to notify their customers within 12 months of the exceedance. Concern has been expressed that this requirement is not sufficiently timely since dental fluorosis occurs as a result of exposure to high levels of fluoride while the tooth enamel is being laid down. Waiting 12 months to provide public notification may result in young children being exposed to high levels of fluoride during the time at which they are most vulnerable. The Agency will consider any such revisions, if they are still appropriate, once the results of the NAS evaluation are available.

c. *Preliminary Decision.* EPA is continuing its analyses of relevant studies that have been published since 1986 regarding the adverse effects of fluoride on the skeletal system to determine if these data support consideration of whether to revise the current MCLG. As a part of this effort, the Agency plans to request that NAS update the fluoride health risk assessment and review the RSC assumptions. The Agency therefore believes it is not appropriate to revise the NPDWR for fluoride at this time. When the results of the NAS assessment are available, and if they support consideration of whether a revision to the MCLG and/or MCL may be appropriate, EPA will revisit this "not revise" decision.

### 38. Glyphosate

a. *Background.* EPA published the current NPDWR for glyphosate on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.7 mg/L. The Agency developed the MCLG based on an RfD of 0.1 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to glyphosate. The revised risk assessment will consider relevant studies that have become available on the toxicity of glyphosate including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for glyphosate is appropriate at this time because a reassessment of the health risks resulting from exposure to glyphosate is ongoing.

### 39. Heptachlor

a. *Background.* EPA published the current NPDWR for heptachlor on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.0004 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for heptachlor since the NPDWR was published; however, ATSDR completed a toxicological profile for heptachlor in 1993 (ATSDR, 1993). This assessment and other recent information do not warrant a review of the cancer classification because there are inadequate data to support a nonlinear dose-response relationship (USEPA, 2002i). Accordingly, the MCLG remains at zero and the Agency believes that a further review of the health effects of heptachlor is not warranted at this time.

The current MCL for heptachlor is based on a PQL of 0.0004 mg/L. As a part of the Six-Year Review, EPA analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. The results of these analyses indicate that some improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State laboratories exhibit greater than 90 percent laboratory passing rates at concentrations around the current PQL of 0.0004 mg/L. Because most of the laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL corresponding to the 75 percent passing rate might exist for heptachlor. While this information is indicative of a possibly lower PQL, the WS data are insufficient at this time to actually recalculate what the lower PQL for heptachlor might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of heptachlor in the more recent WS studies,

laboratories predominantly used EPA Methods 508 (GC/MS), 505 (GC microextraction), and 525.2 (Purge and Trap GC), which have MDLs of 0.0000015 mg/L, 0.000003 mg/L, and 0.00015 mg/L, respectively. A 10 times MDL multiplier predicts PQLs of 0.000015 mg/L, 0.00003 mg/L, and 0.0015 mg/L. EPA chose the intermediate value, rounded up to 0.0001 mg/L, and used this value as a threshold in the occurrence analysis discussed in this section.

Since the analytical feasibility analysis indicates that the PQL for heptachlor (and therefore the MCL) could possibly be lower if EPA had

more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BAT for heptachlor is GAC. Compliance technologies for small systems include GAC, PAC, and POU GAC. Since heptachlor is a moderately adsorbed contaminant, EPA believes that the BAT and compliance technologies are still practical and would not pose any limitations for heptachlor at a possibly lower MCL.

The results of EPA's review of possible "other regulatory revisions" did not identify any heptachlor-specific issues (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for heptachlor to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if the PQL were recalculated (USEPA, 2002g; USEPA, 2002h). Table V-9 shows the results of the detailed occurrence and exposure analyses based on the 16-State cross-section for the current MCL (0.0004 mg/L) and the possible PQL/MCL based on the analytical feasibility analysis (0.0001 mg/L).

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**Table V-9: Heptachlor Occurrence<sup>1</sup>**

Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.0004	14,245	0 (0-0)	0.000% (0.000% - 0.000%)	
Possible PQL/MCL <sup>4</sup> 0.0001	14,245	0 (0-0)	0.0000140% (0.000% - 0.000%)	
Population Served by Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.0004	96,563,400	0 (0-0)	0.000% (0.000% - 0.000%)	
Possible PQL/MCL <sup>4</sup> 0.0001	96,563,400	0 (0-0)	0.000000242% (0.000% - 0.000%)	
Notes:				
<sup>1</sup> 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 threshold.				
<sup>2</sup> 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.				
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).				
<sup>4</sup> The "possible PQL/MCL" is the possibly lower PQL/MCL as estimated by the analytical feasibility analysis.				

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Based on the detailed occurrence and exposure analysis, heptachlor is unlikely to occur at the current MCL or any potential MCL revision for the States used in the cross-section. Since all heptachlor uses were canceled in the United States in 1988 (except for fire ant use), and since it is subject to the United Nations Prior Informed Consent

procedure (USEPA, 2002g; USEPA, 2002h), EPA expects the occurrence of heptachlor in PWSs to be rare.

c. *Preliminary Decision.* Although there are new data that support consideration of a slightly lower PQL (and therefore a possibly lower MCL), EPA does not believe a revision to the NPDWR for heptachlor is appropriate at this time. The Agency does not have

sufficient data at this time on which to base a PQL recalculation and hence an MCL revision. Also, the Agency believes that any change in the PQL would be minimal and unlikely to significantly improve the level of public health protection because heptachlor appears to occur very infrequently at concentrations at or below the current MCL.

#### 40. Heptachlor Epoxide

a. *Background.* EPA published the current NPDWR for heptachlor epoxide, a degradate of heptachlor, on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.0002 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for heptachlor epoxide since the NPDWR was published; however, ATSDR completed a toxicological profile for heptachlor epoxide in 1993 (ATSDR, 1993). This review did not find data that would warrant a review of the cancer classification because there are inadequate data to support a nonlinear dose response. Accordingly, the MCLG remains at zero and the Agency believes that a further review of the health effects of heptachlor epoxide is not warranted at this time.

The current MCL for heptachlor epoxide is based on a PQL of 0.0002 mg/L. As a part of the Six-Year Review, EPA analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. The results of these analyses indicate that a slight

improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State laboratories exhibit greater than 85 percent laboratory passing rates at concentrations around the current PQL of 0.0002 mg/L. Because most of the laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL corresponding to the 75 percent passing rate might exist for heptachlor epoxide. While this information is indicative of a possibly lower PQL, the WS data are insufficient at this time to actually recalculate what the lower PQL for heptachlor epoxide might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of heptachlor epoxide in the more recent WS studies, laboratories predominantly used EPA Methods 505 (GC microextraction), 508 (GC/MS), and 525.2 (Purge and Trap GC), which have MDLs of 0.000004 mg/L, 0.000059 mg/L, and 0.00013 mg/L, respectively. A 10 times MDL multiplier predicts PQLs of 0.00004 mg/L, 0.00059 mg/L, and 0.0013 mg/L. EPA chose the intermediate value, rounded up to 0.0001 mg/L, and used this value as a threshold in the occurrence analysis discussed in this section.

Since the analytical feasibility analysis indicates that the PQL for heptachlor epoxide (and therefore the MCL) could possibly be lower if EPA had more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BAT for heptachlor epoxide is GAC. Compliance technologies for small systems include GAC, PAC, and POU GAC. EPA believes that the BAT and compliance technologies would not pose any limitations for heptachlor epoxide at a possibly lower MCL.

The results of EPA's review of possible "other regulatory revisions" did not identify any issues that are specific to heptachlor epoxide (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for heptachlor epoxide to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if the PQL were recalculated (USEPA, 2002g; USEPA, 2002h). Table V-10 shows the results of the detailed occurrence and exposure analyses based on the 16-State cross-section for the current MCL (0.0002 mg/L), and the possible PQL/MCL based on the analytical feasibility analysis (0.0001 mg/L).

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Table V-10: Heptachlor Epoxide Occurrence <sup>1</sup>					
Systems <sup>2</sup>					
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Systems > Threshold (credible intervals) <sup>3</sup>		
Current MCL 0.0002	14,133	0 (0-0)	0.000%	(0.000% - 0.000%)	
Possible PQL/MCL <sup>4</sup> 0.0001	14,133	0 (0-0)	0.000%	(0.000% - 0.000%)	
Population Served by Systems <sup>2</sup>					
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>		
Current MCL 0.0002	96,222,900	0 (0-0)	0.000%	(0.000% - 0.000%)	
Possible PQL/MCL <sup>4</sup> 0.0001	96,222,900	0 (0-0)	0.000%	(0.000% - 0.000%)	
Notes:					
<sup>1</sup> 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 threshold.					
<sup>2</sup> 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.					
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).					
<sup>4</sup> The "possible PQL/MCL" is the possibly lower PQL/MCL as estimated by the analytical feasibility analysis.					

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Based on detailed occurrence and exposure analysis, it appears that heptachlor epoxide is unlikely to occur at the current MCL or any potential MCL revision for the States used in the cross-section. Since the parent of heptachlor epoxide (i.e., heptachlor) was canceled for use (except for fire ant use) in the United States and since it is subject to the United Nations Prior Informed Consent procedure (USEPA, 2002g; USEPA, 2002h), EPA expects the occurrence of heptachlor epoxide in PWSs to be rare.

c. *Preliminary Decision.* Although there are new data that support consideration of a slightly lower PQL (and therefore a possibly lower MCL), EPA does not believe a revision to the NPDWR for heptachlor epoxide is appropriate at this time. The Agency does not have sufficient data at this time on which to base a PQL recalculation and hence an MCL revision. Also, the Agency believes that any change in the PQL would be minimal and unlikely to significantly improve the level of public health protection because heptachlor epoxide appears to occur infrequently at

concentrations at or below the current MCL.

41. Hexachlorobenzene

a. *Background.* EPA published the current NPDWR for hexachlorobenzene on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.001 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for hexachlorobenzene since the NPDWR was published; however, ATSDR completed a toxicological profile for hexachlorobenzene in 1996 (ATSDR, 1996c). This assessment and other recent information do not warrant a review of the cancer classification because there are inadequate data to support a nonlinear dose-response relationship (USEPA, 2002i). Accordingly, the MCLG remains at zero and the Agency believes that a further review of the health effects of hexachlorobenzene is not warranted at this time.

The current MCL for hexachlorobenzene is based on a PQL of 0.001 mg/L. As a part of the Six-Year Review, EPA analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. The results of these analyses indicate that some improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State laboratories exhibit greater than 90 percent laboratory passing rates at concentrations around the current PQL of 0.001 mg/L. Because most of the laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL corresponding to the 75 percent passing rate might exist for hexachlorobenzene. While this information is indicative of a possibly lower PQL, the WS data are insufficient at this time to actually

recalculate what the lower PQL for hexachlorobenzene might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of hexachlorobenzene in the more recent WS studies, laboratories predominantly used EPA Methods 508 (GC/MS), 505 (GC microextraction), and 525.2 (Purge and Trap GC), which have MDLs of 0.0000077 mg/L, 0.000002 mg/L and 0.000001 mg/L, respectively. A 10 times MDL multiplier predicts PQLs of 0.000077 mg/L, 0.00002 mg/L, and 0.00001 mg/L. EPA chose the highest value, rounded up to 0.0001 mg/L, and then used this value as a threshold in

the occurrence analysis discussed in this section.

Since the analytical feasibility analysis indicates that the PQL for hexachlorobenzene (and therefore the MCL) could possibly be lower if EPA had more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BAT for hexachlorobenzene is GAC. Compliance technologies for small systems include GAC, PAC, and POU GAC. Since hexachlorobenzene is a moderately adsorbed contaminant, EPA believes that the BAT and compliance technologies are still practical and would not pose any limitations for hexachlorobenzene at a possibly lower MCL.

The results of EPA's review of possible "other regulatory revisions" did not identify any issues that are specific to hexachlorobenzene (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for hexachlorobenzene to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if the PQL were recalculated (USEPA, 2002g; USEPA, 2002h). Table V-11 shows the results of the detailed occurrence and exposure analyses based on the 16-State cross-section for the current MCL (0.001 mg/L) and the possible PQL/MCL based on the analytical feasibility analysis (0.0001 mg/L).

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**Table V-11: Hexachlorobenzene Occurrence<sup>1</sup>**

Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3</sup>		Estimated % Systems > Threshold (credible intervals) <sup>3</sup>
Current MCL 0.001	14,011	0	(0 - 0)	0.000% (0.000% - 0.000%)
Possible PQL/MCL <sup>4</sup> 0.0001	14,011	1	(0 - 2)	0.00287% (0.000% - 0.0143%)
Population Served by Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3</sup>		Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>
Current MCL 0.001	94,035,300	0	(0 - 0)	0.000% (0.000% - 0.000%)
Possible PQL/MCL <sup>4</sup> 0.0001	94,035,300	16,600	(0 - 84,300)	0.0176% (0.000% - 0.0896%)
Notes:				
<sup>1</sup> 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 threshold.				
<sup>2</sup> 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.				
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).				
<sup>4</sup> The "possible PQL/MCL" is the possibly lower PQL/MCL as estimated by the analytical feasibility analysis.				

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The detailed occurrence and exposure analysis indicates that

hexachlorobenzene is unlikely to occur at the current MCL or any potential

MCL revision for the States used in the cross-section. Since hexachlorobenzene

uses were canceled in the United States in 1984 and since it is subject to the United Nations Prior Informed Consent procedure (USEPA, 2002g; USEPA, 2002h), EPA expects the occurrence of hexachlorobenzene in PWSs to be rare.

c. *Preliminary Decision.* Although there are new data that support consideration of a possibly lower PQL (and therefore a possibly lower MCL), EPA does not believe a revision to the NPDWR for hexachlorobenzene is appropriate at this time. The Agency does not have sufficient data at this time on which to base a PQL recalculation and hence an MCL revision. In addition, because the occurrence of hexachlorobenzene appears to be minimal between the current MCL and any likely PQL/MCL revision, the Agency believes that any potential revisions to the hexachlorobenzene NPDWR are unlikely to significantly improve the level of public health protection.

#### 42. Hexachlorocyclopentadiene

a. *Background.* EPA published the current NPDWR for hexachlorocyclopentadiene on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.05 mg/L. The Agency based the MCLG on an RfD of 0.007 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency updated the health risk assessment for hexachlorocyclopentadiene in 2001 (USEPA, 2001c). The revised risk assessment considered relevant studies that were available to the Agency on the toxicity of hexachlorocyclopentadiene including its potential developmental and reproductive toxicity. According to the 1986 EPA Guidelines for Carcinogen Risk Assessment (51 FR 33992, September 24, 1986 (USEPA, 1986b)), evaluation of the weight of evidence for carcinogenicity to humans indicates that hexachlorocyclopentadiene is most appropriately categorized as Group E, evidence of noncarcinogenicity to humans, via inhalation exposure. In accordance with EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment (61 FR 17960, April 23, 1996 (USEPA, 1996)), hexachlorocyclopentadiene is not likely to be a human carcinogen by the inhalation route. The potential for carcinogenicity by the oral route is unknown. The updated risk assessment changed the RfD from 0.007 to 0.006 mg/kg/day. The change in RfD was the result of a change in the procedure used to model the data but not a change in the underlying toxicology. The RfD could result in a slight change to the

MCLG and MCL but that change would not lead to any significant improvement in public health protection.

A review of analytical or treatment feasibility is not necessary for hexachlorocyclopentadiene because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any hexachlorocyclopentadiene-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the hexachlorocyclopentadiene NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for hexachlorocyclopentadiene remains appropriate and thus, it is not subject to revision at this time.

#### 43. Lead

a. *Background.* EPA published the current NPDWR for lead on June 7, 1991 (56 FR 26460 (USEPA, 1991b)). The NPDWR established an MCLG of zero and a lead action level of 0.015 mg/L at the 90th percentile of taps tested. The MCLG for lead is based on three factors: (1) the occurrence of a variety of low level health effects for which it is currently difficult to identify clear threshold exposure levels below which there are no risks of adverse health effects; (2) the Agency's policy goal that drinking water should contribute minimal lead to total lead exposures because a substantial portion of the sensitive population already exceeds acceptable blood lead levels; and (3) the classification of lead as B2, probable human carcinogen.

The NPDWR requires water systems to monitor for lead at the tap. Water systems must optimize corrosion control. This requires water systems serving more than 50,000 persons (except those with extremely low levels of lead in their distribution systems) and those smaller size systems that exceed the lead action level to install corrosion control treatment and to monitor for specified water quality control parameters. The NPDWR also includes other TT requirements for those systems exceeding the lead action level. These systems must: (1) Monitor for lead in source water; (2) install source water treatment, if appropriate; (3) conduct public education for as long as they continue to exceed the action level; and (4) replace the portion of lead service line in the distribution system they own, if they continue to exceed the

action level after installing corrosion control treatment and/or source water treatment. EPA published revisions to the lead NPDWR on January 12, 2000 (65 FR 1950 (USEPA, 2000a)). These revisions made changes to monitoring and reporting requirements, public education, and the lead service line replacement requirements but did not affect the lead MCLG, action level, or other TT requirements.

b. *Technical Reviews.* EPA has not identified any new assessments that indicate that it is appropriate to revise the MCLG for lead at this time (USEPA, 2002i). Although ATSDR completed a toxicological profile for lead in 1999 (ATSDR, 1999), the review did not find data that would warrant a change in the MCLG for lead. Because the MCLG remains at zero, the Agency believes that a further review of the health effects of lead is not warranted at this time.

EPA identified several potential research needs which may be considered in the context of an overall drinking water research strategy. These research needs are described in the "Water Treatment Technology Feasibility Support Document of Chemical Contaminants in Support of EPA Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2002k).

Some stakeholders have suggested that EPA allow alternatives to corrosion control treatment (e.g., monitoring and flushing at non-transient, non-community water systems (NTNCWSs)) (USEPA, 2002e). EPA considered these alternatives as a part of the January 2000 revisions and determined that it was not appropriate to make such revisions to the TT requirements for lead and copper (65 FR 1950, January 12, 2000 (USEPA, 2000a)). If new peer-reviewed scientific information becomes available, it will be considered.

EPA also considered several potential revisions to requirements pertaining to the monitoring requirements for lead and copper in drinking water based on concerns recently expressed by stakeholders (USEPA, 2002e). As a part of the Six-Year Review process, EPA considered issues including: (1) Further reduction of the monitoring requirements; (2) monitoring for lead and copper on the same frequency as other inorganic and organic chemicals; (3) expanding the monitoring waiver program to water systems that have not exceeded one-half the lead and copper action levels for three monitoring rounds, regardless of plumbing materials used; (4) revising the protocol by which tap water sampling sites are identified; and (5) allowing fewer than five tap water samples for NTNCWSs

that have fewer than five taps. The Agency addressed all of these issues as a part of the January 2000 revisions. If new peer-reviewed scientific information becomes available, it will be considered.

The current action level and TT requirements are not limited by analytical feasibility, therefore review of these capabilities is not needed. Since none of the analyses indicate a change to the lead regulation at this time, the Agency did not conduct detailed occurrence and exposure analyses.

*c. Preliminary Decision.* EPA does not believe a revision to the NPDWR for lead is appropriate because the Agency is not aware of any new data/information that provides sufficient basis for revising the regulatory requirements at this time. However, the Agency has identified several technology-related issues that could benefit from further research. These research needs will be considered as a part of an overall drinking water research strategy. As more research in this area becomes available, the Agency will consider the results as a part of the review of the lead NPDWR during future review cycles.

#### 44. Lindane ( $\gamma$ -Hexachlorocyclohexane)

*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/L and a cancer classification of C, possible human carcinogen.

*b. Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to lindane. The revised risk assessment will consider relevant studies that have become available on the toxicity of lindane including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2003 or 2004 time frame (USEPA, 2002i).

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for lindane is appropriate at this time because a reassessment of the health risks resulting from exposure to lindane is ongoing.

#### 45. Mercury (Inorganic)

*a. Background.* EPA published the current NPDWR for inorganic mercury on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.002 mg/L. The Agency based the MCLG on a Drinking Water Equivalent

Level (DWEL) of 0.01 mg/L<sup>10</sup> and a cancer classification of D, not classifiable as to human carcinogenicity.

*b. Technical Reviews.* EPA updated the risk assessment for mercury in 1997 as part of the Mercury Study Report to Congress (MSRC) (USEPA, 1997b). The MSRC entailed a review of all available studies on inorganic mercury including reproductive and developmental studies. The MSRC concluded that the database for inorganic mercury is suggestive of effects in animals at doses around 2 mg/kg/day. The data however, are considered insufficient for risk assessment based on any single study or on the database as a whole. Evaluation of data for germ cell mutagenicity led to the conclusion that there is a moderate weight of evidence for potential to produce adverse effects in humans. The MSRC reviewed and kept the 1987 RfD of 0.0003 mg/kg/day based on immune-mediated kidney damage in three studies conducted in a sensitive strain of rats.

The MSRC evaluated data for carcinogenicity of inorganic mercury, largely from studies of mercuric chloride. Based on the absence of human data and limited data in animals, inorganic mercury was categorized as Group C, possible human carcinogen; this determination was posted on IRIS for mercuric chloride (USEPA, 1995). The MSRC also applied the proposed revisions to the Cancer Guidelines (61 FR 17960, April 23, 1996 (USEPA, 1996)) to the evaluation of inorganic mercury. The conclusion was that inorganic mercury is not likely to be a human carcinogen under conditions of exposure generally encountered in the environment. This was based in part on the observation that all tumors were observed at very high doses, in excess of the maximum tolerated dose (MTD) and that likely modes of action for these tumors involved irritation and cytotoxic effects not expected to occur at environmental levels.

The revised risk assessments show that inorganic mercury is not likely to be a carcinogen at levels found in water and that there are insufficient data to categorize inorganic mercury as a developmental toxicant. The EPA RfD has not changed, and thus, EPA does not believe it is appropriate to revise the MCLG at this time.

A review of analytical or treatment feasibility is not necessary for mercury because, in EPA's judgment, changes to

<sup>10</sup>The DWEL was recommended by a panel of experts on mercury, and was derived using the weight of evidence from the entire inorganic mercury database. The DWEL was later back-calculated to an RfD of 0.0003 mg/kg/day (USEPA, 1995).

the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any mercury-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the mercury NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

*c. Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for inorganic mercury remains appropriate and thus, it is not subject to revision at this time.

#### 46. Methoxychlor

*a. Background.* EPA published the current NPDWR for methoxychlor on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.04 mg/L. The Agency based the MCLG on an RfD of 0.005 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

*b. Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to methoxychlor. The revised risk assessment will consider relevant studies that have become available on the toxicity of methoxychlor including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for methoxychlor is appropriate at this time because a reassessment of the health risks resulting from exposure to methoxychlor is ongoing.

#### 47. Monochlorobenzene (Chlorobenzene)

*a. Background.* EPA published the current NPDWR for monochlorobenzene on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.1 mg/L. The Agency based the MCLG on an RfD of 0.02 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

*b. Technical Reviews.* The Agency has not updated the health risk assessment for monochlorobenzene since the NPDWR was published. EPA therefore conducted a literature search for relevant studies on the toxicology of monochlorobenzene including its potential developmental and reproductive toxicity as a part of the Six-Year Review process. The literature search did not identify any new studies

that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

A review of analytical or treatment feasibility is not necessary for monochlorobenzene because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any monochlorobenzene-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the monochlorobenzene NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

*c. Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for monochlorobenzene remains appropriate and thus, it is not subject to revision at this time.

#### 48. Nitrate (as N)

*a. Background.* EPA published the current NPDWR for nitrate on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and MCL of 10 mg/L (as nitrogen (N)). The Agency based the MCLG on an RfD of 1.6 mg/kg/day (as N) and a cancer classification of D, not classifiable as to human carcinogenicity.

*b. Technical Reviews.* The current RfD and the MCLG were established to protect infants, the most susceptible segment of the population. At the request of EPA<sup>11</sup>, NAS completed an assessment of nitrate in 1995 (NAS, 1995) and did not find any new data that would warrant a review of the RfD or cancer classification. The literature search conducted during the Six-Year Review also did not identify any new studies that warrant a review of the RfD or cancer classification (USEPA, 2002i).

The current MCL is not limited by the analytical or treatment feasibility. Review of these capabilities is not necessary since no changes to the MCL are warranted at this time.

As a part of the Six-Year Review, several States have suggested that EPA revise the current monitoring requirements for nitrate to allow less frequent monitoring in systems with consistently low nitrate/nitrite levels. Some have suggested that EPA place nitrate monitoring under the same monitoring framework used for most other inorganic chemicals (USEPA, 2002e). EPA previously considered these suggestions when the Agency

considered chemical monitoring reform and decided not to change the frequency of nitrate monitoring. However, primacy agencies currently have the flexibility to reduce nitrate monitoring for ground water systems from annually to biennial if the Primacy Agency adopts (and EPA approves) an alternative monitoring provision. EPA has established guidance for such alternative monitoring in the Alternative Monitoring Guidelines (USEPA, 1997a). These guidelines were issued after consultation with stakeholders and no new information has been identified that warrants reconsideration of this issue.

Detailed occurrence and exposure analysis is not necessary since none of the analyses indicate a change to the nitrate regulation at this time.

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for nitrate is appropriate at this time because: (1) There are no changes in the health risk assessment for nitrate; and (2) no other new data were identified that indicate the need to revise the NPDWR at this time. (Also see section V.A.49.c of today's action for a discussion of the Agency's decision pertaining to the joint nitrate/nitrite standard.)

#### 49. Nitrite (as N)

*a. Background.* EPA published the current NPDWR for nitrite on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 1.0 mg/L (as N). The Agency based the MCLG on an RfD of 0.16 mg/kg/day (as N) and a cancer classification of D, not classifiable as to human carcinogenicity.

*b. Technical Reviews.* The current RfD and MCLG were established to protect infants, the most susceptible segment of the population. At the request of EPA, NAS completed an assessment of nitrite in 1995 (NAS, 1995) and did not find any new studies that warrant a review of the RfD or cancer classification. The literature search conducted during the Six-Year Review did not identify any new studies that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

The current MCL is not limited by the analytical or treatment feasibility. Review of these capabilities is not necessary since no changes to the MCL are warranted at this time.

As a part of the Six-Year Review of "other regulatory revisions," EPA received several suggestions regarding the current monitoring requirements for nitrite.<sup>12</sup> Stakeholders raised several

potential issues concerning the current monitoring requirements (USEPA, 2002e). These issues include:

- A need for flexibility for States to require systems to collect a distribution system sample for nitrite under certain circumstances, such as if the entry point sample is greater than 50 percent of the MCL, if there is a large amount of ammonia in the raw water, or if chloramines are applied;
- A need for flexibility for States to require systems to monitor for ammonia in raw water; and
- Flexibility to eliminate nitrite monitoring when a disinfection residual is present.

EPA does not believe it has sufficient data at this time on which to base possible changes in monitoring requirements (USEPA, 2002e).

Detailed occurrence and exposure analysis is not necessary since none of the technical analyses indicate a change to the nitrite regulation at this time.

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for nitrite is appropriate at this time because: (1) There are no changes in the health risk assessment for nitrite; and (2) no other new data were identified that indicate the need to revise the NPDWR at this time.

EPA also published an MCLG and an MCL of 10 mg/L (as N) for the sum of nitrate and nitrite on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The Agency established this joint nitrate/nitrite standard to account for the possible additive toxicity of these two chemicals and also to protect against the deterioration of drinking water quality, since the presence of nitrite in water is indicative of water contaminated with sewage. The Agency has not identified any new data as a part of the Six-Year Review process that indicates that this joint nitrate/nitrite standard needs to be revised.

#### 50. Oxamyl (Vydate)

*a. Background.* EPA published the current NPDWR for oxamyl on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.2 mg/L. The Agency based the

non-community water systems (NTNCWSs), and transient non-community water systems (TNCWSs) must monitor for nitrite at each entry point to the distribution system. If the analytical result is less than 1/2 the MCL (0.5 mg/L), then the system must monitor at a frequency specified by the Primary Agency. If the sample result is greater than or equal to 1/2 the MCL (0.5 mg/L) then the entry point that exceeded the trigger level must begin quarterly monitoring. The Primary Agency may reduce the quarterly monitoring to annual monitoring after the system has collected four quarters of data. However, the system must collect subsequent samples during the quarter that yielded the highest analytical result.

<sup>11</sup> This request fulfilled the commitment EPA made to form an inter-agency workgroup to determine what, if any, oncogenic risks exist (56 FR 3526 at 3538, January 30th, 1991 (USEPA, 1991a)).

<sup>12</sup> Current monitoring requirements for nitrite: All community water systems (CWSs), non-transient,



MCLG on an RfD of 0.025 mg/kg/day and a cancer classification of E, evidence of non-carcinogenicity for humans.

b. *Technical Reviews.* The Agency identified a change in the health assessment that supports consideration of whether to revise the MCLG (USEPA, 2002i). EPA updated the risk assessment in 2000. This new risk assessment considered relevant studies that had become available on the toxicity of oxamyl including its potential developmental and reproductive toxicity. The new risk assessment revised the RfD from 0.025 mg/kg/day to 0.001 mg/kg/day (USEPA, 2000e).

Based on the change in the RfD for oxamyl and using a 20 percent RSC<sup>13</sup>, EPA believes that any revision to the MCLG is not likely to be lower than 0.007 mg/L.

In setting the MCLG/MCL in 1992, the Agency determined the PQL for oxamyl to be 0.02 mg/L and analytical

feasibility was not considered to be a limitation. EPA has analyzed more recent WS data to determine if analytical feasibility is likely to be a limiting factor in setting a lower MCL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive methods have been approved and are in use by a wide number of laboratories. The results of these analyses indicate that analytical feasibility is likely to be a limiting factor if EPA were to revise the MCLG and MCL. Although not definitive, the available WS data indicate that the PQL could lie between 0.02 and 0.04 mg/L. EPA used the 0.02 mg/L and the 0.04 mg/L values as thresholds in the occurrence analysis discussed in this section.

Since the health effects technical review supports consideration of whether a revision to the MCLG and MCL may be appropriate, EPA evaluated whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BAT for oxamyl is GAC. Compliance technologies for small systems include GAC, PAC, and POU GAC. EPA believes that the BAT and

compliance technologies are still practical and would not pose any limitations for oxamyl at a possibly lower level (i.e., a possibly lower MCL).

The results of EPA's review of possible "other regulatory revisions" did not identify any issues that are specific to oxamyl (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for oxamyl to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if the PQL were recalculated (USEPA, 2002g; USEPA, 2002h). Table V-12 shows the results of the detailed occurrence and exposure analyses based on the 16-State cross-section for several concentrations: the current MCL (0.2 mg/L), the possible upper and lower PQLs based on the analytical feasibility analysis (0.02 and 0.04 mg/L), and the possible lower limit of any MCLG value (0.007 mg/L). Based on the detailed analysis of 16 cross-section States, it appears that oxamyl is unlikely to occur at the current MCL or any potential MCL value.

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<sup>13</sup>This is the RSC used for the current MCLG and also the default value. EPA has no reason to believe that the RSC for oxamyl would change. See Appendix A for further discussion of the RSC.

Table V-12: Oxamyl Occurrence <sup>1</sup>				
Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.2	13,157	0 (0-0)	0.000% (0.000% - 0.000%)	
Possible upper PQL <sup>4</sup> 0.04	13,157	0 (0-0)	0.000% (0.000% - 0.000%)	
Possible lower PQL <sup>5</sup> 0.02	13,157	0 (0-0)	0.000% (0.000% - 0.000%)	
Possible MCL if feasible to set at MCLG <sup>6</sup> 0.007	13,157	0 (0-0)	0.0000456% (0.000% - 0.000%)	
Population Served by Systems <sup>2</sup>				
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.2	92,345,800	0 (0-0)	0.000% (0.000% - 0.000%)	
Possible upper PQL <sup>4</sup> 0.04	92,345,800	0 (0-0)	0.000% (0.000% - 0.000%)	
Possible lower PQL <sup>5</sup> 0.02	92,345,800	0 (0-0)	0.000% (0.000% - 0.000%)	
Possible MCL if feasible to set at MCLG <sup>6</sup> 0.007	92,345,800	0 (0-0)	0.0000323% (0.000% - 0.000%)	
Notes:				
<sup>1</sup> 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 threshold.				
<sup>2</sup> 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.				
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).				
<sup>4</sup> The "possible upper PQL" is the likely upper limit of any potential PQL revision.				
<sup>5</sup> The "possible lower PQL" is the likely lower limit of any potential PQL revision.				
<sup>6</sup> The "possible MCL if feasible to set at MCLG value" is the lowest level indicated by the new health assessment, assuming there were no limitations due to analytical feasibility.				

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c. *Preliminary Decision.* Although there are new data indicating that it might be possible to lower the MCLG and the MCL, analytical feasibility limitations would limit the extent to which the MCL could be revised at the present time. Because any changes in the NPDWR based on setting the MCL at the limitations of analytical feasibility are unlikely to significantly improve the level of public health protection, EPA does not believe a revision to the NPDWR for oxamyl is appropriate at this time. In addition, because oxamyl appears to occur infrequently at concentrations at or below the current MCL, EPA believes that efforts to

research more sensitive analytical methods and/or to revise the MCL are low priority and should not be pursued at the present time. EPA requests comment on the extent to which oxamyl is likely to occur at levels between 0.007 and 0.2 mg/L at PWSs. Commenters who disagree with the occurrence evaluation should submit data to support their rationale and evidence to show that oxamyl is of national concern at PWSs at the thresholds evaluated. EPA does plan to update the Health Advisory for oxamyl to reflect the new RfD.

## 51. Pentachlorophenol

a. *Background.* EPA published the current NPDWR for pentachlorophenol on July 1, 1991 (56 FR 30266 (USEPA, 1991c)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.001 mg/L, based on analytical feasibility.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to pentachlorophenol. The revised risk assessment will consider relevant studies that have become available on the toxicity of pentachlorophenol

including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for pentachlorophenol is appropriate at this time because a reassessment of the health risks resulting from exposure to pentachlorophenol is ongoing.

52. Picloram

a. *Background.* EPA published the current NPDWR for picloram on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.5 mg/L. The Agency based the MCLG on an RfD of 0.07 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency identified a change in the health assessment that could lead to a change

in the MCLG (USEPA, 2002i). EPA updated the risk assessment in 1998. This new risk assessment considered relevant studies that had become available on the toxicity of picloram including its potential developmental and reproductive toxicity. The new risk assessment revised the RfD from 0.07 mg/kg/day to 0.20 mg/kg/day and classified picloram as Group E, evidence of noncarcinogenicity for humans, according to the 1986 Cancer Guidelines. Picloram has not been evaluated against the Proposed 1996 Cancer Guidelines.

Based on the change in the RfD for picloram and using a 20 percent RSC,<sup>14</sup> EPA believes that any revision to the MCLG is not likely to be higher than 1 mg/L (an increase in the MCLG).

Analytical or treatment feasibility do not pose any limitations for the current MCL and would not be a limiting factor if EPA were to raise the MCLG. The Agency's review of possible "other

regulatory revisions" did not identify any issues that are specific to picloram (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for picloram to determine whether possible changes to the MCL would be likely to result in opportunities for significant cost savings to PWSs and their customers (USEPA, 2002g; USEPA, 2002h). Table V-13 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for the current MCL (0.5 mg/L), and the concentration that would be considered if the EPA revised the MCLG and MCL (i.e., the possible MCLG/MCL of 1 mg/L) based on the new RfD and a 20 percent RSC. Based on the detailed analysis, it appears that picloram is unlikely to occur at concentrations above 0.5 mg/L in the States used for the cross-section.

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**Table V-13: Picloram Occurrence<sup>1</sup>**

Systems <sup>2</sup>			
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Systems > Threshold (credible intervals) <sup>3</sup>
Possible MCLG/MCL <sup>4</sup> 1	12,907	0 (0-0)	0.000% (0.000% - 0.000%)
Current MCL 0.5	12,907	0 (0-0)	0.000% (0.000% - 0.000%)
Population Served by Systems <sup>2</sup>			
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>
Possible MCLG/MCL <sup>4</sup> 1	93,235,500	0 (0-0)	0.000% (0.000% - 0.000%)
Current MCL 0.5	93,235,500	0 (0-0)	0.000% (0.000% - 0.000%)

Notes:

<sup>1</sup> 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 threshold.

<sup>2</sup> 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.

<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).

<sup>4</sup> The "possible MCLG/MCL revision" is the likely upper limit of any revised MCLG/MCL.

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<sup>14</sup>This is the RSC used for the current MCLG and also the default value. EPA has no reason to believe

that the RSC for picloram would change. See Appendix A for further discussion of the RSC.

The results of the detailed occurrence and exposure analysis indicate that few, if any, of the 12,907 systems sampled in the 16 cross-section States might be affected if EPA were to raise the MCLG/MCL.

*c. Preliminary Decision.* Although there are new data that support consideration of whether to revise the MCLG/MCL for picloram, EPA does not believe a revision to the NPDWR for picloram is appropriate at this time. The Agency believes that any change in the MCLG/MCL would be unlikely to provide an opportunity for significant cost savings to PWSs.

#### 53. Polychlorinated Biphenyls (PCBs)

*a. Background.* EPA published the current NPDWR for PCBs on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.0005 mg/L based on analytical feasibility.

*b. Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to PCBs. The revised risk assessment will consider relevant studies that have become available on the toxicity of PCBs including their potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for PCBs is appropriate at this time because a reassessment of the health risks resulting from exposure to PCBs is ongoing.

#### 54. Selenium

*a. Background.* EPA published the current NPDWR for selenium on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.05 mg/L. The Agency based the MCLG on an RfD of 0.005 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

*b. Technical Reviews.* The Agency has not updated the risk assessment for selenium since the NPDWR was published (USEPA, 2002i). However, a 2000 NAS assessment of selenium supports the current RfD based on epidemiological studies of selenosis in humans (NAS, 2000b). The NAS study considered relevant studies that were available on the toxicity of selenium, including its developmental and reproductive toxicity, and established a tolerable upper intake level of 0.4 mg/day for adolescents and adults, a value which is equivalent to the RfD.

A review of analytical or treatment feasibility is not necessary for selenium because changes to the MCLG are not warranted at this time, and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any selenium-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the selenium NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

*c. Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for selenium remains appropriate and thus, it is not subject to revision at this time.

#### 55. Simazine

*a. Background.* EPA published the current NPDWR for simazine on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.004 mg/L. The Agency based the MCLG on an RfD of 0.005 mg/kg/day and a cancer classification of C, possible human carcinogen.

*b. Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to simazine. The revised risk assessment will consider relevant studies that have become available on the toxicity of simazine including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2003 or 2004 time frame (USEPA, 2002i).

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for simazine is appropriate at this time because a reassessment of the health risks resulting from exposure to simazine is ongoing. The Agency is also re-examining all the triazines and their degradation products as part of its CCL in order to fill any necessary research gaps to enable the Agency to determine whether or not to regulate any or all of the contaminants in this group of compounds.

#### 56. Styrene

*a. Background.* EPA published the current NPDWR for styrene on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.1 mg/L. The Agency based the MCLG on an RfD of 0.2 mg/kg/day and a cancer classification of C, possible human carcinogen.

*b. Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to styrene. The revised risk assessment will consider relevant studies that have

become available on the toxicity of styrene including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for styrene is appropriate at this time because a reassessment of the health risks resulting from exposure to styrene is ongoing.

#### 57. 2,3,7,8-TCDD (Dioxin)

*a. Background.* EPA published the current NPDWR for dioxin on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of  $3 \times 10^{-8}$  mg/L based on analytical feasibility.

*b. Technical Reviews.* The Agency has conducted a comprehensive assessment of the exposure and potential human health effects of dioxin including its potential developmental and reproductive toxicity. The draft document has been reviewed by the SAB (USEPA, 2001b). The Agency is presently in the process of addressing SAB and public comments, and expects to complete the risk assessment in the 2002 or 2003 time frame.

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for dioxin is appropriate at this time because a reassessment of the health risks resulting from exposure to dioxin is ongoing.

#### 58. Tetrachloroethylene

*a. Background.* EPA published the current NPDWR for tetrachloroethylene on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.005 mg/L based on analytical feasibility.

*b. Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to tetrachloroethylene. The revised risk assessment will consider relevant studies that have become available on the toxicity of tetrachloroethylene including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

*c. Preliminary Decision.* The Agency does not believe a revision to the NPDWR for tetrachloroethylene is appropriate at this time because a

reassessment of the health risks resulting from exposure to tetrachloroethylene is ongoing.

#### 59. Thallium

a. *Background.* EPA published the current NPDWR for thallium on July 17, 1992 (57 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of 0.0005 mg/L based on an RfD of 0.00007 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity. The NPDWR also established an MCL of 0.002 mg/L based on analytical feasibility.

b. *Technical Reviews.* The results of the health effects technical review identified some information on reproductive effects that indicate the need to update the Agency's risk assessment for thallium (USEPA, 2002i). In light of this information, EPA has initiated a reassessment of the health risks resulting from exposure to thallium and has already solicited scientific information from the public for consideration (67 FR 1212, January 9, 2002 (USEPA, 2002a)). The new risk assessment will consider relevant data on the toxicity of thallium including its potential developmental and reproductive toxicity. Because the new assessment is not expected to be completed until the 2004 or 2005 time frame, EPA does not believe it is appropriate to revise the MCLG at this time.

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for thallium is appropriate at this time. A reassessment of the health risks has been initiated and the Agency does not believe it is appropriate to revise the NPDWR while that effort is in process.

#### 60. Toluene

a. *Background.* EPA published the current NPDWR for toluene on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 1 mg/L. The Agency based the MCLG on an RfD of 0.2 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to toluene. The revised risk assessment will consider relevant studies that have become available on the toxicity of toluene including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the

2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for toluene is appropriate at this time because a reassessment of the health risks resulting from exposure to toluene is ongoing.

#### 61. Toxaphene

a. *Background.* EPA published the current NPDWR for toxaphene on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.003 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for toxaphene since the NPDWR was published; however, ATSDR completed a toxicological profile for toxaphene in 1996 (ATSDR, 1996d). This assessment and other recent information do not warrant a review of the cancer classification because the data indicate that toxaphene is mutagenic and would be evaluated using a linear dose-response approach (USEPA, 2002i). Accordingly, the MCLG remains at zero and the Agency believes that a further review of the health effects of toxaphene is not warranted at this time.

The current MCL for toxaphene is based on a PQL of 0.003 mg/L. As a part of the Six-Year Review, EPA analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. The results of these analyses indicate that some improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State laboratories exhibit greater than 90 percent laboratory passing rates at concentrations around the current PQL of 0.003 mg/L. Because most of the laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL corresponding to the 75 percent passing rate might exist for toxaphene. While this information is indicative of a possibly lower PQL, the WS data are insufficient at this time to actually recalculate what the lower PQL for toxaphene might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of toxaphene in the more recent WS studies, laboratories predominantly used EPA Methods 508 (GC/MS) and 505 (Purge and Trap GC). No MDL data are available for EPA Method 508 and the MDL for 505 is listed as 0.001 mg/L. A 10 times MDL multiplier based on EPA Method 505 predicts a PQL of 0.01 mg/L, which is higher than the current PQL. Therefore, the 10 times multiplier could not be used to predict a lower PQL and EPA did not use this higher value as a threshold in the occurrence analysis discussed in this section. Instead, EPA used concentration thresholds of one-half the current MCL and the lower limit of detection reported by the States. EPA believes if a lower PQL does exist, that the magnitude of the change would be minimal.

Since the analytical feasibility analysis indicates that the PQL for toxaphene (and therefore the MCL) could possibly be lower if EPA had more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BAT for toxaphene is GAC. Compliance technologies for small systems include GAC, PAC, and POU GAC. EPA believes that the BAT and compliance technologies are still practical and would not pose any limitations for toxaphene at a possibly lower MCL.

The results of EPA's review of possible "other regulatory revisions" did not identify any issues that are specific to toxaphene (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for toxaphene to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if EPA had sufficient data to recalculate the PQL (USEPA, 2002g; USEPA, 2002h). Table V-14 shows the results of the detailed occurrence and exposure analyses based on the 16-State cross-section for the current MCL (0.003 mg/L), one-half the current MCL (0.0015 mg/L), and the lower level of detection reported by the States (0.001 mg/L).

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Table V-14: Toxaphene Occurrence <sup>1</sup>					
Systems <sup>2</sup>					
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3</sup>		Estimated % Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.003	13,805	0	(0 - 0)	0.000%	(0.000% - 0.000%)
½ the Current MCL 0.0015	13,805	0	(0 - 0)	0.000%	(0.000% - 0.000%)
Lower level of detection reported by States 0.001	13,805	1 <sup>4</sup>	(0 - 0)	0.000145%	(0.000% - 0.000%)
Population Served by Systems <sup>2</sup>					
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3</sup>		Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.003	95,108,100	0	(0 - 0)	0.000%	(0.000% - 0.000%)
½ the Current MCL 0.0015	95,108,100	0	(0 - 0)	0.000%	(0.000% - 0.000%)
Lower level of detection reported by States 0.001	95,108,100	800	(0 - 0)	0.000833%	(0.000% - 0.000%)
Notes:					
<sup>1</sup> 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 threshold.					
<sup>2</sup> 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.					
<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).					
<sup>4</sup> Model output resulted in an estimate of less than half a system; however, the fraction was rounded up to one.					

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The detailed occurrence and exposure analysis indicates that toxaphene is unlikely to occur at the current MCL or any potential MCL revision for the States used in the cross-section. Since toxaphene uses were canceled in the United States in 1990 and since it is subject to the United Nations Prior Informed Consent (USEPA, 2002g; USEPA, 2002h), EPA expects the occurrence of toxaphene in PWSs to be rare.

c. *Preliminary Decision.* Although there are new data that support consideration of a possibly lower PQL (and therefore a possibly lower MCL), EPA does not believe a revision to the NPDWR for toxaphene is appropriate at

this time. The Agency does not have sufficient data at this time on which to base a PQL recalculation and hence an MCL revision. Also, the Agency believes that any change in the PQL would be minimal and unlikely to significantly improve the level of public health protection because toxaphene appears to occur infrequently at concentrations at or below the current MCL.

62. 2,4,5-TP (Silvex; 2,4,5-Trichlorophenoxypropionic Acid)

a. *Background.* EPA published the current NPDWR for 2,4,5-TP on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.05 mg/L. The Agency based the MCLG on an RfD of 0.008 mg/kg/day

and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for 2,4,5-TP since the NPDWR was published. Therefore, as part of the Six-Year Review process, EPA conducted a literature search for relevant data on the toxicology of 2,4,5-TP including its potential developmental and reproductive toxicity. The literature search did not identify any new studies that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

A review of analytical or treatment feasibility is not necessary for 2,4,5-TP because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the

results of EPA's review of possible "other regulatory revisions" did not identify any 2,4,5-TP-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the 2,4,5-TP NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for 2,4,5-TP remains appropriate and thus, it is not subject to revision at this time.

#### 63. 1,2,4-Trichlorobenzene

a. *Background.* EPA published the current NPDWR for 1,2,4-trichlorobenzene on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG and an MCL of 0.07 mg/L. The Agency based the MCLG on an RfD of 0.01 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for 1,2,4-trichlorobenzene since the NPDWR was published. Therefore, as part of the Six-Year Review process, EPA conducted a literature search for relevant data on the toxicology of 1,2,4-trichlorobenzene, including its potential developmental and reproductive toxicity. The literature search did not identify any new studies that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

A review of analytical or treatment feasibility is not necessary for 1,2,4-trichlorobenzene because changes to the MCLG are not warranted at this time and the current MCL is set at the MCLG. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any 1,2,4-trichlorobenzene-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the 1,2,4-trichlorobenzene NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for 1,2,4-trichlorobenzene remains appropriate and thus, it is not subject to revision at this time.

#### 64. 1,1,1-Trichloroethane

a. *Background.* EPA published the current NPDWR for 1,1,1-trichloroethane on July 8, 1987 (52 FR 25690 (USEPA, 1987)). The NPDWR established an MCLG and an MCL of 0.20 mg/L. The Agency developed the MCLG based on an RfD of 0.035 mg/kg/day derived from an inhalation study

and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to 1,1,1-trichloroethane. The revised risk assessment will consider relevant studies that have become available on the toxicity of toluene including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2003 or 2004 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for 1,1,1-trichloroethane is appropriate at this time because a reassessment of the health risks resulting from exposure to 1,1,1-trichloroethane is ongoing.

#### 65. 1,1,2-Trichloroethane

a. *Background.* EPA published the current NPDWR for 1,1,2-trichloroethane on July 17, 1992 (57 FR 31776 (USEPA, 1992)). The NPDWR established an MCLG of 0.003 mg/L based on an RfD of 0.004 mg/kg/day and a cancer classification of C, possible human carcinogen. The NPDWR also established an MCL of 0.005 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency has not updated the health risk assessment for 1,1,2-trichloroethane since the NPDWR was published. Therefore, as part of the Six-Year Review process, EPA conducted a literature search for relevant data on the toxicology of 1,1,2-trichloroethane including its potential developmental and reproductive toxicity. The literature search did not identify any studies that warrant a review of the RfD or the cancer classification (USEPA, 2002i).

The current MCL for 1,1,2-trichloroethane is based on a PQL of 0.005 mg/L. As a part of the Six-Year Review, EPA analyzed more recent WS data to determine if it might be possible to recalculate the PQL (USEPA, 2002d). In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. The results of these analyses indicate that a slight improvement in analytical feasibility might exist. Evaluation of the WS data shows that EPA Regional and State laboratories exhibit greater than 90 percent laboratory passing rates at concentrations around the current PQL of 0.005 mg/L. Because most of the laboratory passing rates exceeded the 75 percent criterion typically used to derive a PQL from WS studies, this information indicates that a lower PQL

corresponding to the 75 percent passing rate might exist for 1,1,2-trichloroethane. While this information is indicative of a possibly lower PQL, the WS data are insufficient at this time to actually recalculate what the lower PQL for 1,1,2-trichloroethane might be.

Using information about the analytical methods most widely used to report results in the WS studies, the MDLs for these methods, and the 10 times MDL multiplier, EPA estimated what the possibly lower PQL/MCL might be. For the analysis of 1,1,2-trichloroethane in the more recent WS studies, laboratories predominantly used EPA Methods 524.2 (GC/MS) and 502.2 (Purge and Trap GC), which both have upper limit MDLs of 0.00003 mg/L. A 10 times MDL multiplier predicts a PQL of 0.0003 mg/L. Since this value is below the current MCLG, this supports consideration of whether the MCL might be set at the MCLG if sufficient data were available to recalculate the PQL. EPA did not use the possibly lower PQL as a threshold in the occurrence analysis but instead used 0.003 mg/L (the current MCLG) since this is the lowest level to which the MCL would possibly be revised.

Since the analytical feasibility analysis indicates that the PQL for 1,1,2-trichloroethane (and therefore the MCL) could possibly be lower if EPA had more definitive data to recalculate the PQL, EPA considered whether treatment feasibility is likely to pose any limitations (USEPA, 2002k). The current BATs for 1,1,2-trichloroethane include both PTA and GAC. Small system compliance technologies for 1,1,2-trichloroethane include GAC and several aeration technologies. EPA believes that these BATs and compliance technologies are still practical and would not pose any limitations for 1,1,2-trichloroethane at a possibly lower level.

The results of EPA's review of possible "other regulatory revisions" did not identify any issues that are specific to 1,1,2-trichloroethane (USEPA, 2002e).

EPA evaluated the results of the occurrence and exposure analyses for 1,1,2-trichloroethane to determine whether changes to the MCL might be appropriate and likely to result in additional public health protection if sufficient data were available to recalculate the PQL and subsequently set the MCL at the MCLG (USEPA, 2002g; USEPA, 2002h). Table V-15 shows the results of the detailed occurrence and exposure analyses based on the 16-State cross-section for the current MCL (0.005 mg/L) and the potentially revised MCL (0.003 mg/L)

based on setting the MCL at the MCLG. unlikely to occur at the current MCL or  
Based on the detailed analysis, it appears that 1,1,2-trichloroethane is

any potential MCL revisions in the States used for the cross-section.  
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Table V-15: 1,1,2-Trichloroethane Occurrence <sup>1</sup>					
Systems <sup>2</sup>					
Threshold (in mg/L)	16 Cross-Section States - Total Systems with Data	Estimated # Systems > Threshold (credible intervals) <sup>3</sup>		Estimated % Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.005	22,284	0	(0-0)	0.000%	(0.000% - 0.000%)
Potentially revised MCL <sup>4</sup> 0.003	22,284	0	(0-0)	0.000%	(0.000% - 0.000%)
Population Served by Systems <sup>2</sup>					
Threshold (in mg/L)	16 Cross-Section States - Total Population Served by Systems with Data	Estimated Population Served by Systems > Threshold (credible intervals) <sup>3</sup>		Estimated % Population Served by Systems > Threshold (credible intervals) <sup>3</sup>	
Current MCL 0.005	110,366,500	0	(0-0)	0.000%	(0.000% - 0.000%)
Potentially revised MCL <sup>4</sup> 0.003	110,366,500	0	(0-0)	0.000%	(0.000% - 0.000%)

Notes:

<sup>1</sup> 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 threshold.

<sup>2</sup> 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.

<sup>3</sup> "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 Regulatory Review" (USEPA, 2002g).

<sup>4</sup> The "potentially revised MCL" is the based on setting the MCL at the MCLG, if EPA had sufficient data to recalculate the PQL and if it were found that the analytical feasibility was not a limiting factor.

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c. *Preliminary Decision.* Although there are new data that support consideration of whether a lower PQL is possible (and therefore a possibly set the MCL at the MCLG), EPA does not believe a revision to the NPDWR for 1,1,2-trichloroethane is appropriate at this time. The Agency believes that any potential revision to the MCL is unlikely to significantly improve the level of public health protection because 1,1,2-trichloroethane appears to occur infrequently at concentrations at or below the current MCL.

66. Trichloroethylene

a. *Background.* EPA published the current NPDWR for trichloroethylene on July 8, 1987 (52 FR 25690 (USEPA, 1987)). The NPDWR established an MCLG of zero based on a cancer classification of B2, probable human carcinogen. The NPDWR also established an MCL of 0.005 mg/L based on analytical feasibility.

b. *Technical Reviews.* EPA has initiated a reassessment of the health risks resulting from exposure to trichloroethylene. The revised risk assessment will consider relevant studies that have become available on the toxicity of trichloroethylene including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for trichloroethylene is appropriate at this time because a reassessment of the health risks resulting from exposure to trichloroethylene is ongoing.

67. Vinyl Chloride

a. *Background.* EPA published the current NPDWR for vinyl chloride on July 8, 1987 (52 FR 25690 (USEPA, 1987)). The NPDWR established an MCLG of zero based on a cancer classification of A, known human

carcinogen. The NPDWR also established an MCL of 0.002 mg/L based on analytical feasibility.

b. *Technical Reviews.* The Agency updated the health risk assessment of vinyl chloride in 2000 (USEPA, 2000k). The updated risk assessment included relevant studies that were available on the toxicity of vinyl chloride including its potential developmental and reproductive toxicity. According to the 1986 EPA Guidelines for Carcinogen Risk Assessment, vinyl chloride is categorized as Group A, known human carcinogen. Under the Proposed Guidelines for Carcinogen Risk Assessment (61 FR 17960, April 23, 1996 (USEPA, 1996)), EPA concluded that vinyl chloride is a known human carcinogen by the inhalation route of exposure, based on human epidemiological data and, by analogy, by the oral and dermal routes.

The current MCL for vinyl chloride is based on a PQL of 0.002 mg/L. As a part



of the Six-Year Review, EPA analyzed WS data to determine if it might be possible to recalculate the PQL. In addition, the Agency evaluated whether more sensitive analytical methods have been approved and put into use by a wide number of laboratories. Based on these analyses, the Agency believes the current PQL, and therefore the MCL, is still appropriate (USEPA, 2002d).

A review of treatment feasibility is not necessary for vinyl chloride because no changes to the MCLG or the MCL are warranted at this time. In addition, the results of EPA's review of possible "other regulatory revisions" did not identify any vinyl chloride-specific issues (USEPA, 2002e). Since EPA did not identify a health or technology basis for revising the vinyl chloride NPDWR, the Agency did not conduct a detailed occurrence and exposure analysis.

c. *Preliminary Decision.* After reviewing the results of the pertinent technical analyses, the Agency believes the NPDWR for vinyl chloride remains appropriate and thus, it is not subject to revision at this time.

#### 68. Xylenes (Total)

a. *Background.* EPA published the current NPDWR for total xylenes on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 10 mg/L. The Agency based the MCLG on an RfD of 2 mg/kg/day and a cancer classification of D, not classifiable as to human carcinogenicity.

b. *Technical Reviews.* The Agency has initiated a reassessment of the health risks resulting from exposure to xylenes. The revised risk assessment will consider relevant studies that have become available on the toxicity of xylenes including its potential developmental and reproductive toxicity. The Agency expects the new risk assessment to be completed in the 2002 or 2003 time frame (USEPA, 2002i).

c. *Preliminary Decision.* The Agency does not believe a revision to the NPDWR for xylenes is appropriate at this time because a reassessment of the health risks resulting from exposure to xylenes is ongoing.

#### B. What Preliminary Decision Has EPA Made Regarding the Total Coliform Rule?

##### 1. Background

EPA published the TCR on June 29, 1989 (54 FR 27544 (USEPA, 1989b)). The TCR is one of several EPA regulations that protect the public from pathogens in drinking water. The TCR requires all PWSs to monitor for the

presence of total coliforms in the distribution system. Total coliforms are a group of closely related bacteria that are (with few exceptions) not harmful to humans. They are natural and common inhabitants of the soil and ambient waters (e.g., lakes, rivers and estuaries), as well as in the gastrointestinal tract of animals. A few of these coliforms (fecal coliforms, including *Escherichia coli* or *E. coli*<sup>15</sup>) only grow within the intestinal tract of humans and other warm-blooded animals. Total coliforms may be injured by environmental stresses (e.g., lack of nutrients) and water treatment (e.g., chlorine disinfection) in a manner similar to most bacterial pathogens and many virus pathogens. Therefore, EPA considers them a useful indicator of bacterial and many viral waterborne enteric pathogens. More specifically, for drinking water, total coliforms are used to determine the adequacy of water treatment and the integrity of the distribution system. The absence of total coliforms in the distribution system minimizes the likelihood that fecal pathogens are present. Thus, total coliforms are used to determine the vulnerability of a system to fecal contamination.

The 1989 TCR set an MCLG of zero for total coliforms because EPA was not aware of any data in the scientific literature supporting a particular value for the concentration of coliforms below which no known or anticipated adverse health effects occur, with an adequate margin of safety. The TCR requires systems to monitor for total coliforms at a frequency proportional to the number of people served. If any sample is total coliform-positive, the system must:

- Test the positive culture for the presence of either fecal coliforms or *E. coli*;
- Take one set of 3–4 repeat samples at sites located within five or fewer sampling sites adjacent to the location of the routine positive sample within 24 hours; and
- Take at least 5 routine samples the next month of operation.

##### 2. Technical Reviews

Since the TCR was promulgated in 1989, few technical papers on the

<sup>15</sup> EPA is aware that *Escherichia coli* O157 may be found in fecally contaminated drinking water. To date, however, none of the EPA-approved methods for *E. coli* and fecal coliforms in drinking water detect *E. coli* O157. Nevertheless, *E. coli* O157, as is true with nonpathogenic *E. coli* strains, is always associated with fecal waste (outside the laboratory) and should be as susceptible to disinfection as the nonpathogenic strains. Therefore, the presence of *E. coli* O157 should always be accompanied by other *E. coli* strains that are detectable by the EPA-approved methods.

occurrence of coliforms in treated water have been published. Much of the recent technical data on coliforms are associated with biofilm studies, specifically the factors that facilitate the growth of coliforms and other microbes within the distribution system (e.g., LeChevallier *et al.*, 1991, 1996; LeChevallier, 1999). In addition, several studies have been published describing the performance of new coliform methods (e.g., Brenner *et al.*, 1993; Grant, 1997).

One recent study examined the relationship between total coliforms and waterborne disease outbreaks (Craun *et al.*, 1997). According to the study results, coliforms were found in 84 percent of the 187 systems during an outbreak investigation, but in the months before any outbreak, they were only detected by 26 percent of these systems. For outbreaks caused by *Cryptosporidium* or *Giardia*, coliforms were only found during 38 percent of the outbreaks. The study, as well as data from the 1993 outbreak of waterborne cryptosporidiosis in Milwaukee (MacKenzie, *et al.*, 1994), continues to support the premise that coliforms are an inadequate indicator for *Cryptosporidium* oocysts and *Giardia* cysts in treated waters, presumably because these protozoa are appreciably more resistant to disinfection than the coliform indicators.

Since promulgation of the TCR, EPA has received comments from a number of stakeholders. Stakeholders have suggested modifications to reduce the burden of implementing the TCR. EPA has determined that an opportunity for implementation burden reduction exists and will analyze the effect that such changes would have on public health protection as part of the Agency's regulatory development/revision process. Only those measures which reduce the TCR implementation burden while still assuring public health protection will be considered by EPA.

##### 3. Preliminary Decision

EPA intends to undertake a rulemaking process to initiate possible revisions to the TCR. As part of this process, EPA believes it may be appropriate to include this rulemaking in a wider effort to review and address broader issues associated with drinking water distribution systems. This would be one way of addressing some of the recommendations of the Microbial/Disinfection Byproducts (M/DBP) Federal Advisory Committee in the Stage 2 M/DBP Agreement in Principle (65 FR 83015, December 29, 2000 (USEPA, 2000h)). As part of the TCR rulemaking, EPA plans to assess the

effectiveness of the current TCR in reducing public health risk, and what technically supportable alternative/additional monitoring strategies are available that would decrease economic burden while maintaining or improving public health protection.

**VI. Request for Comments**

*A. On Which Issues Is EPA Soliciting Public Comment?*

Today's action solicits public comment on the following broad issues.

(1) Is EPA's protocol for the review of the 69 NPDWRs discussed in today's action reasonable and appropriate?

(2) Based on the review, are EPA's revise/not revise conclusions appropriate for each of the 69 NPDWRs?

EPA also invites commenters to submit any new, relevant peer-reviewed data pertaining to the NPDWRs discussed in today's action. Peer-reviewed data are studies/analyses that have been reviewed by qualified individuals (or organizations) who are independent of those who performed the work, but who are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. A peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate

interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific major scientific and/or technical work products and of the documentation that supports them (USEPA, 2000i). Relevant data include studies/analyses pertaining to health effects, analytical feasibility, treatment feasibility, and occurrence/exposure related to the contaminants discussed in today's action.

Table VI-1 summarizes the specific comments requested in today's action and provides a cross reference to the section of today's action where the issue is discussed.

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Description of the Public Input Requested	Corresponding section in Notice pertaining to request
(1) Reasonableness and appropriateness of EPA's protocol	Section IV
(2) Validity of EPA's methodology and assumptions for estimating occurrence and suitability of using a national extrapolation	Section IV.B.5
(3) Appropriateness of EPA's revise/not revise decisions	Section V
(4) Merit of gathering better data on which to recalculate the PQL for dichloromethane.	Section V.A.26
(5) Occurrence data for oxamyl at levels between 0.007 and 0.2 mg/L	Section V.A.50

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EPA also invites commenters to submit any new, relevant peer-reviewed data pertaining to the NPDWRs discussed in today's action.

*B. Request for Comments on Use of Plain Language*

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. We invite your comments on how to make this action easier to understand. For example:

- Have we organized the material to suit your needs?
- Are the decisions in the notice and our rationale for those decisions clearly stated?
- Does the notice contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the notice easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the notice easier to understand?

**VII. EPA's Next Steps**

EPA plans a 60-day comment period following this action. For each NPDWR for which the Agency has published its preliminary revise/not revise decision in today's action, EPA will consider the public comments received and review any new peer-reviewed data submitted in support of those public comments to determine whether a different revise/not revise decision is appropriate in light of the submitted data. The Agency plans to publish its final revise/not revise decisions for these NPDWRs in the August 2002 time frame.

The publication of a decision to revise pursuant to SDWA Section 1412(b)(9) is not the end of the regulatory process, but is the beginning of one. A decision to revise starts a regulatory process for a contaminant that involves more detailed analyses concerning health effects, costs, benefits, occurrence, and other matters relevant to deciding whether and how an NPDWR should be revised. At any point in this process, EPA may find that regulatory revisions are no longer appropriate and may discontinue regulatory revision efforts at that time. Review of that contaminant

would continue in future six-year reviews.

Similarly, a decision not to revise at this time means only that EPA does not believe that regulatory changes to a particular NPDWR are appropriate now, based on lack of new data, ongoing scientific reviews, low priority, or other reasons discussed in this action. Review of these contaminants continues and future six-year reviews may lead to a decision that regulatory changes are appropriate.

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Dated: March 28, 2002.

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### Appendix A: Background on the Calculation of MCLG and Cancer Classification System

Since the identification of contaminants for potential revision may be dependent on whether or not the maximum contaminant level goal (MCLG) could change, a brief explanation of the derivation of the MCLG is warranted. The MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse health effects occur, allowing for an adequate margin of safety. MCLGs are non-enforceable health goals. EPA establishes the maximum contaminant level (MCL) based on the MCLG. The MCL is the maximum permissible level of a contaminant in water which is delivered to any user of a public water system. It is derived based on the MCLG. Prior to the 1996 Amendments to the Safe Drinking Water Act (SDWA), the MCL was set as close to the MCLG as is feasible, taking costs into consideration. The 1996 Amendments to the SDWA permit consideration of costs relative to benefits in establishing a MCL. MCLs are enforceable standards.

For chemicals exhibiting a threshold for toxic effects, EPA establishes the MCLG on the basis of an oral reference dose (RfD). A change in the RfD could lead to a change in the MCLG and thus in the MCL. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime. The RfD is derived as follows:

$$\text{RfD} = \frac{\text{NOAEL or LOAEL or BMD}}{\text{UF} \times \text{MF}}$$

Where:

NOAEL = no-observed-adverse-effect level

LOAEL = lowest-observed-adverse-effect level

BMD = benchmark dose

UF = uncertainty factor

MF = modifying factor

The benchmark dose (BMD) is the statistical lower confidence limit on the dose estimated to produce a predetermined level of change (i.e., 10 percent) in the critical response relative to the control. The uncertainty factor (UF) is used to account for extrapolation uncertainties (e.g., inter-individual variation, interspecies differences, duration of exposure, and use of a LOAEL instead of a NOAEL) and database adequacy. The modifying factor (MF) is used as a judgment factor to account for the confidence in the critical study (or studies) used in the derivation of the RfD (USEPA, 2000f).

The MCLG is then derived from the RfD as follows:

$$\text{MCLG} = \frac{\text{RfD} \times \text{bw} \times \text{RSC}}{\text{I}}$$

Where:

bw = body weight (70 kg for adult<sup>16</sup>)

RSC = relative source contribution, the fraction of the RfD allocated to drinking water

I = daily drinking water intake (2 liters for adults<sup>16</sup>)

The relative source contribution (RSC) is one factor which will determine how much a change in the RfD will lead to a change in the MCLG. RSC refers to the method of accounting for human exposure from multiple sources when setting health-based criteria. The purpose of the RSC is to ensure that the level of a chemical allowed by a criterion or multiple criteria, when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD. The policy of considering multiple sources of exposure when deriving health-based criteria has become common in EPA's risk characterizations, as well as criteria and standard-setting actions. The drinking water program has applied a ceiling level of 80 percent of the RfD and a floor level of 20 percent of the RfD. That is, the MCLG cannot account for more than 80 percent of the RfD, nor less than 20 percent of the RfD. EPA applies an RSC factor of 20 percent to the RfD when adequate exposure data do not exist.

EPA has now revised its RSC method to improve consistency when considering non-water sources of exposure (both ingestion exposures (e.g., food) and exposures other than the oral route (e.g., inhalation)). The approach is called the Exposure Decision Tree. RSC estimates will be made by EPA using this approach, which allows for use of either subtraction or percentage methods, depending on chemical-specific circumstances, within the 20 to 80 percent range described in the previous paragraph. For a detailed discussion on the revised approach, refer to the "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" (USEPA, 2000f).

It has also been the Agency policy to apply an additional safety factor to the RfD for chemicals with equivocal evidence of carcinogenicity. This practice is another factor that must be evaluated to determine the impact of a change in RfD on the MCLG.

For drinking water contaminants regulated prior to the 1996 SDWA, EPA's Office of Water (OW) followed a three-category regulatory cancer classification system (Categories I, II, or III). These categories specify decisions

as to degree of concern for an agent's carcinogenic potential as a contaminant of drinking water, and define to some extent the approach to risk management which is taken for establishing MCLGs. Categories I, II, and III are designations not defined in guidelines but which reflect OW policy.

EPA used the six alphanumeric categories (A, B1, B2, C, D, E) of the 1986 cancer guidelines (51 FR 33992, September 24, 1986 (USEPA, 1986b)) in establishing the MCLG. The six-group classification system is often equated to the three-category system in the National Primary Drinking Water Regulation (NPDWR) Federal Register announcements. Table A-1 describes the three categories and, with few exceptions (e.g., beryllium), their usual equivalent alphanumeric classification. If a chemical is a known or probable human carcinogen (Category I, generally Group A or B), the MCLG is generally set at zero because it is assumed, in the absence of other data, that there is no known threshold for carcinogenicity. If a chemical falls in Group C, an RfD approach along with an additional safety (risk management) factor is used in deriving the MCLG. The methodology used for establishing MCLGs for chemicals with varying degrees of evidence of carcinogenicity is also briefly described in Table A-1.

Recent Agency assessments also use the 1996 Proposed Guidelines for Carcinogen Risk Assessment (61 FR 17960, April 23, 1996 (USEPA, 1996)) or the draft revised Guidelines for Carcinogen Risk Assessment (USEPA, 1999b). The proposed guidelines use standard descriptors as part of the hazard narrative to express the weight-of-evidence for carcinogenic hazard potential. The 1996 descriptors are in three categories: "Known/likely," "cannot be determined," and "not likely." Subdescriptors are provided under these categories to further differentiate an agent's carcinogenic potential. The new descriptors permit consideration of exposure route and mode of action when making an assessment of carcinogenicity. The hazard descriptors of the 1996 proposed Guidelines are given in the text to this action whenever appropriate. None of the chemicals discussed in this action have been evaluated under the 1999 draft revised Guidelines for Carcinogen Risk Assessment.

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<sup>16</sup> The MCLG for nitrite was based on a 4 kg body weight and a 0.64 liter drinking water intake for infants because they are the group most sensitive to the critical effect.

<b>Table A-1: Cancer Classification Systems Used by EPA</b>	
<b>Three-category regulatory approach for establishing MCLGs</b>	<b>Corresponding five-group classification system of 1986 Cancer Guidelines</b>
<b>MCLG generally set at zero</b>	
<b>Category I</b> <b>Known or probable human carcinogens:</b> <b>Strong evidence of carcinogenicity</b> Sufficient human or animal evidence of carcinogenicity.	<b>Generally Group A or Group B</b> <b>A: Human carcinogen</b> Sufficient evidence from epidemiological studies to support a causal association. <b>B: Probable human carcinogen</b> <b>B1:</b> Limited evidence of carcinogenicity from epidemiological studies. <b>B2:</b> Inadequate evidence or no data from epidemiological studies; sufficient evidence from animal studies.
<b>MCLG based on the RfD with an additional safety factor of up to 10 to account for possible carcinogenicity, or is based on excess cancer risk range of 10<sup>-5</sup> to 10<sup>-6</sup></b>	
<b>Category II</b> <b>Limited evidence of carcinogenicity</b> Some limited but insufficient evidence of carcinogenicity from animal data.	<b>Generally Group C</b> <b>Possible human carcinogen</b> Limited evidence of carcinogenicity in animals in the absence of human data.
<b>MCLG established using the RfD approach</b>	
<b>Category III</b> <b>Inadequate or no evidence of carcinogenicity in animals</b>	<b>Group D or Group E</b> <b>D: Not classifiable as to human carcinogenicity</b> Inadequate human and animal evidence of carcinogenicity, or no data available. <b>E: Evidence of non-carcinogenicity for humans</b> No evidence of carcinogenicity in two different animal species, or in both epidemiological and animal studies.

Sources: 51 *FR* 33992, September 24, 1986 (USEPA, 1986b); and 57 *FR* 31776, July 17, 1992 (USEPA, 1992).