6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2016-0627; FRL xxxx-xx]

RIN 2040-ZA26

National Primary Drinking Water Regulations; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issues

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for comments.

SUMMARY: The Safe Drinking Water Act (SDWA) requires the U. S. Environmental Protection Agency (EPA) to conduct a review every six years of existing national primary drinking water regulations (NPDWRs) and determine which, if any, need to be revised. The purpose of the review, called the Six-Year Review, is to evaluate current information for regulated contaminants to determine if there is new information on health effects, treatment technologies, analytical methods, occurrence and exposure, implementation and/or other factors that provides a health or technical basis to support a regulatory revision that will improve or strengthen public health protection. EPA

has completed a detailed review of 76 NPDWRs and at this time has determined that eight NPDWRs are candidates for regulatory revision. The eight NPDWRs are included in the Stage 1 and the Stage 2 Disinfectants and Disinfection Byproducts Rules, the Surface Water Treatment Rule, the Interim Enhanced Surface Water Treatment Rule and the Long Term 1 Enhanced Surface Water Treatment Rule. EPA requests comments on the eight NPDWRs identified as candidates for revision and will consider comments and data as it proceeds with determining whether further action is needed. In addition, as part of this Six-Year Review, EPA identified 12 other NPDWRs that were or continue to be addressed in recently completed, ongoing or pending regulatory actions. EPA thus excluded those 12 NPDWRs from detailed review. This notice is not a final regulatory decision, but rather the initiation of a process that will involve more detailed analyses of factors relevant to deciding whether a rulemaking to revise an NPDWR should be initiated.

DATES: Comments must be received on or before [60 days after publication in the Federal Register].

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2016-0627, to the *Federal eRulemaking Portal:* http://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located

outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit http://www2.epa.gov/dockets/commenting-epa-dockets.

Mail: Water Docket, Environmental Protection Agency, Mail code: 2822T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

Hand Delivery: EPA Docket Center Public Reading Room, EPA Headquarters West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. Hand deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

FOR FURTHER INFORMATION CONTACT: For technical inquiries contact: Richard Weisman, (202) 564–2822, or Kesha Forrest, (202) 564-3632, Office of Ground Water and Drinking Water, Environmental Protection Agency. For general 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 10 a.m. to 5:30 p.m. Eastern Time.

ABBREVIATIONS AND ACRONYMS USED IN THIS ACTION

ADWR–Aircraft Drinking Water Rule

AGI–Acute Gastrointestinal Illness

AOC–Assimilable Organic Carbon

ASDWA–Association of State Drinking Water Administrators

ATSDR–Agency for Toxic Substances and Disease Registry

AWWA–American Water Works Association

BAT–Best Available Technology

CBI–Confidential Business Information

CDC–Centers for Disease Control and Prevention

CFR–Code of Federal Regulations

CT–Concentration x Contact Time

cVOCs–Carcinogenic Volatile Organic Compounds

CWS–Community Water System

DBCP–1,2-Dibromo-3-Chloropropane

DBP–Disinfection Byproducts

D/DBP–Disinfectants/Disinfection Byproducts

D/DBPR–Disinfectants/Disinfection Byproducts Rule

DEHA–Di(2-ethylhexyl)adipate

DEHP–Di(2-ethylhexyl)phthalate

DOC–Dissolved Organic Carbon

DPD–*N*,*N*-diethyl-*p*-phenylenediamine

EDB–Ethylene Dibromide

EJ–Environmental Justice

EO–Executive Order

EPA–U. S. Environmental Protection Agency

EQL–Estimated Quantitation Level

FAC–Federal Advisory Committee

FBRR–Filter Backwash Recycling Rule

FDA–U.S. Food and Drug Administration

FRN–Federal Register Notice

GAC–Granulated Activated Carbon

GWR–Ground Water Rule

GWUDI–Ground Water Under the Direct Influence of Surface Water

HAA5–Haloacetic Acids (five) (sum of monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid and dibromoacetic acid)

HAAs–Haloacetic Acids

HAV–Hepatitis A Virus

HPC–Heterotrophic Plate Count

IARC–International Agency for Research on Cancer

ICR–Information Collection Request

IESWTR–Interim Enhanced Surface Water Treatment Rule

IRIS–Integrated Risk Information System

LT1–Long-Term 1 Enhanced Surface Water Treatment Rule

LT2–Long-Term 2 Enhanced Surface Water Treatment Rule

MCL–Maximum Contaminant Level

MCLG–Maximum Contaminant Level Goal

MDBP–Microbial and Disinfection Byproducts

MDL–Method Detection Limit

MRDL–Maximum Residual Disinfectant Level

MRDLG–Maximum Residual Disinfectant Level Goal

MRL–Minimum Reporting Level

NAS–National Academy of Sciences

NCWS–Non-Community Water System

NDMA–N-Nitrosodimethylamine

NDWAC–National Drinking Water Advisory Council

NIH–National Institutes of Health

NPDWR–National Primary Drinking Water Regulation

NRC–National Research Council

NTNCWS–Non-Transient Non-Community Water System

NTP–National Toxicology Program

PCBs–Polychlorinated Biphenyls

PCE–Tetrachloroethylene

PHS–U.S. Public Health Service

PT–Proficiency Testing

PQL–Practical Quantitation Limit

PWS–Public Water System

qPCR–Quantitative Polymerase Chain Reaction

RfD–Reference Dose

RICP–Research and Information Collection Partnership

RSC–Relative Source Contribution

RTCR–Revised Total Coliform Rule

SDWA–Safe Drinking Water Act

SMCL–Secondary Maximum Contaminant Level

SOC–Synthetic Organic Chemical

SWTR–Surface Water Treatment Rule

SWTRs–Surface Water Treatment Rules (including SWTR, IESWTR and LT1)

SYR–Six-Year Review

TCE–Trichloroethylene

TC/EC–Total Coliforms/*E. coli*

TCR–Total Coliform Rule

THM–Trihalomethanes

TTHM–Total Trihalomethanes (sum of four THMs: chloroform, bromodichloromethane, dibromochloromethane and bromoform)

TNCWS–Transient Non-Community Water System

TOC–Total Organic Carbon

TT–Treatment Technique

UCFWR–Uncovered Finished Water Reservoirs

UCMR–Unregulated Contaminant Monitoring Rule

USGS–U.S. Geological Survey

UV–Ultraviolet

WBDOSS–Waterborne Disease Outbreak Surveillance System

WHO–World Health Organization

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

This action itself does not impose any requirements on individual people or entities. Instead, it notifies interested parties of EPA's review of existing national primary drinking water regulations (NPDWRs) and its conclusions about which of these NPDWRs may warrant new regulatory action at this time. EPA requests public comment on the eight NPDWRs identified as candidates for revision. EPA will consider comments received as the Agency moves forward with determining whether regulatory actions are necessary for the eight NPDWRs.

B. What Should I Consider as I Prepare My Comments for EPA?

Please see Section VII for the topic areas related to this notice for which EPA requests comment and/or information. EPA will accept written or electronic comments (please do not send both). Instructions for submitting comments can be found in the **ADDRESSES** section of this notice. EPA prefers electronic comments. No facsimiles (faxes) will be accepted. Commenters who want EPA to acknowledge receipt of their written comments should also send a self-addressed, stamped envelope.

You may find the following suggestions helpful when preparing your comments:

- Explain your views as clearly as possible.
- Describe any assumptions that you used.
- Provide any technical information and/or data you used that support your views.
- If you estimate potential burden or costs, explain how you arrived at your estimate.

- Provide specific examples to illustrate your concerns.
- Offer alternatives.
- Make sure to submit your comments by the comment period deadline.

To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provide the name, date, and volume / page numbers of the *Federal Register* notice you are commenting on.

II. Six-Year Review - Statutory Requirements and Next Steps

Under the Safe Drinking Water Act (SDWA), as amended in 1996, EPA must periodically review existing NPDWRs and, if appropriate, revise them. Section 1412(b)(9) of the SDWA states: "The Administrator shall, not less often than every six 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 1996 SDWA Amendments, EPA completed and published the results of its first Six-Year Review (Six-Year Review 1) on July 18, 2003 (68 FR 42908, USEPA, 2003b) and the second Six-Year Review (Six-Year Review 2) on March 29, 2010 (75 FR 15500, USEPA, 2010h), after developing a systematic approach, or protocol, for the review of NPDWRs.

In this notice EPA is announcing the results of the third Six-Year Review (Six-Year Review 3). Consistent with the process applied in the Six-Year Review 2, EPA is requesting comments on this notice and will consider the public comments and/or any new, relevant data submitted for the

eight NPDWRs listed as candidates for revision as the Agency proceeds with determining whether revisions of these regulations are necessary. The announcement whether or not the Agency intends to revise an NPDWR (pursuant to SDWA §1412(b)(9)) is not a regulatory decision. Instead, it initiates a process that will involve more detailed analyses of health effects, analytical and treatment feasibility, occurrence, benefits, costs and other regulatory matters relevant to deciding whether a rulemaking to revise an NPDWR should be initiated. The Six-Year Review results do not obligate the Agency to revise an NPDWR in the event that EPA determines during the regulatory process that revisions are no longer appropriate and discontinues further efforts to revise the NPDWR. Similarly, the fact that an NPDWR has not been selected for revision means only that EPA believes that regulatory changes to a particular NPDWR are not appropriate at this time for the reasons given in this action; future reviews may identify information that leads to an initiation of the revision process.

The reasons that EPA has identified an NPDWR as a "candidate for revision" is that, at a minimum, the revision presents a meaningful opportunity to:

- Improve the level of public health protection, and/or
- Achieve cost savings while maintaining or improving the level of public health protection.

III. Stakeholder Involvement in the Six-Year Review Process

The Agency has involved interested stakeholders in the Six-Year Review 3 process. Below are examples of such involvement:

- In November 2014, EPA briefed the National Drinking Water Advisory Council (NDWAC) on the Six-Year Review protocol and the key elements of that protocol as they relate to the microbial and disinfection byproducts (MDBP) rules. The briefing included information on how EPA is implementing NDWAC's previous recommendations (NDWAC, 2000) on the Six-Year Review process in review of the MDBP rules;
- In January 2015, states provided input (through the Association of State Drinking Water Administrators (ASDWA)) on rule implementation issues related to the NPDWRs being reviewed as part of the Six-Year Review 3 (ASDWA, 2016);
- EPA initiated a series of public stakeholder meetings about the review of the Long Term 2 Enhanced Surface Water Treatment Rule (LT2). These meetings were held in accordance with the recommendation of the MDBP Federal Advisory Committee (FAC)[1] to have public meetings following the first round of monitoring under the LT2, and as a result of the Executive Order (EO) 13563 "Improving Regulation and Regulatory Review."[2] EO 13563 states that regulations shall be based "on the open exchange of information and perspectives among state, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole."

[1] https://www.epa.gov/sites/production/files/2015-11/documents/stage_2_m-dbp_agreement_in_principle.pdf.

[2] EO 13563 requires federal agencies to "consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned." The order required each federal agency to develop a plan "consistent with law and its resources and regulatory priorities." https://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf.

Some affected stakeholders recommended that EPA include the LT2 among the Agency's top priorities for review under EO 13563. EPA included the LT2 in its "Improving our Regulations: Final Plan for Periodic Retrospective Review of Existing Regulations" (USEPA, 2011). EPA agreed to "assess and analyze new data/information regarding occurrence, treatment, analytical methods, health effects, and risk from all relevant waterborne pathogens to evaluate whether there are new or additional ways to manage risk while assuring equivalent or improved protection, including with respect to the covering of finished water reservoirs" (USEPA, 2011). EPA hosted three public meetings in Washington, D.C., on December 7, 2011, April 24, 2012 and November 15, 2012. EPA presented information about: the LT2 requirements, monitoring data collected under the LT2, analytical methods, forecasts about the second round of monitoring and the treatment technique requirements. In addition to presentations to educate the public, the meetings included public statements, panel discussions, question and answer sessions and requests by EPA to provide data and information about the implementation of the LT2 to inform the regulatory review.

IV. Regulations Included in the Six-Year Review 3

Table IV-1 lists all 88 NPDWRs established to date. The table also reports the maximum contaminant level goal (MCLG) and the maximum contaminant level (MCL). The MCLG is "set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" (SDWA §1412(b)(4)). The MCL is the maximum permissible level of a contaminant in water delivered to any user of a public water system (PWS) and generally

"is as close to the maximum contaminant level goal as is feasible" (SDWA §1412(b)(4)(B)).[3] Where it is not "economically or technically feasible" to set an MCL, EPA can establish a treatment technique (TT), which must prevent adverse health effects "to the extent feasible" (SDWA §1412(b)(7)(A)). In the case of disinfectants (e.g., chlorine, chloramines and chlorine dioxide), the values reported in the table are not MCLGs and MCLs, but maximum residual disinfectant level goals (MRDLGs) and maximum residual disinfectant levels (MRDLs).

Table IV-1 also includes NPDWRs that EPA identified as candidates for revision in past Six-Year Reviews. During the Six-Year Review 1, EPA identified the Total Coliform Rule (TCR) as a candidate for revision[4]. EPA published the Revised Total Coliform Rule (RTCR) in 2013 (78 FR 10270, USEPA, 2013a). Four additional NPDWRs for acrylamide, epichlorohydrin, tetrachloroethylene (PCE) and trichloroethylene (TCE) were identified as candidates for revision during the Six-Year Review 2. Of the 88 NPDWRs, EPA identified 12 as part of recently completed, ongoing or pending regulatory actions; as a result, these 12 are not subject to a detailed review for the Six-Year Review 3. This action involves the remaining 76 NPDWRs. EPA applied the same protocol used for previous Six-Year Reviews, with minor clarifications (USEPA, 2016f), to the Six-

[3] Under limited circumstances, SDWA §1412(b)(6)(A) also gives the Administrator the discretion to promulgate an MCL that is less stringent than the feasible level and that "maximizes health risk reduction benefits at a cost that is justified by the benefits."

[4] The NPDWRs apply to specific contaminants/parameters or groups of contaminants. Historically, when issuing new or revised standards for these contaminants/parameters, EPA has often grouped the standards together in more general regulations, such as the Total Coliform Rule, the Surface Water Treatment Rule or the Phase V rules. In this action, however, for clarity, EPA discusses the drinking water standards as they apply to each specific regulated contaminant/parameter (or group of contaminants), not the more general regulation in which the contaminant/parameter was regulated.

Year Review 3 process. Section V of this action describes the revised protocol used for the Six-Year Review 3 and Section VI describes the results of the review of the NPDWRs.

In addition to the regulated chemicals, radiological and microbiological contaminants included in the previous reviews, this notice also includes the review of the MDBP regulations that were promulgated under the following actions: the Ground Water Rule (GWR); the Surface Water Treatment Rules (SWTRs); the Disinfectants and Disinfection Byproducts (D/DBP) Rules; and the Filter Backwash Recycling Rule (FBRR). EPA reviewed the LT2 in response to EO 13563 (USEPA, 2011) and as part of the Six-Year Review 3 process.

Table IV-1. NPDWRs Included in Six-Year Review 3

Contaminants/ Parameters	MCLG (mg/L)[1, 3]	MCL or TT (mg/L)[1,2, 3]	Contaminants/ Parameters	MCLG (mg/L)[1, 3]	MCL or TT (mg/L)[2, 3]
Acrylamide	0	TT	Ethylbenzene	0.7	0.7
Alachlor	0	0.002	Ethylene dibromide (EDB)	0	0.00005
Alpha/photon emitters	0 (pCi/L)	15 (pCi/L)	Fluoride	4.0	4.0
Antimony	0.006	0.006	*Giardia lamblia*[4]	0	TT
Arsenic	0	0.01	Glyphosate	0.7	0.7
Asbestos	7 (million fibers/L)	7 (million fibers/L)	Haloacetic acids (HAA5)	n/a[5]	0.06
Atrazine	0.003	0.003	Heptachlor	0	0.0004
Barium	2	2	Heptachlor epoxide	0	0.0002
Benzene	0	0.005	Heterotrophic bacteria[6]	n/a	TT
Benzo[a]pyrene	0	0.0002	Hexachlorobenzene	0	0.001
Beryllium	0.004	0.004	Hexachlorocyclopentadiene	0.05	0.05
Beta/photon emitters	0 (millirems /yr)	4 (millirems /yr)	Lead	0	TT
Bromate	0	0.01	*Legionella*	0	TT
Cadmium	0.005	0.005	Lindane	0.0002	0.0002
Carbofuran	0.04	0.04	Mercury (inorganic)	0.002	0.002
Carbon tetrachloride	0	0.005	Methoxychlor	0.04	0.04
Chloramines	4	4	Monochlorobenzene (Chlorobenzene)	0.1	0.1
Chlordane	0	0.002	Nitrate (as N)	10	10
Chlorine	4	4	Nitrite (as N)	1	1
Chlorine dioxide	0.8	0.8	Oxamyl (Vydate)	0.2	0.2

Chlorite	0.8	1	Pentachlorophenol	0	0.001
Chromium (total)	0.1	0.1	Picloram	0.5	0.5
Copper	1.3	TT	Polychlorinated biphenyls (PCBs)	0	0.0005
Cryptosporidium	0	TT	Radium	0 (pCi/L)	5 (pCi/L)
Cyanide	0.2	0.2	Selenium	0.05	0.05
2,4-Dichlorophenoxyacetic acid (2,4-D)	0.07	0.07	Simazine	0.004	0.004
Dalapon	0.2	0.2	Styrene	0.1	0.1
Di(2-ethylhexyl)adipate (DEHA)	0.4	0.4	2,3,7,8-TCDD (Dioxin)	0	3.00E-08
Di(2-ethylhexyl)phthalate (DEHP)	0	0.006	Tetrachloroethylene	0	0.005
1,2-Dibromo-3-chloropropane (DBCP)	0	0.0002	Thallium	0.0005	0.002
1,2-Dichlorobenzene (o-Dichlorobenzene)	0.6	0.6	Toluene	1	1
1,4-Dichlorobenzene (p-Dichlorobenzene)	0.075	0.075	Total coliforms (under ADWR[7] and RTCR[8])	n/a	TT
1,2-Dichloroethane (Ethylene dichloride)	0	0.005	Total Trihalomethanes (TTHM)	n/a[9]	0.08
1,1-Dichloroethylene	0.007	0.007	Toxaphene	0	0.003
cis-1,2- Dichloroethylene	0.07	0.07	2,4,5-TP (Silvex)	0.05	0.05
trans-1,2- Dichloroethylene	0.1	0.1	1,2,4-Trichlorobenzene	0.07	0.07
Dichloromethane (Methylene chloride)	0	0.005	1,1,1-Trichloroethane	0.2	0.2
1,2-Dichloropropane	0	0.005	1,1,2-Trichloroethane	0.003	0.005
Dinoseb	0.007	0.007	Trichloroethylene	0	0.005
Diquat	0.02	0.02	Turbidity[6]	n/a	TT
E. coli	0	MCL[10] and TT[8]	Uranium	0	0.030
Endothall	0.1	0.1	Vinyl Chloride	0	0.002
Endrin	0.002	0.002	Viruses	0	TT
Epichlorohydrin	0	TT	Xylenes (total)	10	10

1. MCLG: the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety.
2. MCL: the maximum level allowed of a contaminant in water which is delivered to any user of a public water system.
   TT: an enforceable procedure or level of technological performance which public water systems must follow to ensure control of a contaminant.
3. Units are in milligrams per liter (mg/L) unless otherwise noted. Milligrams per liter are equivalent to parts per million. For chlorine, chloramines and chlorine dioxide, values presented are MRDLG and MRDL.
4. The current preferred taxonomic name is *Giardia duodenalis*, with *Giardia lamblia* and *Giardia intestinalis* as synonymous names. However, *Giardia lamblia* was the name used to establish the MCLG in 1989. Elsewhere in this document, this pathogen will be referred to as *Giardia* spp. or simply *Giardia* unless discussing information on an individual species.
5. There is no MCLG for all five haloacetic acids. MCLGs for some of the individual contaminants are: dichloroacetic acid (zero), trichloroacetic acid (0.02 mg/L), and monochloroacetic acid (0.07 mg/L). Bromoacetic acid and dibromoacetic acid are regulated with this group, but have no MCLGs.
6. Includes indicators that are used in lieu of direct measurements (e.g., of heterotrophic bacteria, turbidity).
7. The Aircraft Drinking Water Rule (ADWR) 40 CFR Part 141 Subpart X, promulgated October 19, 2009, covers total coliforms.
8. Under the RTCR, a PWS is required to conduct an assessment if it exceeded any of the TT triggers identified in 40 CFR §141.859(a). It is also required to correct any sanitary defects found through the assessment.
9. There is no MCLG for total trihalomethanes (TTHM). MCLGs for some of the individual contaminants are: bromodichloromethane (zero), bromoform (zero), dibromochloromethane (0.06 mg/L), and chloroform (0.07 mg/L).
10. A PWS is in compliance with the *E. coli* MCL unless any of the conditions identified under 40 CFR §141.63(c) occur.

V. EPA's Protocol for Reviewing the NPDWRs Included in This Action

A. What Was EPA's Review Process?

Overview

This section provides an overview of the process the Agency used to review the NPDWRs discussed in this action. The protocol document, "EPA Protocol for the Third Review of Existing National Primary Drinking Water Regulations," contains a detailed description of the process the Agency used to review the NPDWRs (USEPA, 2016f). The foundation of this protocol was developed for the Six-Year Review 1 based on the recommendations of the NDWAC (2000). The

Six-Year Review 3 process is very similar to the process implemented during the Six-Year Review 1 and the Six-Year Review 2, with some clarifications to the elements related to the review of NPDWRs included in the MDBP rules. Figure V-1 presents an overview of the Six-Year review protocol and review outcomes.

The primary goal of the Six-Year Review process is to identify and prioritize NPDWRs for possible regulatory revision. The two major outcomes of the detailed review are either:

1. The NPDWR is not appropriate for revision and no action is necessary at this time.
2. The NPDWR is a candidate for revision.

The reasons for a Six-Year Review outcome of "not appropriate for revision at this time" can include:

- Regulatory action - recently completed, ongoing or pending. The NPDWR was recently completed, is being reviewed in an ongoing action, or is subject to a pending action.
- Ongoing or planned health effects assessment. The NPDWR has an ongoing health effects assessment (i.e., especially for those NPDWRs with an MCL set at the MCLG or where the MCL is based on the SDWA cost benefit provision), or EPA is considering whether a new health effects assessment is needed.
- No new information. EPA did not identify any new, relevant information that indicates changes to the NPDWR.
- Data gaps/emerging information. There are data gaps or emerging information that need to be evaluated.

- Low priority and/or no meaningful opportunity. New information indicates a possible change to the MCLG and/or MCL but changes to the NPDWR are not warranted due to one or more of the following reasons: (1) possible changes present negligible gains in public health protection; (2) possible changes present limited opportunity for cost savings while maintaining the same or greater level of health protection; and (3) possible changes are a low priority because of competing workload priorities, limited return on the administrative costs associated with rulemaking and the burden on states and the regulated community associated with implementing any regulatory change that would result.

Alternatively, the reasons for a Six-Year Review outcome that an NPDWR is a "candidate for revision" are that, at a minimum, the revision presents a meaningful opportunity to:

- Improve the level of public health protection, and/or
- Achieve cost savings while maintaining or improving the level of public health protection.

Individual regulatory provisions of NPDWRs that are evaluated as part of the Six-Year Review are: MCLG, MCL, MRDLG, MRDL, TT, other treatment technologies such as best available technology (BAT), and regulatory requirements, such as monitoring requirements.

For example, the microbial regulations include TT requirements because there is no reliable method that is economically and technically feasible to measure the microbial contaminants covered by those regulations. These TT requirements rely on the use of indicators that can be measured in drinking water, such as the concentration of a disinfectant, to provide public health protection. As

part of the Six-Year Review 3, EPA evaluated new information related to the use of those indicators to determine if there is a meaningful opportunity to improve the level of public health protection. Results of EPA's review of the MDBP regulations are presented in Sections VI.B.3 and VI.B.4.

For the purpose of this document (except where noted for clarity), discussions of the review of MCLGs and MCLs should be assumed to also apply to the review of MRDLGs and MRDLs for disinfectants.

Basic Principles

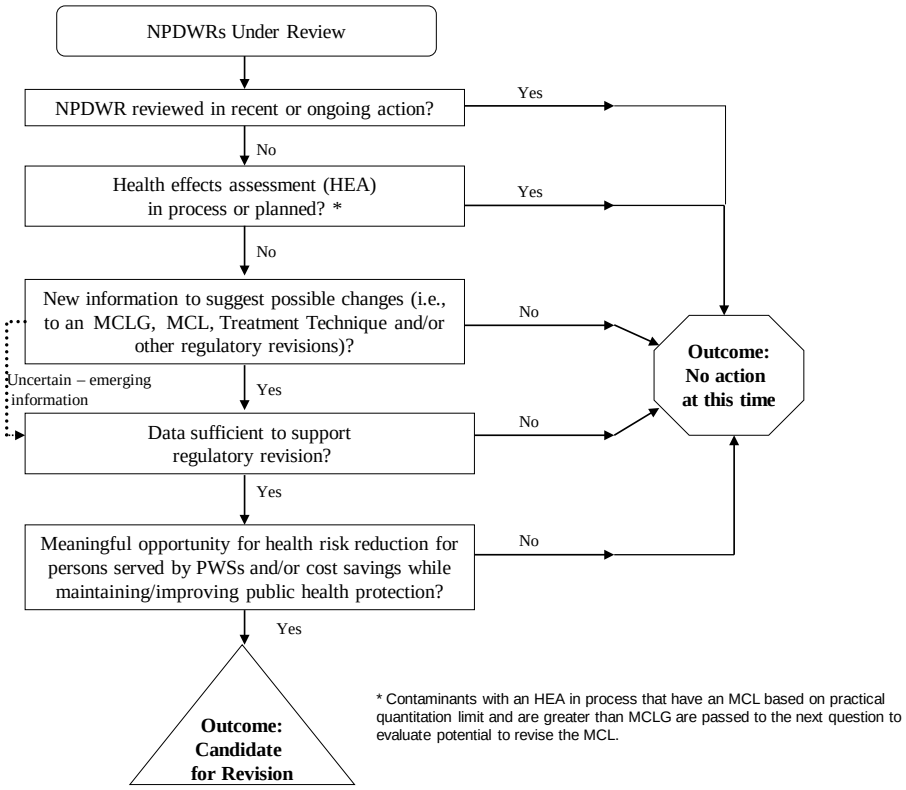
EPA applied a number of basic principles to the Six-Year Review process:

- The Agency sought to avoid redundant review efforts. Because EPA has reviewed information for certain NPDWRs as part of recently completed, ongoing or pending regulatory actions, these NPDWRs are not subject to the detailed review in this notice.
- The Agency does not believe it is appropriate to consider revisions to NPDWRs for contaminants with an ongoing or planned health effect assessment and for which the MCL is set equal to the MCLG or based on benefit-cost analysis. This principle stems from the fact that any new health effects information could affect the MCL via a change in the MCLG or the assessment of the benefits associated with the MCL. Therefore, EPA noted that these NPDWRs are not appropriate for revision and no action is necessary at this time if the health effects assessment would not be completed during the review period for each contaminant that has either an MCL that is equal to its MCLG or an MCL that is based on the 1996 SDWA Amendments' cost-benefit provision. If the health

effects assessment is completed before the next Six-Year Review, EPA will consider these NPDWRs at that time.

- In evaluating the potential for new information to affect NPDWRs, EPA assumed no change to existing policies and procedures for developing NPDWRs. For example, in determining whether new information affected the feasibility of analytical methods for a contaminant, the Agency assumed no change to current policies and procedures for calculating practical quantitation levels.
- EPA considered new information from health effects assessments that were completed by the information cutoff date. Assessments completed after this cutoff date will be reviewed by EPA during the next review cycle or (if applicable) during the revision of an NPDWR. The information cutoff date for the Six-Year Review 3 was December 2015.
- During the review, EPA identified areas where information is inadequate or unavailable (data gaps) or emerging and is needed to determine whether revision to an NPDWR is appropriate. To the extent EPA is able to fill data gaps or fully evaluate the emerging information, the Agency will consider the information as part of the next review cycle.
- EPA may consider accelerating review and potential revision for a particular NPDWR before the next review cycle when justified by new public health risk information.
- Finally, EPA assured scientific analyses supporting the review were consistent with the Agency's peer review policy (USEPA, 2015a).

Figure V-1. Six-Year Review Protocol Overview and Review Outcomes



B. *How Did EPA Conduct the Review of the NPDWRs?*

The protocol for the Six-Year Review 3 is broken down into a series of questions that can inform a decision about the appropriateness of revising an NPDWR. These questions are logically ordered into a decision tree. This section provides an overview of each of the review elements that EPA considered for each NPDWR during the Six-Year Review 3, including the following: initial review, health effects, analytical feasibility, occurrence and exposure, treatment feasibility, risk balancing and other regulatory revisions. The final review combines the findings from all of these review elements to recommend whether an NPDWR is a candidate for revision. Further information

about the review elements is described in the protocol document (USEPA, 2016f). Results from the review of these elements are presented in Section VI.

1. Initial Review

EPA's initial review of all the contaminants included in the Six-Year Review 3 involved a simple identification of the NPDWRs that have either been recently completed, or are being reviewed in an ongoing or pending action since the last Six-Year Review (cutoff date was August 2008). In addition, the initial review also identified contaminants with ongoing health effects assessments that have an MCL equal to the MCLG. Excluding such contaminants from the Six-Year Review 3 prevents duplicative agency efforts.

2. Health Effects

The principal objectives of the health effects review are to identify: (1) contaminants for which a new health effects assessment indicates that a change in the MCLG might be appropriate (e.g., because of a change in cancer classification or a change in reference dose (RfD)), and (2) contaminants for which new health effects information indicates a need to initiate a new health effects assessment.

To meet the first objective, EPA reviewed the results of health effects assessments completed before December 2015, the information cutoff date for the Six-Year Review 3.

To meet the second objective, the Agency conducted an extensive literature review to identify peer-reviewed studies published before December 2015. The Agency reviewed

the studies to determine whether there was new health effects information, such as reproductive and developmental toxicity data, that could potentially affect the MCLG, or otherwise change the Agency's understanding of the health effects of contaminants under consideration. EPA then evaluated the need to plan the initiation of a new health effects assessment.

3. Analytical Feasibility

When establishing an NPDWR, EPA identifies a practical quantitation limit (PQL), which is "the lowest achievable level of analytical quantitation during routine laboratory operating conditions within specified limits of precision and accuracy", as noted in the November 13, 1985, *Federal Register* notice (50 FR 46880, USEPA, 1985). EPA has a separate process in place to approve new analytical methods for drinking water contaminants; therefore, review and approval of potential new methods is outside the scope of the Six-Year Review protocol. EPA recognizes, however, that the approval and adoption in recent years of new and/or improved analytical methods may enable laboratories to quantify contaminants at lower levels than was possible when NPDWRs were originally promulgated. This ability of laboratories to measure a contaminant at lower levels could affect its PQL, the value at which an MCL is set when it is limited by analytical feasibility. Therefore, the Six-Year Review process includes an examination of

whether there have been changes in analytical feasibility that could possibly change the PQL for the subset of the NPDWRs that reached this stage of the review.

To determine if changes in analytical feasibility could possibly support changes to PQLs, EPA relied primarily on two alternate approaches to develop an estimated quantitation limit (EQL): an approach based on the minimum reporting levels (MRLs) obtained as part of the Six-Year Review 3 Information Collection Request (ICR), and an approach based on method detection limits (MDLs).

An MRL is the lowest level or contaminant concentration that a laboratory can reliably achieve within specified limits of precision and accuracy under routine laboratory operating conditions using a given method. The MRL values provide direct evidence from actual monitoring results about whether quantitation below the PQL using current analytical methods is feasible. An MDL is a measure of analytical method sensitivity. MDLs have been used in the past to derive PQLs for regulated contaminants.

EPA used the EQL as a threshold for occurrence analysis to help the Agency determine if there may be a meaningful opportunity to improve public health protection. It should be noted, however, that the use of an EQL does not necessarily indicate the Agency's intention to promulgate a new PQL. Any revision to PQLs will be part of

future rulemaking efforts if EPA has determined that an NPDWR is a candidate for revision.

4. Occurrence and Exposure Analysis

The occurrence and exposure analysis is conducted in conjunction with other review elements to determine if there is a meaningful opportunity to revise an NPDWR by:

- Estimating the extent of contaminant occurrence, i.e., the number of PWSs in which contaminants occur at levels of interest (health-effects-based thresholds or analytical method limits), and
- Evaluating the number of people potentially exposed to contaminants at these levels.

To evaluate national contaminant occurrence under the Six-Year Review 3, EPA reviewed data from the Six-Year Review 3 ICR database (SYR3 ICR database), the UCMR datasets (USEPA, 2016j) and other relevant sources.

For the Six-Year Review 3, EPA collected SDWA compliance monitoring data through use of an ICR (75 FR 6023, USEPA, 2010a). EPA requested that all states and primacy entities (tribes and territories) voluntarily submit their compliance monitoring data for regulated contaminants in public drinking water systems. Specifically, EPA requested the submission of compliance monitoring data and related information collected between January 2006 and December 2011 for regulated contaminants and related parameters (e.g., water quality indicators). Forty-six states plus eight primacy agencies provided data. The assembled data constitute the largest, most comprehensive set of drinking water compliance monitoring data ever compiled and analyzed by EPA

to inform decision making, containing almost 47 million records from approximately 167,000 PWSs, serving approximately 290 million people nationally. Through extensive data management efforts, quality assurance evaluations, and communications with state data management staff, EPA established the SYR3 ICR database (USEPA, 2016i). The number of states and PWSs represented in the dataset varies across contaminants because of variability in state data submissions and contaminant monitoring schedules. Except as noted in Section VI, EPA believes that these data are of sufficient quality to inform an understanding of the national occurrence of regulated contaminants and related parameters. Details of the data management and data quality assurance evaluations are available in the supporting document (USEPA, 2016q). The resulting database is available online on the Six-Year Review website (https://www.epa.gov/dwsixyearreview).

5. Treatment Feasibility

An NPDWR either identifies the BAT for meeting an MCL, or establishes enforceable TT requirements. EPA reviews treatment feasibility to ascertain if there are technologies that meet BAT criteria for a hypothetical more stringent MCL, or if there is new information that demonstrates an opportunity to improve public health protection through revision of an NPDWR TT requirement.

To be a BAT, the treatment technology must meet several criteria such as having demonstrated consistent removal of the target contaminant under field conditions. Although treatment feasibility and analytical feasibility together address the technical

feasibility requirement for an MCL, historically, treatment feasibility has not been a limiting factor for MCLs. The result of this review element is a determination of whether treatment feasibility would pose a limitation to revising an MCL or provide an opportunity to revise the TT requirement.

6. Risk-Balancing

EPA reviews risk-balancing to examine how the Six-Year Review can address tradeoffs in risks among different NPDWRs and take into account unregulated contaminants as well. Under this review, EPA considers whether a change to an MCL and/or TT will increase the public health risk posed by one or more contaminants, and, if so, the Agency considers revisions that will balance overall risks. This review element is relevant only to the NPDWRs included in the MDBP rules, which were promulgated to address risk-balancing between microbial and DBP requirements, and among differing types of DBPs. The risk-balancing approach was based on the SDWA requirements that EPA "minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants the concentrations of which may be affected by the use of a TT or process that would be employed to attain the maximum contaminant level or levels" (SDWA §1412(b)(5)(B)(i)).

EPA reviewed risk-balancing between microbial and DBP contaminants. For example, EPA considered the potential impact on DBP concentrations should there be a consideration to increase the stringency of microbial NPDWRs. This approach also was used during the development of more recent MDBP rules such as the LT2 rule and the

Stage 2 Disinfectants/Disinfection Byproducts Rule (D/DBPR) rule. In addition, EPA reviewed risk-balancing between different types of DBP contaminants. Depending on the stringency of potential DBP regulations, compliance strategies used by the regulated community might have the effect of increasing the concentrations of other types of contaminants, both regulated and unregulated. EPA considered these potential compliance strategies when conducting its Six-Year Review 3 with a goal to balance the overall health risks.

7. Other Regulatory Revisions

In addition to possible revisions to MCLGs, MCLs and TTs, EPA evaluated whether other revisions are needed to regulatory provisions, such as monitoring and system reporting requirements. EPA focused this review element on issues that were not already being addressed through alternative mechanisms, such as a recently completed, ongoing or pending regulatory action. EPA also reviewed implementation-related NPDWR concerns that were "ready" for rulemaking – that is, the problem to be resolved had been clearly identified, along with specific options to address the problem that could be shown to either clearly improve the level of public health protection, or represent a meaningful opportunity for achieving cost savings while maintaining the same level of public health protection. The result of this review element is a determination regarding whether EPA should consider revisions to the monitoring and/or reporting requirements of an NPDWR.

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

The 1996 amendments to SDWA require special consideration of sensitive life stages and populations (e.g., infants, children, pregnant women, elderly and individuals with a history of serious illness) in the development of drinking water regulations (SDWA §1412(b)(3)(C)(V)). As a part of the Six-Year Review 3, EPA completed a literature search covering developmental and reproductive endpoints (e.g., fertility, embryo survival, developmental delays, birth defects and endocrine effects) for information published as of December 2015 for regulated chemicals that had not been the subject of a health effects assessment during this review period. EPA reviewed the results of the literature searches to identify any studies that might suggest a need to revise MCLGs. These studies were considered in EPA's review of NPDWRs, which is discussed in Section VI.

D. How Did EPA Factor Environmental Justice Concerns Into the Review?

Executive Order (EO) 12898, "Federal Actions to Address Environmental Justice in Minority Populations or Low-Income Populations," establishes a federal policy for incorporating environmental justice (EJ) into federal agency missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies and activities on minority and low-income populations. EPA evaluates potential EJ concerns when developing regulations. This Six-Year Review was developed in compliance with EO 12898. Should the Six-Year Review lead to a decision to revise an NPDWR, any subsequent rulemakings will include an EJ component and an opportunity for public comment.

VI. Results of EPA's Review of NPDWRs

Table VI-1 lists the results of EPA's review for each of the 76 NPDWRs discussed in this section of this action, along with the principal rationale for the review outcomes. Table VI-1 also includes a list of the 12 NPDWRs that have been recently completed, or have ongoing or pending regulatory actions.

Table VI-1. Summary of Six-Year Review 3 Results

Not Appropriate for Revision at this Time	Recently completed, ongoing or pending regulatory action	1,2-Dichloroethane (Ethylene dichloride)	*E. coli*
		1,2-Dichloropropane	Lead
		Benzene	Tetrachloroethylene (PCE)
		Carbon Tetrachloride	Total coliforms (under ADWR and RTCR)
		Copper	Trichloroethylene (TCE)
		Dichloromethane (Methylene chloride)	Vinyl chloride
Not Appropriate for Revision at this Time[2]	Health effects assessment in process (as of December 2015) or contaminant nominated for health assessment	Alpha/photon emitters	Mercury[1]
		Arsenic	Nitrate[1]
		Atrazine	Nitrite[1]
		Benzo(a)pyrene (PAHs)	o-Dichlorobenzene[1]
		Beta/photon emitters	p-Dichlorobenzene[1]
		Cadmium[1]	Polychlorinated biphenyls (PCBs)
		Chromium	Radium
		Di(2-ethylhexyl) phthalate (DEHP)[1]	Simazine
		Ethylbenzene	Uranium[1]
		Glyphosate	
	No new information, NPDWR remains appropriate after review	1,2-Dibromo-3-chloropropane (DBCP)	Dalapon
		2,4,5 -TP (Silvex)	Di(2-ethylhexyl)adipate (DEHA)
		Antimony	Dinoseb
		Asbestos	Endrin
		Bromate	Ethylene dibromide

		Chloramines (under D/DBPR)	Pentachlorophenol
		Chlorine (under D/DBPR)	Thallium
		Chlorine dioxide	trans-1,2-Dichloroethylene
		Chlorobenzene (monochlorobenzene)	Turbidity
	Low priority and/or no meaningful opportunity	1,1,1-Trichloroethane	Epichlorohydrin
		1,1,2-Trichloroethane	Fluoride
		1,1-Dichloroethylene	Heptachlor
		1,2,4-Trichlorobenzene	Heptachlor epoxide
		2,3,7,8-TCDD (Dioxin)	Hexachlorobenzene
		2,4-D	Hexachlorocyclopentadiene
		Acrylamide	Lindane
		Alachlor	Methoxychlor
		Barium	Oxamyl (Vydate)
		Beryllium	Picloram
		Carbofuran	Selenium
		Chlordane	Styrene
		cis-1,2-Dichloroethylene	Toluene
		Cyanide	Toxaphene
		Diquat	Xylenes
		Endothall	
Candidate for Revision	New information	Chlorite	Heterotrophic Bacteria
		Cryptosporidium (under SWTR, IESWTR, LT1)	*Legionella*
		Giardia lamblia	TTHM
		Haloacetic Acids (HAA5)	Viruses (under SWTR)

1. Contaminants nominated for Integrated Risk Information System (IRIS) assessments per SYR Protocol.
2. LT2, FBRR, and GWR also identified as not appropriate for revision at this time. See Section VI.B.4 for additional information on the results of EPA's review of these regulations.

A. What Are the Review Result Categories?

For each of the 76 NPDWRs discussed in detail in the following sections of this action, the review outcomes fall in one of the following categories:

1. The NPDWR is Not Appropriate for Revision at This Time.

The current NPDWR remains appropriate and no action is necessary at this time. In this category, NPDWRs are grouped under the following subcategories:

- Health effects assessment in process (as of December 2015) or contaminant nominated for health assessment,
- No new information and NPDWR remains appropriate after review,
- Data gaps/emerging information, and
- No meaningful opportunity.

2. The NPDWR is a Candidate for Revision.

The NPDWR is a candidate for revision based on the review of new information.

B. What Are the Detailed Results of EPA's Third Six-Year Review Cycle?

1. Chemical Phase Rules/Radionuclides Rules

Background

The NPDWRs for chemical contaminants, collectively called the Phase Rules, were promulgated between 1987 and 1992 (after the 1986 SDWA amendments). In December 2000, EPA promulgated final radionuclide regulations, which were issued as interim rules in July 1976. Information related to the review for fluoride is discussed separately in Section VI.B.2.

Summary of Review Results

EPA has decided that it is not appropriate at this time to revise any of the NPDWRs covered under the Phase Rules or Radionuclide Rules. These NPDWRs were determined not to be candidates for revision for one or more of the following reasons: there was no new information to suggest possible changes in MCLG/MCL; new information did not present a meaningful opportunity for health risk reduction or cost savings while maintaining/improving public health protection; or there was an ongoing or pending regulatory action. Details related to the review of all Phase Rules and Radionuclide Rules contaminants can be found in the "Chemical Contaminant Summaries for the Third Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2016b).

Initial Review

The initial review identified 12 chemical contaminants with NPDWRs under the Chemical Phase Rules that were being considered as part of ongoing or pending regulatory actions, and 61 chemical or radionuclide NPDWRs were identified as appropriate for review. The NPDWRs with ongoing or pending regulatory actions included eight carcinogenic volatile organic compounds (cVOCs), lead, copper, acrylamide and epichlorohydrin.

In 2011, EPA announced its plans to address a group of regulated and unregulated cVOCs in a single regulatory effort. The eight regulated VOCs being currently evaluated for a potential cVOCs group regulation include: benzene; carbon tetrachloride; 1,2-dichloroethane; 1,2-dichloropropane; dichloromethane; PCE; TCE;

and vinyl chloride. The regulatory revisions to TCE and PCE, initiated as an outcome of the Six-Year Review 2, are also being considered as part of the group regulatory effort. Since a regulatory effort is ongoing for these eight contaminants, they were excluded from a detailed review as part of the third Six-Year Review.

The NPDWRs for acrylamide and epichlorohydrin were also previously identified as candidates for regulatory revision and were pending regulatory action. The polyacrylamides and epichlorohydrin-based polymers available today for water treatment have lower residual monomer content than when EPA promulgated residual content as a TT (USEPA, 2016s). For example, the 90th percentile concentration of acrylamide residual monomer levels was approximately one-half the residual level listed in the current TT and no residual epichlorohydrin was detected. The health benefits associated with the lower impurity levels are already being realized by communities throughout the country; therefore, a regulatory revision will minimally affect health risk. Given resource limitations, competing workload priorities, and administrative costs and burden to states to adopt any regulatory changes associated with the rulemaking, as well as limited potential health benefits, these NPDWRs are considered a low priority and no longer candidates for revision at this time.

EPA is also currently considering Long-Term Revisions to the Lead and Copper Rule; and therefore, evaluation of that NPDWR under the Six-Year Review process would be redundant.

Health Effects

The principal objectives of the health effects review are to identify: (1) contaminants for which a new health effects assessment indicates that a change in MCLG might be appropriate (e.g., because of a change in cancer classification or an RfD), and (2) contaminants for which the Agency has identified new health effects information suggesting a need to initiate a new health effects assessment.

Before identifying chemical NPDWR contaminants for which an updated MCLG may be appropriate, EPA first identified chemicals with ongoing or planned EPA health effects assessments. As of December 31, 2015, 19 chemical/radiological contaminants reviewed had ongoing or planned formal EPA health effects assessments. Table VI-2 below lists the 19 contaminants with ongoing or planned EPA assessments and the status of those reviews.

Table VI-2. Six-Year Review Chemical/Radiological Contaminants with Ongoing or Planned EPA Health Assessments

Chemical/Radionuclide	Status
Alpha/photon emitters	EPA is conducting a review of alpha and beta photo emitters.
Arsenic, inorganic	Inorganic arsenic is being assessed by the EPA IRIS Program. The assessment status can be found at: (https://cfpub.epa.gov/ncea/iris2/atoz.cfm).
Atrazine	Atrazine and simazine are being assessed under EPA's pesticide registration review process.
Benzo(a)pyrene	Benzo(a)pyrene is being assessed by the EPA IRIS Program. The assessment status can be found at: (https://cfpub.epa.gov/ncea/iris2/atoz.cfm).
Beta/photon emitters	EPA is conducting a review of alpha and beta photo emitters.
Cadmium	Cadmium is included in the EPA IRIS Multi-Year Agenda.
Chromium (VI) as part of total Cr)	Chromium VI is being assessed by the EPA IRIS Program. The assessment status can be found at: (https://cfpub.epa.gov/ncea/iris2/atoz.cfm).

DEHP	DEHP is included in the EPA IRIS Multi-Year Agenda.
Ethylbenzene	Ethylbenzene is being assessed by the EPA IRIS Program. The assessment status can be found at: (https://cfpub.epa.gov/ncea/iris2/atoz.cfm).
Glyphosate	GlyphosateGlyphosate is being assessed under EPA's pesticide registration review process.
Mercury	Mercury is included in the EPA IRIS Multi-Year Agenda.
Nitrate	Nitrate is included in the EPA IRIS Multi-Year Agenda.
Nitrite	Nitrite is included in the EPA IRIS Multi-Year Agenda.
o-Dichlorobenzene	o-Dichlorobenzene is included in the EPA IRIS Multi-Year Agenda.
p-Dichlorobenzene	p-Dichlorobenzene is included in the EPA IRIS Multi-Year Agenda.
PCBs	PCBs are being assessed by the EPA IRIS Program. The assessment status can be found at: (https://cfpub.epa.gov/ncea/iris2/atoz.cfm).
Radium (226, 228)	EPA is conducting a review of radium.
Simazine	Atrazine and simazine are being assessed under EPA's pesticide registration review process.
Uranium	Uranium is included in the EPA IRIS Multi-Year Agenda.

For chemicals that were not excluded due to an ongoing or planned health effects assessment by EPA, or by the National Academy of Sciences (NAS), commissioned by EPA, a more detailed review was undertaken. Of the chemicals that underwent a more detailed review, EPA identified 21 for which there have been official Agency changes in the RfD and/or in the cancer risk assessment from oral exposure or new relevant non-EPA assessments that might support a change to the MCLG. These 21 chemicals were further evaluated as part of the Six-Year Review 3 to determine whether they were candidates for regulatory revision. Table VI-3 lists the 21 chemicals with available new health effects information and the sources of the relevant new information. As shown in this table, 11 chemical contaminants have

information that could support a lower MCLG and 10 contaminants have new information that could support a higher MCLG.

Table VI-3. Chemicals with Available New Health Assessment that Could Support a Change in MCLG

Chemical	Relevant New Assessment
Potential Decrease in MCLG	
Carbofuran	USEPA,2008a (OPP)
Cyanide	USEPA,2010e (IRIS)
cis-1,2-Dichloroethyelene	USEPA, 2010d (IRIS)
Endothal	USEPA, 2005f (OPP)
Hexachloropentadiene	USEPA, 2001a (IRIS)
Methoxychlor	CalEPA 2010a
Oxamyl	USEPA, 2010f (OPP)
Selenium	Health Canada 2014
Styrene	CalEPA 2010b
Toluene	USEPA, 2005c (IRIS)
Xylenes	USEPA, 2003a (IRIS)
Potential Increase in MCLG	
Alachlor	USEPA, 2006a (OPP)
Barium	USEPA, 2005b (IRIS)
Beryllium	USEPA, 1998a (IRIS)
1,1-Dichloroethylene	USEPA, 2002b (IRIS)
2,4 Dichlorophenoxy-acetic Acid	USEPA, 2013b (OPP)
Diquat	USEPA, 2002a (OPP)
Lindane	USEPA, 2002d (OPP)
Picloram	USEPA, 1995 (OPP)
1,1,1-Trichloroethane	USEPA, 2007a (IRIS)
1,2,4-Trichlorobenzene	ATSDR, 2010

Details of the health effects review of the chemical and radiological contaminants are documented in the "Six-Year Review 3 − Health Effects Assessment for Existing Chemical and Radionuclides National Primary Drinking Water Regulations − Summary Report" (USEPA, 2016h).

Analytical Feasibility

EPA performed analytical feasibility analyses for the contaminants that reached this portion of the review. These contaminants included the 11 chemical contaminants identified under the health effects review as having potential for a lower MCLG and an additional 14 contaminants with MCLs based on analytical feasibility and MCLs higher than the current MCLGs. The document "Analytical Feasibility Support Document for the Third Six-Year Review of National Primary Drinking Water Regulations: Chemical Phase Rules and Radionuclides Rules" (USEPA, 2016a) describes the first step in the process EPA used to evaluate whether changes in PQL are possible in those instances where the MCL is limited, or may be limited, by analytical feasibility. The EQL analysis is documented in the " Development of Estimated Quantitation Levels for the Third Six-Year Review of National Primary Drinking Water Regulations (Chemical Phase Rules)" (USEPA, 2016d).

Table VI-4 shows the outcomes of EPA's analytical feasibility review for two general categories of drinking water contaminants: contaminants where health effects assessments indicate potential for lower MCLGs; and contaminants where existing MCLs are based on analytical feasibility.

- *A health effects assessment indicates potential for lower MCLG.* This category includes the 11 contaminants identified in the health effects review as having information indicating the potential for a lower MCLG. EPA reviewed analytical feasibility to determine if analytical feasibility could limit the

potential for MCL revisions. For six contaminants (carbofuran, cyanide, endothall, methoxychlor, oxamyl and styrene), the current PQL is higher than the potential new MCLG identified in the health effects review. For these contaminants, the PQL assessment did not support reduction of the current PQL, or data were inconclusive or insufficient to reach a conclusion. Consequently, analytical feasibility could be a limiting factor for setting the MCL equal to the potential new MCLG. The current PQL is not a limiting factor for the remaining five contaminants identified by the health effects review for possible changes in their MCLG (i.e., cis-1,2-dichloroethylene, hexachlorocyclopentadiene, selenium, toluene and xylene).

- *Contaminants for which existing MCLs are based on analytical feasibility.* This category includes 14 contaminants with existing MCLs that are greater than their MCLGs because they are limited by analytical feasibility. Two of the contaminants (thallium and 1,1,2-trichloroethanetrichloroethane) are non-carcinogenic and have a non-zero MCLG and the remaining 12 contaminants are carcinogens with MCLGs equal to zero. EPA evaluated whether the PQL could be lowered for each of these contaminants. For one contaminant, 1,1,2-trichloroethane, EPA concluded that new information from Proficiency Testing (PT) studies, along with MRL and MDL data, indicate the potential to revise the PQL. For two contaminants (dioxin and PCBs), data from PT studies were inconclusive, but MRL and MDL data indicated the potential to

revise the PQL. For five contaminants (chlordane, heptachlor, heptachlor epoxide, hexachlorobenzene and toxaphene) data from PT and MRL studies were inconclusive, but MDL data indicate the potential to revise the PQL. For the remaining five contaminants, either EPA did not have sufficient new information to evaluate analytical feasibility or EPA concluded that new information does not indicate the potential for a PQL revision.

Where these evaluations indicated the potential for a PQL reduction, Table VI-4 lists the type of data that support this conclusion. The notation "PT" indicates that the PQL reassessment based on PT data (USEPA, 2016a) supports the reduction. The notations "MRL" and "MDL" indicates that these two approaches support PQL reduction. The findings based on PT offer more certainty. When the PQL reassessment outcome is that the current PQL remains appropriate, Table VI-4 shows the result "Data do not support PQL reduction."

Table VI-4. NPDWRs Included in Analytical Feasibility Reassessment and Result of that Assessment

Contaminant	Current PQL (µg/L)	Analytical Feasibility Reassessment Result
11 Contaminants Identified Under the Health Effects Review as Having Potential for Lower MCLG		
Carbofuran	7	Data do not support PQL reduction
Cyanide	100	Data do not support PQL reduction
cis-1,2-Dichloroethylene	5	PQL not limiting
Endothall	90	PQL reduction supported (MRL, MDL)
Hexachlorocyclopentadiene	1	PQL not limiting
Methoxychlor	10	PQL reduction supported (PT, MRL)
Oxamyl	20	PQL reduction supported (MRL, MDL)
Selenium	10	PQL not limiting

Styrene	5	PQL reduction supported (PT, MRL, MDL)
Toluene	5	PQL not limiting
Xylene	5	PQL not limiting
14 Contaminants with MCLs based on Analytical Feasibility and Higher than MCLGs		
Benzo(a)pyrene	0.2	Data do not support PQL reduction
Chlordane	2	PQL reduction supported (MRL, MDL)
1,2-Dibromo-3-chloropropane (DBCP)	0.2	Data do not support PQL reduction
Di(2-ethylhexyl)phthalate (DEHP)	6	Data do not support PQL reduction
Ethylene dibromide (EDB)	0.05	Data do not support PQL reduction
Heptachlor	0.4	PQL reduction supported (MDL)
Heptachlor Epoxide	0.2	PQL reduction supported (MDL)
Hexachlorobenzene	1	PQL reduction supported (PT, MDL)
Pentachlorophenol	1	Data do not support PQL reduction
PCBs	0.5	Data do not support PQL reduction
Dioxin	3.0×10^{-5}	PQL reduction supported (MRL, MDL)
Thallium	2	Data do not support PQL reduction
Toxaphene	3	PQL reduction supported (MDL)
1,1,2-Trichloroethane	5	PQL reduction supported (PT, MRL, MDL)

Occurrence and Exposure

Using the SYR3 ICR database, EPA conducted an assessment to evaluate national occurrence of regulated contaminants and estimate the potential population exposed to these contaminants. The details of the current chemical occurrence analysis are documented in "The Analysis of Regulated Contaminant Occurrence Data from Public Water Systems in Support of the Third Six-Year Review of National Primary Drinking Water Regulations: Chemical Phase Rules and Radionuclides Rules" (USEPA, 2016p). Based on benchmarks identified in the health effects and analytical feasibility analyses, EPA conducted the occurrence and exposure analysis for 18 contaminants.

This analysis shows that these 18 contaminants occur at levels above the identified benchmark in a very small percentage of systems, which serve a very small percentage of the population, indicating that revisions to NPDWRs are unlikely to provide a meaningful opportunity to improve public health protection across the nation. Therefore, these contaminants were not identified as candidates for regulatory revision. Table VI-5 lists the benchmarks used to conduct the occurrence analysis, the total number of systems with mean concentrations exceeding a benchmark and the estimated population served by those systems.

Table VI-5. Occurrence and Potential Exposure Analysis for Chemical NPDWRs

Contaminant	Benchmark[1] (ug/L)	Number (and Percentage) of Systems with a Mean Concentration Higher than Benchmarks	Population Served by Systems with a Mean Concentration Higher than Benchmarks (and Percentage of Total Population)
Contaminants Identified Under the Health Effects Review as Having Potential for Lower MCLG			
Carbofuran	> 5 µg/L	1 (0.00%)	993 (0.0004%)
Cyanide	> 50 µg/L	98 (0.27%)	574,038 (0.27%)
cis-1,2-Dichloroethylene	> 10 µg/L	4 (0.01%)	5,569 (0.00%)
Endothall	> 50 µg/L	1 (0.01%)	993 (0.001%)
Hexachlorocyclopentadiene	> 40 µg/L	0 (0.00%)	0 (0.00%)
Methoxychlor	> 1 µg/L	1 (0.003%)	993 (0.000%)
Oxamyl	> 9 µg/L	2 (0.01%)	9,742 (0.004%)
Selenium	> 40 µg/L	49 (0.10%)	135,685 (0.05%)
Styrene	> 0.5 µg/L	117 (0.210%)	571,425 (0.217%)
Toluene	> 600 µg/L	0 (0.00%)	0 (0.00%)
Xylene	> 1,000 µg/L	2 (0.004%)	825 (0.0003%)
Contaminants with MCLs Based on Analytical Feasibility and Higher than MCLGs			
Chlordane	> 1 µg/L	3 (0.01%)	1,353 (0.001%)
Heptachlor	> 0.1 µg/L	3 (0.01%)	1,643 (0.00%)
Heptachlor Epoxide	> 0.04 µg/L	14 (0.04%)	11,659 (0.005%)
Hexachlorobenzene	> 0.1 µg/L	6 (0.016%)	8,703 (0.004%)
2,3,7,8-TCDD (Dioxin)	> 0.000005 µg/L	2 (0.06%)	1,450 (0.002%)
Toxaphene	> 1 µg/L	6 (0.02%)	715,106 (0.32%)

1,1,2-Trichloroethane	> 3 µg/L	0 (0.00%)	0 (0.00%)

In addition, EPA performed a source water occurrence analysis for the 10 chemical contaminants in which updated health effects assessments indicated the possibility to increase (i.e., render less stringent) the MCLG values. EPA conducted this analysis to determine if there was a meaningful opportunity to achieve cost savings while maintaining or improving the level of public health protection. The data available to characterize contaminant occurrence was limited because there is no comprehensive dataset that characterizes source water quality for drinking water systems. Data from the U.S. Geological Survey (USGS) National Water Quality Assessment program and the U.S. Department of Agriculture Pesticide Data Program water monitoring survey provide useful insights into potential contaminant occurrence in source water. The analysis of the available contaminant occurrence data for potential drinking water sources indicated relatively low contaminant occurrence in the concentration ranges of interest. As a consequence, EPA could not conclude that there is a meaningful opportunity for system cost savings by increasing the MCLG and/or MCL for these 10 contaminants. The results of this analysis were documented in "Occurrence Analysis for Potential Source Waters for the Third Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2016e).

Treatment Feasibility

Currently, all of the MCLs for chemical and radiological contaminants are set equal to the MCLGs or PQLs or are based on benefit-cost analysis; none are currently

limited by treatment feasibility. EPA considers treatment feasibility after identifying contaminants with the potential to lower the MCLG/MCL that constitute a meaningful opportunity to improve public health. No such contaminants were identified in the occurrence and exposure analysis described above.

Other Regulatory Revisions

In addition to possible revisions to MCLGs, MCLs and TTs, EPA considered whether other regulatory revisions are needed to address implementation issues, such as revisions to monitoring and system reporting requirements, as a part of the Six-Year Review 3. EPA used the protocol to evaluate which implementation issues to consider (USEPA, 2016f). EPA's protocol focused on items that were not already being addressed, or had not been addressed, through alternative mechanisms (e.g., as a part of a recent or ongoing rulemaking).

Implementation Issues Identified for the Six-Year Review 3

EPA compiled information on implementation related issues associated with the Chemical Phase Rules. EPA also identified unresolved implementation issues/concerns from previous Six-Year Reviews. EPA shared the list of identified potential implementation issues with a group of state representatives convened by ASDWA to obtain input from state drinking water agencies concerning the significance and relevance of the issues (ASDWA, 2016). The complete list of implementation issues related to the Phase Rules and Radionuclide Rules is presented in "Consideration of Other Regulatory Revisions in Support of the Third Six-Year

Review of the National Primary Drinking Water Regulations: Chemical Phase Rules and Radionuclide Rules" (USEPA, 2016c).

The Agency determined that the following three issues, identified by state stakeholders, were within the scope of NPDWR review and were the most substantive:

a. Nitrogen monitoring in consecutive systems and the distribution system,
b. Alternative nitrate-nitrogen MCL of 20 mg/L for non-community water systems (NCWSs), and
c. Synthetic organic chemical (SOC) detection limits.

Table VI-6 provides a brief description of the three issues and the Agency's findings to date.

Table VI-6. Chemical Rule Implementation Issues Identified That Fall within the Scope of an NPDWR Review

Implementation Issue	Description and Findings
Nitrogen Monitoring in Consecutive Systems and the Distribution System	Current nitrite and nitrate standards are measured at the point of entry to the distribution system. Under some conditions, nitrification of ammonia in water system distribution networks could potentially result in increased total nitrite or nitrate concentrations at the point of use. To address the concern, certain water systems could develop and implement a nitrification monitoring program, which would include changing or adding additional monitoring locations.

	Research is needed to further evaluate the extent of this potential issue, including development of criteria to identify the specific systems where distribution system monitoring could be targeted. If the outcome of the research suggests that the magnitude of the problem represents a meaningful opportunity to improve public health protection, the regulation could be considered for revision.
Alternative Nitrate-Nitrogen MCL of 20 mg/L for NCWS	EPA evaluated the possibility of removing or further restricting the option for some NCWSs to use an alternative nitrate-nitrogen MCL of up to 20 mg/L. The nitrate-nitrogen MCL in PWSs is 10 mg/L. However, §141.11 of the Code of Federal Regulations (CFR) provides that states have the discretion to allow some NCWSs to use an alternative nitrate-nitrogen MCL of up to 20 mg/L if certain conditions are met, including conditions where water will not be available to children under six months of age. Other provisions related to this issue are included in §141.23 of the CFR, which pertains to monitoring. This section states: "Transient, non-community water systems shall conduct monitoring to determine compliance with the nitrate and nitrite MCL in §§141.11 and 141.62 (as appropriate) in accordance with this section." The monitoring section does not address non-transient non-community water systems (NTNCWSs) eligibility to use an alternative nitrate MCL. Two potential concerns identified with the current rule provisions are: • Potential health concerns other than methemoglobinemia associated with the ingestion of nitrate-nitrogen, such as possible effects on fetal development. • The fact that the alternative MCL was initially intended to be used by entities such as industrial plants that do not provide drinking water to children under six months of age (44 FR 42254, USEPA, 1979). Industrial plants are generally considered to be NTNCWSs. Therefore, it

	is possible the alternative MCL was intended to apply specifically to NTNCWSs and not transient non-community water systems (TNCWSs). The Agency has nominated nitrate and nitrite for an IRIS assessment as a result of the Six-Year Review process, and both of these contaminants are listed in the IRIS multi-year plan. An updated assessment is needed that evaluates health effects other than methemoglobinemia. Specifically, an assessment is needed that evaluates potential health effects of nitrate-nitrogen at levels between 10 and 20 mg/L on adult populations. When completed, the IRIS assessment may support initiation of a rule revision if potential adverse health effects were identified at drinking water concentrations below the alternative nitrate MCL of 20 mg/L for populations other than infants less than six-months of age.
Synthetic Organic Chemical (SOC) Detection Limits	According to states, some laboratories have reported difficulty in achieving the detection limits for some SOCs on a regular basis. Section 40 CFR 141.24(h)18 provides detection limits for the SOCs, including some pesticides. PWSs that do not detect a SOC contaminant above these concentrations may qualify for reduced monitoring frequency for individual contaminants. It was reported that some SOCs may have detection limits that are lower than levels that can be economically and efficiently achieved by laboratories using approved methods. Thus, some water systems may not be able to qualify for reduced monitoring if the laboratories cannot achieve the listed detection limits. This issue was also identified as a concern by the states during the Six-Year Review 2. To address the SOC method detection limits, the Agency investigated the MRL values for SOCs from the SYR 3 ICR and found there was an existing approved analytical method for each SOC that laboratories can use to achieve the appropriate detection limits in order to reduce monitoring requirements.

	Using the MRL values, the Agency evaluated the percentage of records in the ICR database at or below the detection limit. EPA considered this percentage as an indication of laboratories' collective ability to detect contaminant concentrations at or below these levels. The Agency found that for most of the SOCs, nearly half of the records were at or below the detection limit listed in the regulation while other SOCs had a sufficient number of records below the detection limit to determine that there was an approved analytical method that could be used.

2. Fluoride

Background

Fluoride can occur naturally in drinking water as a result of the geological composition of soils and bedrock. Some areas of the country have high levels of naturally occurring fluoride. EPA established the current NPDWR to reduce the public health risk associated with exposure to high levels of naturally occurring fluoride in drinking water sources.

Low levels of fluoride are frequently added to drinking water systems as a public health protection measure for reducing the incidence of cavities. The decision to fluoridate a community water supply is made by the state or local municipality, and is not mandated by EPA or any other federal entity. The U.S. Public Health Service (PHS) recommendation for community water fluoridation is 0.7 mg/L (U. S. Department of Health and Human Services, 2015). Fluoride is also added to various consumer products (such as toothpaste and mouthwash) because of its beneficial effects at low level exposures.

EPA published the current NPDWR on April 2, 1986 (51 FR 11396, USEPA, 1986) to reduce the public health risk associated with exposure to high levels of naturally occurring fluoride in drinking water sources. The current NPDWR established an MCLG and MCL of 4.0 mg/L to protect against the most severe stage of skeletal fluorosis (referred to as the "crippling" stage) (NRC, 2006a). EPA also established a secondary maximum contaminant level (SMCL) for fluoride of 2.0 mg/L to protect against moderate and severe dental fluorosis, which was considered at the time to be a cosmetic effect. As provided under the statute, the SMCL is not enforceable in the same manner as the MCL. Public notification is required when PWSs exceed the MCL or SMCL.

EPA has reviewed the NPDWR for fluoride in previous Six-Year Review cycles. As a result of the first Six-Year Review (68 FR 42908, USEPA, 2003b), EPA requested that the National Research Council (NRC) of the National Academies of Sciences (NAS) conduct a review of the health and exposure data on orally ingested fluoride. In 2006, the NRC published the results of its review and concluded that severe dental fluorosis is an adverse health effect when it causes both a thinning and pitting of the enamel, a situation that compromises the function of the enamel in protecting against decay and infection (NRC, 2006a). The NRC recommended that EPA develop a dose-response assessment for severe dental fluorosis as the critical effect and update an assessment of fluoride exposure from all sources.

During the Six-Year Review 2, the Agency was in the process of developing a dose-response assessment of the non-cancer impacts of fluoride on severe dental fluorosis and the skeletal system. In addition, EPA was in the process of updating its evaluation of the relative source contribution (RSC) of drinking water to total fluoride exposure considering the contributions from dental products, foods, pesticide residues, and other sources such as ambient air and medications. These assessments were not completed at the time of the Six-Year Review 2; thus, no action was taken under the Six-Year Review 2 (75 FR 15500, USEPA, 2010h).

In 2010, EPA published fluoride health assessments. The "Dose Response Analysis for Non-Cancer Effects" (USEPA, 2010b) identified an oral RfD for fluoride of 0.08 milligrams per kilograms per day (mg/kg/day) based on studies of severe dental fluorosis among children in the six months to 14 year age group (USEPA, 2010b). The "Exposure and Relative Source Contribution Analysis" (USEPA, 2010c) concluded that the RSC values for drinking water range from 40 to 70 percent, with the higher values associated with infants fed with powdered formula or concentrate reconstituted with residential tap water (70%) and with adults (60%). The major contributors to total daily fluoride intakes for these age groups are drinking water, commercial beverages, solid foods and swallowed fluoride-containing toothpaste (USEPA, 2010c).

Summary of Review Results

The Agency has determined that a revision to the NPDWR for fluoride is not appropriate at this time. EPA acknowledges information regarding the exposure and health effects of fluoride (as discussed later in the "Health Effects" and "Occurrence and Exposure" sections). However, with EPA's identification of several other significant NPDWRs as candidates for near-term revision (see Sections VI.B.3 and VI.B.4), potential revision of the fluoride NPDWR is a lower priority that would divert significant resources from the higher priority candidates for revision that the Agency has identified, as well as other high priority work within the drinking water office. These other candidates for revision include the Stage 1 and Stage 2 Disinfectants and Disinfection Byproducts Rules (D/DBPRs) that apply to approximately 42,000 PWSs, and for which EPA has identified the potential to further reduce bladder cancer risks attributed to exposure to DBPs; the Surface Water Treatment Rules, for which the Agency has identified the potential to further reduce risks from a myriad of serious waterborne diseases (e.g., giardiasis, cryptosporidiosis, legionellosis, hepatitis, meningitis and encephalitis) for approximately 12,000 surface water systems; and the pending revisions to the lead and copper NPDWR which apply to approximately 68,000 PWSs.

While EPA has evaluated the available health effects and exposure information related to fluoride (as discussed later in the "Health Effects" and "Occurrence and Exposure" sections), the Agency also recognizes that new studies on fluoride are currently being performed. These include new studies that address health endpoints of

concern other than dental fluorosis. Based on the NRC recommendations, EPA evaluated dental fluorosis for the purposes of this action. EPA will continue to monitor the evolving science, and, when appropriate, will reconsider the fluoride NPDWR's relative priority for revision and take any other available and appropriate action to address fluoride risks under SDWA.

Finally, most community water systems (CWSs) that provide fluoridation of their drinking water have already lowered their fluoridation level to a single level of 0.7 mg/L from a previous range of 0.7 to 1.2 mg/L to accommodate the updated PHS recommendation (U. S. Department of Health and Human Services, 2015). The U.S. Food and Drug Administration (FDA) also issued a letter to bottled water manufacturers recommending that they not add fluoride to bottled water in excess of the revised PHS recommendations (FDA, 2015). In addition, the FDA stated it intends to revise the quality standard regulation for fluoride added to bottled water to be consistent with the updated PHS recommendation. Therefore, EPA anticipates that a significant portion of the population's exposure to fluoride in drinking water, as well as some commercial beverages that use fluoridated water from CWSs and certain bottled water, has already been or will be reduced. Notwithstanding this action's decision, EPA will continue to address risk associated with fluoride in drinking water, with a specific focus on the small systems with naturally occurring fluoride in their source waters.

Initial Review

EPA did not identify any recent, ongoing or pending action on fluoride that would exclude fluoride from the Six-Year Review 3.

Health Effects

The NRC (2006a) evaluated the impact of fluoride on reproduction and development, neurotoxicity and behavior, the endocrine system, genotoxicity, cancer and other effects, in addition to the tooth and bone effects. At fluoride levels below 4.0 mg/L, the NRC found no evidence substantial enough to support adverse effects other than severe dental fluorosis and skeletal fractures. The NRC concluded that the available data were inadequate to determine if a risk of effects on other endpoints exists at an MCLG of 4.0 mg/L and made recommendations for additional research.

EPA assessments (USEPA, 2010b; 2010c) found that the RSC values are lower than the RSC of 100 percent used to derive the original MCLG of 4.0 mg/L, where EPA assumed that drinking water was the sole source of exposure to fluoride. EPA has concluded that information on the dose-response and exposure assessment may support lowering the MCLG to reflect levels that would protect against risk of severe dental fluorosis and skeletal fractures.

As part of this Six-Year Review, EPA reviewed health effects data on the impact of fluoride on reproduction and development, neurotoxicity and behavior, the endocrine system, genotoxicity, cancer and other effects that were identified by the NRC as requiring additional research (NRC, 2006a). EPA noted limitations in some of these studies such as lack of details and confounding factors. Overall, the new data

were insufficient to alter the NRC conclusion that severe dental fluorosis is the critical health effects endpoint for the MCLG.

Based upon the recommendations of the NRC, EPA has evaluated dental fluorosis as a critical endpoint of concern for this Six-Year Review (USEPA, 2010b; 2010c). However new studies are underway to examine other health endpoints (i.e., developmental neurobehavior effects, endocrine disruption and genotoxicity). One example is an ongoing National Toxicology Program (NTP) systematic review of animal studies that examined the impact of fluoride on learning and memory (NTP, 2016). For more information about fluoride developmental neurotoxicity visit the National Toxicology Program website at https://ntp.niehs.nih.gov/pubhealth/hat/noms/fluoride/neuro-index.html. Additional information related to the review of the fluoride NPDWR is provided in the "Six-Year Review 3 Health Effects Assessment Summary Report" (USEPA, 2016h).

Analytical Feasibility

The current PQL for fluoride is 0.5 mg/L (USEPA, 2009a). EPA has not identified any changes in analytical feasibility that could limit its ability to revise the MCL/MCLG for fluoride.

Occurrence and Exposure

EPA analyzed fluoride occurrence using the SYR3 ICR database, which contains fluoride analytical results from approximately 47,000 PWSs in 49 states/entities from 2006 to 2011. Sample records for fluoridated water (i.e., in which a system adds

fluoride to maintain a concentration in the 0.7 to 1.2 mg/L range) were omitted from the analysis because the fluoridated systems would not be impacted by revisions to the fluoride NPDWR. EPA estimated the number and percent of systems that have mean fluoride concentrations exceeding various benchmarks and the corresponding estimates of population served by those systems. The data indicated that about 130 systems (0.3 percent), serving approximately 60,000 people (0.03 percent), had an estimated system mean concentration exceeding the current MCL of 4.0 mg/L, whereas more than 900 systems (2 percent), serving approximately 1.5 million people (0.8 percent), had an estimated system mean concentration greater than the SMCL of 2.0 mg/L. Among these systems, many are small systems (serving fewer than 10,000 people) and very small systems (serving fewer than 500 people). Evaluations based on mean (or average) fluoride concentrations generally reflect an approximation of chronic (long-term) exposure. It is important to note that these average concentration-based evaluations help to inform Six-Year Review results, but do not assess compliance with regulatory standards nor should be viewed as compliance forecasts for PWSs.

Treatment Feasibility

A BAT or small system compliance technology for fluoride was not established in the Code of Federal Regulations (40 CFR 141.62). However, EPA (1998d) identified activated alumina and reverse osmosis as BATs for fluoride.

Activated alumina is the most commonly used treatment technology for fluoride removal. It is capable of removing fluoride to concentrations well below the MCL of 4.0 mg/L, but with a shortened media life at lower target concentrations. Membrane technologies, such as reverse osmosis, nanofiltration, and electrodialysis, are also capable of removing fluoride to very low levels (<0.3 mg/L). They are often used to remove fluoride along with other contaminants such as total dissolved solids, arsenic, and uranium. In general, these technologies are costly and complex to operate – and thus likewise present potential challenges for small water systems (USEPA, 2014a).

3. Disinfectants/Disinfection Byproducts Rules (D/DBPRs)

Background

The D/DBPRs were promulgated in two stages – Stage 1 in 1998 (63 FR 69390, USEPA, 1998b) and Stage 2 in 2006 (71 FR 388, USEPA, 2006d). Disinfection byproducts (DBPs) are formed when the disinfectants commonly used in PWSs to kill microorganisms react with organic and inorganic matter in source water. DBPs have been associated with potential adverse health effects, including cancer and developmental and reproductive effects. Monitoring parameters within the D/DBPRs consist of the following: DBPs – TTHM, HAA5, bromate and chlorite; disinfectants – chlorine, chloramines and chlorine dioxide; and water quality indicators – total organic carbon (TOC) and alkalinity. The rules include MCLGs/MRDLGs, as well as

MCLs/MRDLs and TT requirements, which were developed for individual parameters considering their health risks.

For organic DBPs, the concern is potential increased risk of cancer and short-term adverse reproductive and developmental effects. For bromate, the concern is potential increased risk of cancer. Chlorite (a regulated DBP) and chlorine dioxide (a disinfectant) are associated with methemoglobinemia, and for infants, young children and pregnant women, effects on the thyroid are also of concern. For chlorine and chloramines, health effects include eye/nose irritation and stomach discomfort (for chloramines, also anemia).

The D/DBPRs apply to all sizes of CWSs and non-transient non-community water systems (NTNCWSs) that chemically disinfect their water or receive chemically disinfected water (that is, involving any disinfectants other than ultraviolet (UV) light), as well as transient non-community water systems (TNCWSs) that add chlorine dioxide. The rules require that these systems comply with established MCLs, TTs, operational evaluation levels for DBPs and MRDLs for disinfectants.

A major challenge for water suppliers is balancing the risks from microbial pathogens and DBPs. The risk-balancing tradeoff approach was intended to lower the overall risks from DBP mixtures while continuing to provide public health protection from microbial risks.

Summary of Review Results

EPA has identified the following NPDWRs within the D/DBPRs as candidates for revision under this Six-Year Review cycle because of the opportunity to further reduce public health risk from exposure to DBPs: chlorite, HAA5 and TTHM. This result is based on a scientific review of publicly available information. EPA's review process follows the protocol described in Section V of this notice. New information has strengthened the weight of evidence supporting an association between chlorination DBPs and bladder cancer risk compared to the information available during development of the existing D/DBPRs. New information also is available related to the reproductive/developmental effects discussed in the Stage 2 D/DBPR. In addition, new toxicological data are available to support the development of MCLGs for some individual DBPs currently lacking MCLGs (for example, dibromoacetic acid).

This result will also provide for additional opportunity to address concerns with unregulated DBPs: for example, nitrosamines and chlorate. In the *Federal Register* notice for Preliminary Regulatory Determination 3 (79 FR 62715, USEPA, 2014b), the Agency stated that "because chlorate and nitrosamines are DBPs that can be introduced or formed in PWSs partly because of disinfection practices, the Agency believes it is important to evaluate these unregulated DBPs in the context of the review of the existing DBP regulations. DBPs need to be evaluated collectively, because the potential exists that the strategy used to control a specific DBP could

increase the concentrations of other DBPs. Therefore, the Agency is not making a regulatory determination for chlorate and nitrosamines at this time."

Chlorate and chlorite are two different oxidation states of chlorine and are chemically inter-convertible. They occur, and can co-occur, when hypochlorite solution and/or chlorine dioxide are applied during the drinking water treatment process. Chlorite is a regulated DBP. New information has shown that the relative source contribution for chlorite could be lower than previously estimated in the existing D/DBPRs, which could lead to a lower MCLG, and that there are common health endpoints associated with exposure to chlorite and chlorate.

Compliance monitoring data evaluated for the Six-Year Review 3 show widespread occurrence of DBPs and their organic precursors (as measured as TOC) in drinking water. Research that has been published since the development of the Stage 2 D/DBPR has improved EPA's understanding of the effectiveness of and limitations associated with various treatment approaches, such as those for removal of precursors, use of disinfectants other than chlorine and localized treatment.

Given that this is the first time EPA is conducting a Six-Year Review of the D/DBPRs, extensive information about review findings is provided below, with further information provided in EPA's "Six-Year Review 3 Technical Support Document for Disinfectants/Disinfection Byproducts Rules" (USEPA, 2016l). Additional information related to the review of D/DBPRs is provided in the "Six-Year Review 3 Technical Support Document for Chlorate" (USEPA, 2016k) and the

"Six-Year Review 3 Technical Support Document for Nitrosamines" (USEPA, 2016o).

Initial Review

There are no recently completed, ongoing or pending regulatory actions on the D/DBPRs that would exclude them from the Six-Year Review 3.

Health Effects

Under the Stage 1 and 2 D/DBPRs, toxicology studies for specific DBPs and disinfectant residuals were used to inform MCLGs (and cancer potency factors where MCLGs are zero) and MRDLGs. Epidemiology studies were used to estimate potential risks from DBP mixtures (due to cancer and developmental/reproductive effects) and support the benefits analysis. Epidemiology studies supported a potential association between exposures to elevated THM4 levels in chlorinated drinking water and cancer, but the evidence was insufficient to establish a causal relationship. The most consistent evidence was for bladder cancer. For the development of the benefits analysis for both the Stage 1 and the Stage 2 D/DBPRs, EPA used five bladder cancer case-control epidemiology studies that were conducted in the 1980s and 1990s (Cantor et al., 1985; 1987; McGeehin et al., 1993; King and Marrett, 1996; Freedman et al., 1997; Cantor et al., 1998). In addition, EPA used one meta-analysis (Villanueva et al., 2003) and one pooled analysis (Villanueva et al., 2004). The five case-control studies used similar (though not identical) exposure metrics based on years of exposure to chlorinated drinking water (primarily chlorinated surface water) to

estimate odds ratios. All five studies showed an increase in the odds ratio for bladder cancer incidence with an increased duration of exposure. Using the published odds ratio results from these five studies, EPA calculated an estimate for the lifetime cancer risk (population attributable risk) that ranged from 2 to 17 percent; between 2 and 17 percent of bladder cancers occurring in the U.S. could be attributed to long-term exposure to chlorinated drinking water at the time of the Stage 1 D/DBPR. Detailed explanations of these calculations can be found in the benefits analysis for the Stage 2 D/DBPR (USEPA, 2005a). The evidence from the studies in 1985 to 1998, the meta-analysis in 2003 and the pooled analysis in 2004 was strong enough to support the benefit analysis with several thousand potential bladder cancer cases per year estimated as being avoided from the combined effects of the Stage 1 and Stage 2 D/DBPRs (USEPA, 2005a).

Studies from the 1970s to 2005 also suggested a possible association between adverse developmental/reproductive health effects and exposure to chlorinated drinking water. Effects were observed in all areas but lacked consistency across studies and did not provide enough of a basis to quantify risks or benefits. The adverse developmental/reproductive effects consisted of effects on fetal growth (small for gestational age, low birth weight and pre-term delivery), effects on viability (spontaneous abortion, stillbirth) and malformations (neural tube, oral cleft, cardiac or urinary defects).

Since the development of the Stage 2 D/DBPR, EPA has identified additional sources of information related to health effects of DBPs. New toxicological information could be used to develop MCLGs for the following regulated DBPs (within HAA5): dibromoacetic acid (NTP, 2007), other brominated haloacetic acids not currently regulated, including bromochloroacetic acid (NTP, 2009) and bromodichloroacetic acid (NTP, 2014), plus additional unregulated DBPs such as nitrosamines and chlorate (USEPA, 2016k; 2016o).

EPA has identified new epidemiological, pharmacokinetic and pharmacodynamic studies that, considered together with studies available during the development of the Stage 2 D/DBPR, add to the weight of evidence for bladder cancer being associated with exposure to chlorination DBPs (notably those containing bromine) in drinking water.

Pharmacokinetic and pharmacodynamic studies (Ross and Pegram, 2003; 2004; Leavens et al., 2007; Stayner et al., 2014; Kenyon et al., 2015), in conjunction with epidemiology studies (Villanueva et al., 2007; Kogevinas et al., 2010; Cantor et al., 2010), indicate that non-ingestion routes of exposure (dermal and inhalation) from some brominated DBPs may play a significant role in influencing increased bladder cancer risk, and that there may be greater concern about sub-populations with certain genetic characteristics (polymorphisms). EPA's "Six-Year Review 3 Technical Support Document for Disinfectants/Disinfection Byproducts Rules" (USEPA, 2016l)

characterizes the research that informs the mode of action by which brominated DBPs may be contributing to bladder cancer.

While uncertainties remain regarding the degree to which specific DBPs contributed to the bladder cancer incidence observed in epidemiology studies, the collective data suggest a stronger case for causality than when the Stage 2 D/DBPR was promulgated (Regli et al., 2015; USEPA, 2016l). However, the Agency recognizes there are also different perspectives on this issue, including suggestions about areas for additional research (Hrudey et al., 2015).

Further, the Agency has identified new information about health effects from unregulated DBPs. This includes health effects information on chlorate and nitrosamines that, along with occurrence/exposure information, was previously noted in the Preliminary Regulatory Determination 3 (79 FR 62715, USEPA, 2014b). The Agency is considering the health effects of chlorate and nitrosamines within the broader context of the health effects of regulated DBPs (USEPA, 2016k; 2016o).

EPA also identified information about the relative cytotoxicity and genotoxicity of many other unregulated DBPs (Richardson et al., 2007; Richardson et al., 2008; Plewa and Wagner 2009; Plewa et al., 2010; Fernández et al., 2010; Richardson and Postigo, 2011; Yang et al., 2014). Data from *in vitro* mammalian cell testing, which compared the cytotoxicity and genotoxicity of iodinated, brominated, and chlorinated DBPs, showed that the iodinated DBPs (those containing iodine) were generally more toxic than the brominated DBPs (those containing bromine), which were in turn more

toxic than the chlorinated DBPs (those containing chlorine). Nitrogen-containing DBPs, including haloacetonitriles, haloacetamides and halonitromethanes, were more cytotoxic and genotoxic than the haloacids and halomethanes that did not contain nitrogen.

Approximately 40 new studies about developmental/reproductive effects have become available since the development of the Stage 2 D/DBPR. These studies address endpoints such as fetal growth (low birth weight, small for gestational age and pre-term delivery), congenital anomalies and male reproductive outcomes. These studies continue to support a potential health concern, though, as discussed above, the relationship of DBP exposure to these types of adverse outcomes may not be well enough understood to permit quantification of risks or benefits. A recent "four-lab study" on the effects of DBP mixtures on animals, conducted by EPA researchers (Narotsky et al., 2011; 2013; 2015), suggests diminished concern for many developmental/reproductive endpoints.

EPA also examined data about health effects for inorganic DBPs, including information showing that the RSC for chlorite could be lower than 80 percent (which could potentially support lowering the MCLG) because there is more dietary exposure than previously assumed due to the increased use of chlorine dioxide and acidified sodium chlorite as disinfectants in the processing of foods (U.S. EPA, 2006e; WHO, 2008). In addition, chlorate, chlorite and chlorine dioxide may share common health endpoints, namely hematological and thyroid effects (Couri and

Abdel-Rahman, 1980; Bercz et al., 1982; Moore and Calabrese, 1982; Abdel-Rahman et al., 1984; Khan et al., 2005; Orme et al., 1985; NTP, 2005; USEPA, 2006e; WHO, 2008; Lee et al, 2013; Nguyen et al, 2014).

The Agency did not identify any relevant data that suggest an opportunity to revise the MCLG for bromate, or the MRDLG for chlorine or chloramines.

Analytical Feasibility

The Agency has not identified any improvements to analytical feasibility that could lead to improvements to the NPDWRs included in the D/DBPRs. Development of these rules was not constrained by the availability of analytical methods, and new EPA-approved methods that would revise this finding have not been identified. Should new, EPA-approved methods for one or more D/DBPRs be identified, that information might be able to help inform potential future regulatory development efforts.

Occurrence and Exposure

In this Six-Year Review evaluation of D/DBP occurrence and exposure, EPA evaluated compliance monitoring information collected under the SYR3 ICR, which was previously discussed in Section V.B.4. EPA also evaluated information from the DBP ICR database (USEPA, 2000a) that had been used to prepare the original D/DBPRs. Additionally, EPA used data from the third monitoring cycle of the Unregulated Contaminant Monitoring Rule (UCMR3) to evaluate chlorate occurrence in 2013-2015, and data from the UCMR2 to evaluate nitrosamine occurrence in 2008-

2010. This information is briefly described below, with additional information in EPA's "Six-Year Review 3 Technical Support Document for Disinfectants/Disinfection Byproducts Rules" (USEPA, 2016l).

It is important to note that the information collected through the SYR3 ICR spans the years 2006-2011. As such, it primarily reflects occurrence following the effective date for the Stage 1 D/DBPR, but prior to the effective date for the Stage 2 D/DBPR. These evaluations help to inform Six-Year Review results but do not assess compliance with regulatory standards.

New information since the promulgation of the Stage 2 D/DBPR has improved our understanding on DBP formation and occurrence. As part of this Six-Year Review, EPA has identified literature describing more than 600 specific DBPs that have been found in drinking water (e.g., Richardson et al., 2007); these include chlorinated, brominated and iodinated DBPs, as well as nitrogenous compounds. Additionally, EPA identified literature on the sources of precursors (both organic and inorganic), as well as the influence that different precursors have on DBP formation. For example, some of this literature discusses the extent to which brominated or iodinated DBPs might form as a result of source water bromide or iodide concentrations (Nguyen et al., 2005; Duirk et al, 2011; Lui et al., 2012; Zhang et al., 2012; Callinan et al., 2013; Emelko et al., 2013; Mikkelson et al., 2013; Rice et al., 2013; Samson et al., 2013; Rice and Westerhoff, 2014).

Overview of DBP Occurrence

EPA collected occurrence information for THMs (includes TTHM along with information on four individual species), HAAs (includes HAA5 along with information on five individual species), bromate and chlorite as part of the SYR3 ICR.

Data from the SYR3 ICR show that concentrations at or above the MCLs for TTHM and HAA5 were found in many surface water systems and, to a lesser degree, in ground water systems. Approximately 32 percent of surface water systems and five percent of ground water systems reported at least one instance of TTHM occurrence at a concentration greater than or equal to the MCL of 80 µg/L. For HAA5, approximately 19 percent of surface water systems and two percent of ground water systems reported at least one instance of occurrence at a concentration greater than or equal to the MCL of 60 µg/L. EPA anticipates that many of these peak concentrations will have been significantly lowered based on implementation of the 2006 Stage 2 D/DBPR, which was designed, in part, to lower such occurrences.

Approximately nine percent of systems had one or more samples that were greater than or equal to the bromate MCL of 10 µg/L. Approximately four percent of systems had one or more samples that were greater than or equal to the chlorite MCL of 1,000 µg/L.

The occurrence of six nitrosamine species was evaluated by EPA using data from the UCMR2. These data showed elevated concentrations of

nitrosamines (relative to their health reference levels) in multiple drinking water systems, especially N-nitrosodimethylamine (NDMA) in systems that use chloramines (USEPA, 2016o). The Agency is seeking public comment regarding potential approaches that provide enhanced protection from health risks posed by nitrosamines in drinking water systems.

The occurrence of chlorate was evaluated by EPA using data from the UCMR3 (USEPA, 2016j). These data showed that chlorate levels above the health reference level of 210 µg/L occurred frequently in systems that use hypochlorite, chlorine dioxide or chloramines. In addition, EPA evaluated the co-occurrence of chlorite and chlorate and noted that these contaminants often co-occur (USEPA, 2016k). The Agency is seeking public comment regarding potential approaches that provide enhanced protection from health risks posed by chlorite, chlorate and chlorine dioxide. See Section VII for more information.

The American Water Works Association (AWWA), through the Water Industry Technical Action Fund #266, conducted its own survey of post-Stage 2 D/DBPR occurrence for systems that serve more than 100,000 people. Results from the AWWA survey (Samson, 2015) provide an overview of DBP occurrence for 395 systems across 44 states, covering a time period from 1980 to 2015.

In December 2015, EPA issued a proposal for the fourth cycle of the UCMR (80 FR 76897, USEPA, 2015b). That proposal includes provisions for collection of data about unregulated haloacetic acids and related precursors. Such data would help EPA to develop a better understanding of patterns of occurrence for those contaminants.

Overview of Water Quality Indicator Occurrence

The Stage 1 D/DBPR requires that DBP precursors (measured as TOC) be monitored in source and treated drinking water. EPA evaluated compliance monitoring data from surface water systems for TOC in source and treated water, using the SYR3 ICR database. Data from 2011 showed that approximately 70 percent of all plants had average TOC concentrations greater than 2 mg/L in their source water and that approximately 29 percent of plants had average TOC concentrations greater than 2 mg/L in their treated water. Under the Stage 1 D/DBPR, a system is not required to further remove TOC when its treated water TOC level, prior to the point of continuous chlorination, is less than 2 mg/L. The reader is referred to later portions of this notice under “DBP Precursor Removal” for information about EPA’s evaluation of TOC data relative to the Stage 1 D/DBPR TOC removal requirement.

As discussed in the background portion of this section, the D/DBPRs require systems to maintain disinfectant residual levels (reported as free

and/or total chlorine) in accordance with the MRDL requirements. EPA evaluated free and total chlorine measurements (collected during coliform sampling) from the SYR3 ICR database and found that very few records exceeded 4.0 mg/L (the MRDL for chlorine and chloramine residuals). Additional information is provided in "Six-Year Review 3 Technical Support Document for Disinfectants/Disinfection Byproducts Rules" (USEPA, 2016l).

Treatment Feasibility

During the development of the Stage 1 and Stage 2 D/DBPRs, a variety of technologies were evaluated for their effectiveness, applicability, unintended consequences and overall feasibility for achieving compliance with the TT requirements and MCLs, as well as providing a basis for the BATs (63 FR 69390; 71 FR 388; USEPA, 1998b; 2005a; 2005g; 2006d; 2007b).

Since the Stage 2 D/DBPR, the Agency has identified information that improves our understanding of technologies available for lowering occurrence of and exposure to regulated and unregulated DBPs. The information addresses the full spectrum of drinking water system operations, including removal of organic precursors to DBPs (measured as TOC), disinfection practices, source water management and localized treatment. The information is briefly discussed below, with additional information in EPA's "Six-Year Review 3 Technical Support Document for Disinfectants/Disinfection Byproducts Rules" (USEPA, 2016l). Overall, the information collectively indicates that: (1) greater removals of DBP precursors can

and are being achieved compared to the TT requirement under the Stage 1 D/DBPR; and (2) occurrence of DBPs can be further controlled.

DBP Precursor Removal

The SYR3 ICR database (USEPA, 2016i) includes paired source and treated water TOC data. This information was used to evaluate the extent to which TOC was removed from source waters (i.e., percent removal) relative to the Stage 1 D/DBPR TOC removal requirement (i.e., requirement per the 3x3 matrix, which was established based on three different ranges of raw water TOC and alkalinity levels, respectively). This TT requirement is applicable to surface water systems that have conventional treatment plants, unless such systems meet the alternative criteria (63 FR 69390, USEPA, 1998b). The analytical results of TOC removal (i.e., comparing TOC levels from source water to treated water) can help to characterize national treatment baselines among these treatment plants.

The data show a wide range of percent TOC removal for each combination of raw water TOC and alkalinity levels provided in the Stage 1 D/DBPR TT requirement. The data also indicate that the mean removal for each element of the 3x3 matrix was six to 19 percent greater than the requirement. These observations are consistent with the notion that "since the Stage 1 D/DBPR does not require that all coagulable dissolved organic matter be removed,

there is a potential for additional removal of organic matter beyond that required by the 3x3 matrix" (McGuire et al., 2014).

Some of the TOC removal greater than the Stage 1 D/DBPR requirement may reflect operational optimization of conventional treatment, including use of innovative coagulants/coagulant aids and/or use of biofiltration (Yan et al., 2008; Hasan et al., 2010; McKie et al., 2015; Azzeh et al., 2015; Delatolla et al., 2015; Pharand et al., 2015). Studies have shown that biological filtration can also reduce precursors of the DBPs other than TTHM/HAA5 (Sacher et al., 2008; Farré et al., 2011; Liao et al., 2014; Krasner et al., 2015). As noted by McGuire et al. (2014), if the removal of precursors for DBPs other than TTHM/HAA5 becomes part of the treatment goals, then performance parameters in addition to TOC may also be needed (e.g., parameters indicating both vulnerability and nitrosamine formation potential).

As was known during development of the Stage 1 and the Stage 2 D/DBPRs, granular activated carbon (GAC) and membranes can be added to existing treatment trains to achieve additional reductions of DBP formation potential. One longstanding issue has been the extent to which organic precursor removal may cause a shift of chlorinated species to more brominated species (as described earlier in this Section under the "Health Effects") when the bromide level is relatively high in source water (Summers et al., 1993; Symons et al., 1993). The ICR Treatment Study database

(USEPA, 2000b) provides extensive bench- and pilot-scale data by which to evaluate the effects of GAC and membrane removal of TOC and resulting shifts in brominated THMs. EPA's recent analysis of these data generally shows increased percent reduction of brominated THMs as TOC removal by GAC increases (e.g., from a target effluent level of two mg/L to one mg/L), especially for source waters with high bromide concentrations (USEPA, 2016l). It also shows that bromoform formation increases as bromide concentrations increase and that bromoform becomes the dominating species when source water bromide concentrations exceed 200 µg/L.

Disinfection Practices

Various combinations of disinfectants and precursor removal processes have been used to achieve DBP MCLs, while also meeting the requirements of the microbial standards. Data from successive national drinking water datasets (including the DBP ICR, UCMR2 and UCMR3 datasets) show that the percentage of systems using disinfectants other than chlorine has increased during the past two decades, as had been forecasted in the "Economic Analysis of Stage 2 D/DBPR" (USEPA, 2005a). For example, data from the UCMR3 (2013-2015) and the DBP ICR (1998) have shown a relative increase in use of chloramines, which is associated with the formation of nitrosamines, as a disinfection practice.

EPA reviewed information related to the extent to which different types of DBPs may form when disinfectants are applied at different points in the treatment train and/or in combination with other disinfectants. EPA recognized that the extent to which occurrence and associated health effects data may be lacking for one group of DBP contaminants versus another, as well as for DBP mixtures, may make treatment decisions challenging when trying to evaluate DBP risk tradeoffs.

Source Water Management

New information shows that source waters with relatively elevated sewage contributions have been associated with increased nitrosamine formation (Westerhoff et al., 2015; Krasner et al., 2013) and that source waters with elevated bromide levels from industrial discharges have been associated with increased brominated THMs (McTigue et al., 2014; States et al., 2013). Such factors as these impacts can increase the challenge of controlling DBPs during treatment and distribution. Weiss et al. (2013) developed a model for making source water selection decisions based on real-time DBP precursor concentrations.

Information shows that bank filtration can reduce dissolved organic carbon (DOC) and nitrogenous DBP precursors (Brown et al., 2015; Krasner et al., 2015), as well as removing pathogens (USEPA, 2016m).

Localized Treatment

Localized treatment in distribution systems, such as aeration in storage tanks, sometimes with the addition of GAC, has also been shown to reduce elevated levels of THMs (Walfoort et al., 2008; Fiske et al., 2011; Brooke and Collins, 2011; Johnson et al., 2009; Duranceau, 2015). Aeration approaches have been most successful in reducing concentrations of chloroform and the more volatile brominated species but may have little impact on less volatile species (Johnson et al., 2009; Duranceau, 2015).

Risk-Balancing

The Agency has considered the risk-balancing aspects of the MDBP rules and has determined that potential revisions to the D/DBPRs could provide greater protection of public health while still being protective of microbial risks. The risk-balancing activities considered by the Agency include those between the microbial and disinfection byproduct rules, as well as those between different groups of DBPs. This includes risk-balancing for the THMs and HAAs included in the D/DBPRs, additional brominated HAAs, nitrosamines identified in the *Federal Register* notice for the Preliminary Regulatory Determination 3 (79 FR 62715, USEPA, 2014b) and other DBP groups such as iodinated DBPs. It also includes risk-balancing for inorganic DBPs such as chlorite and chlorate (79 FR 62715, USEPA, 2014b).

Potential revisions could offer enhanced protection from both regulated and unregulated DBPs. Potential revisions that consider areas such as further constraints on precursors, and/or more targeted constraints on precursors (e.g., based on

watershed vulnerabilities), could minimize the formation of harmful DBPs without compromising protection against microbial risks. These potential revisions were identified based on a preliminary, qualitative assessment; it is important to note that further assessment would be an important component of any further rulemaking activities. For example, a watershed vulnerability characterization that includes information about wastewater (i.e., sewage) contributions, land use (point/non-point sources of pollution), and streamflow variations over time (for example, sewage contributions during low flow conditions), could help to inform considerations about DBP formation potentials and possible control strategies.

The Agency is seeking public comment regarding potential revisions to D/DBPR. See Section VII for more information. Further discussion about potential revisions to existing D/DBPRs will occur as part of a separate regulatory development process.

Other Regulatory Revisions

In addition to evaluating information about health effects, analytical feasibility, occurrence and exposure, treatment feasibility and risk-balancing related to the NPDWRs included in the D/DBPRs, EPA considered whether other regulatory revisions are needed, such as revisions to monitoring and system reporting requirements, as a part of the Six-Year Review 3. EPA used the protocol to evaluate which of these implementation issues to consider (USEPA, 2016f). As with the Chemical Phase Rules/Radionuclides Rules, EPA shared the list of identified potential implementation issues with the ASDWA to obtain input from state drinking

water agencies concerning the significance and relevance of the issues (ASDWA, 2016). Implementation issues will be considered as part of the activities associated with potential future rulemaking efforts; some of these might be addressed through regulatory revision or clarification, while others might be handled through guidance.

Examples of implementation-related considerations include the following:

Stage 2 D/DBPR Consecutive System Monitoring

Monitoring in some combined distribution systems may be insufficient to adequately characterize DBP exposure. Some large, hydraulically complex combined water distribution systems may be conducting monitoring that is not adequate to characterize exposure throughout the distribution system.

Stage 2 D/DBPR Compliance Monitoring — Chlorine Burn

Compliance monitoring for DBPs in some systems may not fully capture DBP levels to which customers may be exposed during certain portions of the year. Systems that use chloramines as a residual disinfectant (generally as part of a compliance strategy to meet DBP MCLs) often temporarily switch to free chlorine as the residual disinfectant for a period (from two to eight weeks) in order to control nitrification in the distribution system. This practice is commonly called a “chlorine burn.” During the chlorine burn, higher levels of DBPs are expected to be formed. Systems often conduct their compliance monitoring outside of the chlorine burn period; and therefore, potentially

higher TTHM and HAA5 levels may not be included in compliance calculations.

4. Microbial Contaminants Regulations

Background

Except for the 1989 Total Coliform Rule, which was reviewed under the Six-Year Review 1, this is the first time EPA is conducting a Six-Year Review of the following microbial contaminant regulations:

- Surface Water Treatment Rule (SWTR),
- Interim Enhanced Surface Water Treatment Rule (IESWTR),
- Long Term 1 Enhanced Surface Water Treatment Rule (LT1),
- Long Term 2 Enhanced Surface Water Treatment Rule (LT2),
- Filter Backwash Recycling Rule (FBRR), and
- Ground Water Rule (GWR).

As discussed in Section V, the Initial Review branch of the protocol identifies NPDWRs with recent or ongoing actions and excludes them from the review process to prevent duplicative agency efforts. The cutoff date for the NPDWRs reviewed under the Six-Year Review 3 was August 2008. Based on the Initial Review, EPA excluded the Aircraft Drinking Water Rule, which was promulgated in 2009, and the Revised Total Coliform Rule (RTCR) (the revision of the 1989 TCR), which was promulgated in 2013.

In this notice, the SWTR, the IESWTR and the LT1 are collectively referred to as the SWTRs because of the close association among the three rules (IESWTR and LT1 were amendments to the SWTR – additional information provided in Section VI.B.4.a). The LT2 is discussed separately in this notice because EPA reviewed the LT2 in accordance with the Six-Year Review requirements and the Executive Order 13563 "Improving Regulation and Regulatory Review" (also known as Retrospective Review). Background information on each of the microbial contaminants regulations is presented in the subsequent sections.

The microbial contaminants regulations establish treatment technique (TT) requirements in lieu of MCLs. The review elements of the microbial contaminants regulations are: initial review, health effects, analytical feasibility, occurrence and exposure, treatment feasibility, risk-balancing and other regulatory revisions.

At this time, the SWTRs are being identified as a candidate for regulatory revision, but the LT2, the FBRR and the GWR are not. A summary of review findings of each rule is described in the subsequent sections. Additional information is provided in the "Six-Year Review 3 Technical Support Document for Microbial Contaminant Regulations" (USEPA, 2016n) and the "Six-Year Review 3 Technical Support Document for Long-Term 2 Enhanced Surface Water Treatment Rule" (USEPA, 2016m).

a. SWTRs

Background

EPA promulgated the SWTR in June 1989. It requires all water systems using surface water sources or ground water under the direct influence of surface water (GWUDI) sources (also known as Subpart H systems) to remove (via filtration) and/or inactivate (via disinfection) microbial contaminants (54 FR 27486, USEPA, 1989). Under the SWTR, EPA established NPDWRs for *Giardia*, viruses, *Legionella*, turbidity and heterotrophic bacteria and set MCLGs of zero for *Giardia lamblia*, viruses and *Legionella*. Under the IESWTR (63 FR 69477, USEPA, 1998c) and the LT1 (67 FR 1812, USEPA, 2002c), EPA established an NPDWR for *Cryptosporidium* and set an MCLG of zero.

The SWTRs established TT requirements in lieu of MCLs in these NPDWRs. The 1989 SWTR established TT requirements for systems to control *G. lamblia* by achieving at least 99.9 percent (3-log) removal/inactivation by filtration and/or disinfection, and to control viruses by achieving at least 99.99 percent (4-log) removal/inactivation (54 FR 27486, USEPA, 1989). For a few systems able to meet source water criteria and site-specific conditions (e.g., protective watershed control program and other conditions), they were permitted to achieve the TT requirements by using disinfection only.

The SWTR also established TT requirements for disinfectant residuals (54 FR 27486, USEPA, 1989). The residual disinfectant concentration at the entry

point to the distribution system may not be less than 0.2 mg/L for more than four hours. The residual disinfectant concentration in the distribution system "cannot be undetectable in more than 5 percent of the samples each month, for any two consecutive months that the system serves water to the public." (40 CFR 141.72). A detectable residual may be established by: (1) an analytical measurement or (2) having a heterotrophic bacteria concentration less than or equal to 500 per mL measured as heterotrophic plate count (HPC). The purpose of these disinfectant residual requirements was to:

- Ensure that the distribution system is properly maintained and identify and limit contamination from outside the distribution system when it might occur,
- Limit growth of heterotrophic bacteria and *Legionella* within the distribution system, and
- Provide a quantitative limit, which if exceeded would trigger remedial action.

The SWTR also established sanitary survey requirements. The purpose of the sanitary survey requirements, which include consideration of distribution system vulnerabilities, is to identify water system deficiencies that could pose a threat to public health and to permit correction of such deficiencies.

As part of the development of the SWTR, EPA needed to clarify which systems would be regulated under Subpart H. In particular, EPA needed to

clarify when systems that could be considered as ground water systems were more appropriate to regulate as surface water systems (for example, systems where the drinking water intake was in a riverbed, not in the river). Thus, to identify a system as either ground or surface water, the SWTR defined "ground water under the direct influence of surface water (GWUDI)." GWUDI is any water beneath the surface of the ground with: (1) significant occurrence of insects or other macroorganisms, algae or large-diameter pathogens such as *Giardia lamblia*, or (2) significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity or pH that closely correlate to climatological or surface water conditions. The final SWTR defined GWUDI as being regulated as surface waters because *Giardia* contamination of infiltration galleries, springs and wells have been found (Hoffbuhr et al., 1986; Hibler et al., 1987). Some contamination of springs and wells have resulted in giardiasis outbreaks (Craun and Jakubowski, 1986). Direct influence was to be determined for individual sources in accordance with criteria established by the state (54 FR 27486, USEPA, 1989). The GWUDI designation identifies PWSs using ground water that must be regulated as if they are surface water systems. All other PWSs using ground water are regulated by the GWR.

Surface water and GWUDI systems use concentration x time (CT) tables published by EPA to determine log-inactivation credits for the use of a

disinfectant to meet the disinfection TT requirements. The "SWTR Guidance Manual" provides CT tables for *Giardia* and virus inactivation by free chlorine, chloramines, ozone and chlorine dioxide (USEPA, 1991). EPA obtained these CT values from bench-scale experiments with hepatitis A virus (HAV).

The IESWTR applies to all PWSs using surface water, or GWUDI, which serve 10,000 or more people. The IESWTR established TT requirements for *Cryptosporidium* by requiring filtered systems to achieve at least a 99 percent (two-log) removal, revising the definition of GWUDI and watershed control program under the SWTR to include *Cryptosporidium*, requiring sanitary surveys for all surface water and GWUDI systems, and setting disinfection profiling and benchmarking requirements to prevent increases in microbial risk while systems complied with the Stage 1 D/DBPR. The LT1 (67 FR 1812, USEPA, 2002c) extended the requirements from the IESWTR to systems serving fewer than 10,000 people.

Summary of Review Results

EPA identified the following NPDWRs under the SWTR as candidates for revision under the Six-Year Review 3 because of the opportunity to further reduce residual risk from pathogens (including opportunistic pathogens such as *Legionella*) beyond the risk addressed by the current SWTR:

- *Giardia lamblia*,

- heterotrophic bacteria,
- *Legionella*,
- viruses, and
- *Cryptosporidium* (also under IESWTR and LT1).

This result is based on a scientific review of available information, following the protocol described in Section V. Based on the availability of new information, the review focused on the following major provisions of the SWTRs:

- Requirements to maintain a minimum disinfectant residual in the distribution system,
- GWUDI classification, and
- CT criteria for virus disinfection.

Collectively, the new information suggests an opportunity to revise the TT provisions of the SWTRs to provide greater protection of public health. More detailed information about the review results related to the major provisions of the SWTRs is provided in the following subsections.

Requirements to Maintain a Minimum Disinfectant Residual in the Distribution System

EPA evaluated information related to the maintenance of a minimum disinfectant level in the distribution system and determined that there is an opportunity to reduce residual risk from pathogens

(includes opportunistic pathogens such as *Legionella*) beyond the risk addressed by the SWTRs. The detectable concentration of disinfectant residual in the distribution system may not be adequately protective of microbial pathogens because of concerns about analytical methods and the potential for false positives (Wahman and Pressman, 2015; Westerhoff et al., 2010). Maintaining a disinfectant residual above a set numerical value in the distribution system may improve public health protection from a variety of pathogens. Such a change could have benefits for controlling occurrence of all types of pathogens in distribution systems, except for those most resistant to disinfection, such as *Cryptosporidium*.

Given our understanding of the distribution system vulnerabilities (e.g., NRC, 2006b), there may be opportunities to enhance the criteria for indicating distribution system integrity, as well as the potential health risk that may be associated with pathogens potentially growing and released from biofilms. These opportunities include revisiting the distribution system disinfectant residual criteria and revisiting the existing alternative HPC criteria. The NRC report (2006b) describes that water quality integrity is an important factor that water professionals must take into account for the protection of public health, and that the sudden loss of disinfectant residuals can indicate a

change in water quality or system characteristics. However, the report was inconclusive on the level of disinfectant residual that should be provided in distribution systems.

GWUDI Classification

EPA reviewed information on disease outbreaks, a randomized controlled intervention study, pathogenic protozoan occurrence data and studies evaluating parasitic protozoan removal surrogates and hydrogeologic studies, all of which were completed since the SWTR was published. The information suggests that there is an opportunity to provide greater public health protection by improved identification of unrecognized GWUDI PWSs. The data suggest that the SWTR regulation and guidance has performed well in identifying GWUDI for the PWS systems most at risk from *Giardia* and *Cryptosporidium* presence in ground water. However, the information (e.g., Colford et al., 2009) suggests that a subset of GWUDI systems are also at risk but are potentially misclassified as ground water systems, and therefore, not subject to requirements that provide protection against parasitic protozoans. Improved public health protection may result if there is improved recognition of GWUDI systems, including those that may disinfect but do not provide engineered filtration or have not conducted a demonstration of performance to document the necessary

Cryptosporidium alternative treatment and removal required under the LT2. The potential public health improvement is most relevant to those systems that have a large surface water component and poor subsurface removal capabilities but are not yet recognized as GWUDI and warrants further examination in any rulemaking activities.

EPA suggests that the number of potentially misclassified GWUDI PWSs may be estimated by: (1) waterborne disease outbreak compilations, (2) the UCMR3 occurrence data (aerobic spore detections and concentrations), and (3) the SYR2 ICR and the SYR3 ICR (total coliform detections). EPA's preliminary characterization of the number of the potentially misclassified GWUDI PWSs is described in the "Six-Year Review 3 Technical Support Document for Microbial Contaminant Regulations" (USEPA, 2016n).

CT Criteria for Virus Disinfection

EPA evaluated whether the current CT criteria based on hepatitis A virus (HAV) are sufficiently protective against other types of viruses. EPA reviewed disinfection studies relevant to the CT tables published in the "1991 SWTR Guidance Manual" (USEPA, 1991). Over the years, many studies have indicated that HAV is less chlorine-resistant than some enteroviruses, such as Coxsackie virus B5 (Black et al., 2009; Cromeans et al., 2010; Keegan et al., 2012), and also less

chloramine-resistant than adenovirus (Sirikanchana et al., 2008; Hill and Cromeans, 2010). Based on this review, EPA identified a potential need to update CT values for virus inactivation by free chlorine or chloramines, particularly for water with a relatively high pH. This assessment is also relevant to the LT2 and the GWR, which refer to the same CT tables in the original "1991 SWTR Guidance Manual."

Health Effects

This section summarizes EPA's review of the information related to human health risks from exposure to microbial contaminants in drinking water. EPA evaluated whether any new toxicological data, or waterborne endemic infection or infectious disease information, would justify modifying the MCLGs. EPA reviewed information that included data from the Waterborne Disease and Outbreak Surveillance System (WBDOSS) collected by the Centers for Disease Control and Prevention (CDC) (http://www.cdc.gov/healthywater/surveillance/drinking-surveillance-reports.html) and other available data that documents drinking water-associated outbreaks.

MCLGs

The SWTRs set MCLGs of zero for *Giardia lamblia*, viruses, *Cryptosporidium*, and *Legionella* since any exposure to these microbial pathogens presents a potential health risk. In the Six Year

Review 3, EPA did not identify new information related to potentially revising these MCLGs. New dose-response data from some waterborne pathogens are available from both human and animal exposure studies (Teunis et al., 2002a; 2002b; Armstrong and Haas, 2007; 2008; Buse et al., 2012). Concurrently, new models seek to use the new data to provide improved infectivity, morbidity and mortality predictions (Messner et al., 2014; USEPA, 2016m). The newer models are specifically designed to address low dose exposure typical of drinking water rather than high dose exposure typical of food ingestion or vaccine studies.

Waterborne Disease Outbreaks Associated with Drinking Water

EPA reviewed information from the Waterborne Disease and Outbreaks Surveillance System about the occurrences and causes of drinking water-associated outbreaks. This surveillance system is the primary source of data concerning such outbreaks in the U.S. (Beer et al., 2015). The drinking water-associated outbreak data from 1971-2012 illustrate that there is an observable reduction of reported outbreaks over that time frame, which may be, at least in part, due to the implementation of the TCR and the SWTR beginning in 1991.

Although the historic number of drinking water-associated outbreaks is declining, CDC notes that the level of surveillance and

reporting activity, as well as reporting requirements, varies across states and localities. For these reasons, outbreak surveillance data likely underestimate actual values, and should not be used to estimate the total number of outbreaks or cases of waterborne disease (Beer et al., 2015).

Deficiencies at private wells and premise plumbing systems are increasingly responsible for disease outbreaks associated with drinking water (Beer et al., 2015). Premise plumbing is the portion of the distribution system from the water meter to the consumer tap in homes, schools, and other buildings (NRC, 2006b). In 2011-2012, the two most frequent deficiencies related to drinking-water-associated outbreaks were *Legionella* in premise plumbing systems (66 percent) and untreated ground water (13 percent) (Beer et al., 2015).

In addition to epidemic illness, sporadic illness (i.e., isolated cases not associated with an outbreak) accounts for an unknown but probably significant portion of waterborne disease and is more difficult to recognize (71 FR 65573, USEPA, 2006b).

Collectively, the data indicate that outbreaks associated with drinking water may have been reduced as a result of drinking water regulations. However, opportunities remain to address disease outbreaks associated with distribution systems and untreated ground

water and, at the same time, to potentially address some of the waterborne disease outbreaks associated with little to no disinfectant residual in the distribution system (Geldreich et al., 1992; Bartrand et al., 2014).

The precise burden of disease is not well quantified. Five primarily waterborne diseases (giardiasis, cryptosporidiosis, Legionnaires' disease, otitis externa, and non-tuberculous mycobacterial infection) were responsible for over 40,000 hospitalizations per year at a cost of nearly $1 billion per year (Collier et al., 2012). Given this information, there are opportunities for substantial cost savings if such incidence can be reduced through better risk management. Most of these costs are attributed to *Legionella* and non-tuberculous mycobacteria. These bacteria can proliferate under favorable conditions at locations in the premise plumbing and in some parts of the distribution system that are further from the central parts of the system, where water has aged the longest and where there may be very little to no disinfectant residual. Further, the quality of the water delivered to building systems and households can affect these pathogens' ability for growth and disease transmission. There are opportunities to enhance the current disinfectant residual requirements to more effectively kill pathogens or contain their growth, and to better indicate, through a stronger signal

of the absence of a residual, when targeted improvements to treatment practices or distribution conditions may provide greater public health protection.

GWUDI-Related Disease Outbreaks

Wallender et al. (2014) summarized CDC outbreak data for the years 1971-2008 and determined that GWUDI was a "contributing factor" in 11 percent (six percent with *Giardia* etiology) of all outbreaks using untreated ground water. The total number of untreated ground water outbreaks during this time period was 248. Three quarters of the outbreaks involved PWSs. These findings indicate that some of the ground water systems examined by CDC that are not currently required to disinfect are contaminated with pathogens. Reclassifying these potentially "unrecognized" GWUDI PWSs may provide greater public health protection against microbial contamination because these PWSs would be subject to stricter requirements. As an example, a 2007 outbreak of giardiasis occurred in a New Hampshire community (205 homes) using untreated ground water (Daly et al., 2010). This GWUDI misclassification-related outbreak was the largest giardiasis drinking water-associated outbreak in the preceding 10 years.

Randomized Controlled Intervention Study

A randomized, controlled, triple-blinded drinking water intervention study was conducted in Sonoma County, California (Colford et al., 2009). The purpose of the study was to determine the proportion of acute gastrointestinal illnesses (AGI) attributable to drinking water. Sonoma County obtained water from five horizontal collector wells along the Russian River, four regulated as ground water and one regulated as GWUDI (part of the year). Colford et al. (2009) found that highly credible AGI in the population aged 55 and over was attributable to drinking water exposure. Illness occurred even though the water utility met all federal, state and local drinking water regulations.

Pathogenic Protozoa Occurrence in Ground Water

In a karst aquifer in France, 18 ground water samples were taken from the Norville (Haute-Normandie) public water supply well (5,000 customers, chlorine treatment) and tested for *Cryptosporidium* oocysts. Thirteen of the 18 samples were found to be *Cryptosporidium* positive by solid-phase cytometry; the maximum concentration was four oocyst per 100 L (Khaldi et al., 2011). These data show that *Cryptosporidium* in karst ground water includes, for some highly vulnerable systems, *Cryptosporidium* occurrence resulting from poor *Cryptosporidium* removal during infiltration from the surface rather than poor removal

during induced infiltration from nearby surface water. Because the SWTR definition assumes that all *Cryptosporidium* in PWS wells is transported from adjacent surface water, it is silent on the issue of *Cryptosporidium* transport directly from the surface, as apparently was the case in Norville, France. Karst aquifers are a vital ground water resource in the U.S. According to the USGS, about 40 percent of the ground water used for drinking water comes from karst aquifers (USGS, 2004).

Analytical Feasibility

Analytical Methods for Chlorine Residuals

Because of concerns about analytical methods and the potential for false positives, the detectable concentration of disinfectant residuals in the distribution system may not be adequately protective of microbial pathogens. To further inform these concerns, EPA reviewed analytical methods that have been approved for free chlorine, total chlorine and chlorine dioxide under the SWTR and the D/DBPRs. Nearly all utilities use either the DPD (*N*,*N*-diethyl-*p*-phenylenediamine) or amperometric titration methods to measure distribution system disinfectant residual, and these measurements are generally performed in the field (Wahman and Pressman, 2015). A number of constituents can interfere with measurements of disinfectant residuals. In general,

most strong oxidants will interfere with measurement of chlorine. In addition, color, turbidity and particles will also interfere with colorimetric techniques such as DPD.

For some systems using chloramines (a mixture of biocidal inorganic chloramines, of which monochloramine is the most effective), the presence of organic chloramines can be problematic since these related compounds have minimal biocidal properties, they can interfere with residual monitoring, and they can give the false impression that the finished water contains more active disinfectant than is actually present (Wahman and Pressman, 2015; Westerhoff et al., 2010). Organic chloramines will continue to form in the distribution system while inorganic chloramines decay, and thus areas of the distribution system with relatively high water ages may have residuals containing a significant amount of organic chloramines (Wahman and Pressman, 2015).

In addition, EPA reviewed research published regarding potential improvements to methods or technologies used in the determination of free or total chlorine (Dong et al., 2012; Tang et al., 2014; Saad et al., 2005). Analytical methods that can measure inorganic chloramines without the organic chloramine interferences are available, but not approved for determining compliance with NPDWRs. Field test kits

based on the indophenol method are available that can specifically measure monochloramine without inclusion of mass from dichloramine or organic chloramines (Lee et al., 2007).

Use of Aerobic Spores as Pathogenic Protozoa Surrogates

EPA's existing microbial contaminants regulations require monitoring of pathogenic protozoa in source water (e.g., *Cryptosporidium*) and microorganisms that indicate a possible pathway for contamination (e.g., total coliform, *E. coli*). In this Six-Year Review, EPA evaluated additional microorganisms that could be used to identify PWSs most at risk from *Cryptosporidium* in ground water. New data suggest that aerobic spores are useful surrogates for *Cryptosporidium* occurrence and removal. Aerobic spores originate in shallow soil. The spore presence in a sample from a PWS well indicates that there is a pathway for water infiltration into the well, either vertically from the surface or horizontally from nearby surface water.

EPA previously used aerobic spores as surrogate measures of *Cryptosporidium* removal by alternative treatment in a demonstration of field performance (USEPA, 2010f). Field demonstrations showed that the spores performed well in demonstrating two-log removal of *Cryptosporidium* at Casper, Wyoming, and Kennewick, Washington

(USEPA, 2010f). Spores also performed well in demonstrating that a Nebraska PWS was unable to achieve better than two-log removal of *Cryptosporidium*, and that UV or other engineered treatment would be required (State of Nebraska, 2013). Headd and Bradford (2015) summarized the relevant scientific literature, conducted spore and *Cryptosporidium* laboratory experiments, and performed porous media transport modeling. They found that spores are suitable *Cryptosporidium* surrogates in ground water. These new data suggest that aerobic spores are useful as surrogates for *Cryptosporidium* removal estimates via subsurface passage (USEPA, 2010f) and may be useful as supplemental surrogates to improve recognition of GWUDI systems.

Locas et al. (2008) found that aerobic spores were present in six of nine wells sampled in Quebec, Canada, and in 45 of 109 samples taken. The authors conclude that aerobic spore presence is an indicator of a change in water quality and warrants further investigation to determine the source of potential contamination.

In EPA's investigation of virus occurrence in untreated PWS wells under the UCMR3, 252 of 793 wells (317 of 1,047 samples) were positive for aerobic spores (USEPA, 2016j). Measured concentrations spanned three orders of magnitude, with about three percent having

over 100 spore-forming units per 100 ml). Because aerobic spores originating in soil are found in GWUDI and ground water PWS wells, the UCMR3 data suggest that aerobic spores could be used as an indicator of the susceptibility of PWS wells to surface water infiltration. Together with other indicators and/or parasitic protozoa data from PWS wells, newer methods including spores (occurrence, concentration, and/or removal estimates) might be useful in identifying unrecognized GWUDI PWS wells. The LT2 Toolbox Guidance Manual identified aerobic spores as the indicator to determine *Cryptosporidium* removal for systems using bank filtration for LT2 additional treatment requirements (USEPA, 2010f).

Occurrence and Exposure

Coliform and/or *E. coli* occurrence can be an indication of conditions supporting bacterial growth or an intrusion event into the distribution system. On the other hand, the absence of coliforms and/or *E. coli* does not necessarily mean the absence of pathogens that are more resistant to the disinfectant residual. Detection of coliform bacteria is commonly associated with low distribution system disinfectant residuals. According to LeChevallier et al. (1996), disinfectant residuals of 0.2 mg/L or more of free chlorine, or 0.5 mg/L or more of total chlorine, are associated with reduced levels of coliform bacteria.

To assess the relationship between disinfectant residual and occurrence of indicators for pathogens in distribution systems, EPA evaluated information about chlorine residuals and total coliforms and *E. coli* (TC/EC) using compliance monitoring data from the SYR3 ICR database. EPA paired TC/EC results with field chlorine residual data collected at the same time and location. It is important to note that these evaluations help to inform the SYR3 results, but do not assess compliance with regulatory standards.

EPA found that there was a lower rate of occurrence of both TC and EC as the free or total chlorine residual increased to higher levels (note: total chlorine is often used as a measure for systems that use chloramines). For example, the TC positive rate was less than one percent when chlorine residuals were equal to or greater than 0.2 mg/L of free chlorine or 0.5 mg/L of total chlorine. This relationship between chlorine residuals and occurrence of TC and EC was similar to that reported by the Colorado Department of Public Health and Environment (Ingels, 2015).

A disinfectant residual also serves as an indicator of the effectiveness of distribution system best management practices. Best management practices include flushing, storage tank maintenance, cross-connection control, leak detection and effective pipe replacement and repair practices. The effective implementation of best management practices helps water

suppliers to lower chlorine demand and maintain an adequate disinfectant residual throughout the distribution system. These same practices can also help control DBP formation.

Treatment Feasibility

EPA reviewed new information related to the TT requirements in the SWTR and identified the following treatment-related topics that support potential revisions to the SWTRs to improve public health protection:

- Detectable residual for systems using chloramine disinfection,
- State implementation of disinfection residual requirements,
- Disinfectant residuals for control of *Legionella* in premise plumbing systems,
- HPC alternative to detectable residual measurement, and
- CT criteria for viruses.

In addition, EPA reviewed key findings by the Research and Information Collection Partnership (RICP) on drinking water distribution system issues and research and information needs. The RICP is a working group formed on the recommendation of the Total Coliform Rule Distribution System Advisory Committee to identify specific high-priority research and information collection activities and to stimulate water distribution system research and information collection (USEPA, 2008b; USEPA and Water Research Foundation, 2016).

Detectable Residual for Systems Using Chloramine Disinfection

As discussed in the background portion of this section, for surface water systems or GWUDI systems, the SWTR requires that a disinfectant residual cannot be undetectable in more than five percent of samples each month for any two consecutive months.

EPA identified two issues that have implications for the protectiveness of allowing a detectable residual as a surrogate for bacteriological quality: organic chloramines and nitrification. Organic chloramines affect the effectiveness of disinfectant residuals because they: (1) form during the use of free chlorine or chloramines, (2) interfere with commonly used analytical methods for free and total chlorine measurements, and (3) are poor disinfectants compared to free chlorine and monochloramine (Wahman and Pressman, 2015).

Because chloramination involves introduction of ammonia into drinking water, and decomposition of chloramines can further release ammonia in the distribution system, chloramine use comes with the risk of distribution system nitrification (i.e., the biological oxidation of ammonia to nitrite and eventually nitrate). Drinking water distribution system nitrification is undesirable and can result in water quality degradation. Information shows that maintaining a high enough level of total chlorine or monochloramine residuals in the distribution

system can help prevent both nitrification and residual depletion (Stanford et al, 2014).

State Implementation of Disinfectant Residual Requirements

States may adopt federal drinking water regulations or promulgate more stringent drinking water requirements, including those for disinfectant residuals. Preliminary information shows that 26 states require a detectable disinfectant residual in the distribution system. Twenty of these 26 states require a minimum free chlorine residual of 0.2 mg/L or more (Ingels, 2015; Wahman and Pressman, 2015). Five of the 20 states set standards even more stringent than 0.2 mg/L: Louisiana requires at least 0.5 mg/L free chlorine in its emergency rule, while Florida, Illinois, Iowa, and Delaware require 0.3 mg/L. For minimum total chlorine residual, state requirements vary from 0.05 mg/L (New Jersey) to 1.00 mg/L or higher (Kansas, Oklahoma, Iowa, Ohio, and North Carolina). North Carolina has a numeric requirement for total chlorine residual but not for free chlorine residual.

Colorado has amended its minimum disinfectant residual requirements in the distribution system to be greater than or equal to 0.2 mg/L, effective April 1, 2016 (Ingels, 2015). Pennsylvania recently proposed to strengthen its disinfectant residual requirements by increasing the minimum disinfectant residual in the distribution system

to 0.2 mg/L free or total chlorine (Pennsylvania Bulletin, 2016). Louisiana's Emergency Distribution Disinfectant Residual Rule was established in 2013 to control *Naegleria fowleri*, an amoeba found in several PWSs. That rule requires a minimum free or total chlorine disinfectant level of 0.5 mg/L to be maintained at all times in finished water storage tanks and the entire distribution system (Louisiana Department of Health and Hospitals, 2013). The state agency intends to continue to renew the Emergency Rule until a final rule can be promulgated (Louisiana Department of Health and Hospitals, 2014).

Disinfectant Residuals for Control of *Legionella* in Premise Plumbing Systems

Since the reporting of disease outbreaks due to *Legionella* began in 2001, *Legionella* has been shown to cause more drinking-water-related outbreaks than any other microorganism. Addressing premise plumbing issues is particularly challenging. Premise plumbing may be largely outside of water utilities' operations and management control. Also, the characteristic features of premise plumbing (e.g., low disinfectants residuals, stagnation, and warm temperature) tend to support growth and persistence of opportunistic pathogens.

Studies indicate that distribution systems can play a role in influencing the transmission and contamination of *Legionella* in

premise plumbing systems (Lin et al., 1998; States et al., 2013). Hospitals served by PWSs using chloramines reported fewer outbreaks of legionellosis than those using free chlorine (Kool et al., 1999; Heffelginger et al., 2003). Some building systems supplied by PWSs which have switched to chloramines have seen marked reduction in the colonization of *Legionella* (Flannery et al., 2006; Moore et al., 2006). One implication of these studies is the importance of being able to reliably measure and sustain chloramine residuals to increase the likelihood of its effectiveness at controlling *Legionella* in premise plumbing systems. On the other hand, some studies have indicated that the occurrence of another pathogen, non-tubercular *Mycobacterium*, may increase under chloramination conditions (Pryor et al., 2004; Moore et al., 2006; Duda et al., 2014).

Legionella species can multiply in warm, stagnant water environments, such as in community water storage tanks with low disinfectant residuals during warm months. Cohn et al. (2014) observed increased incidence of legionellosis among institutions and private homes near a community water storage tank when the disinfectant residual in the storage tank dropped (from greater than 0.2 mg/L to less than 0.2 mg/L) during hot summer months. Based on these findings, the authors recommended that, regardless of total

coliform occurrence, remedial actions be taken (e.g., flushing of mains, checking for closed valves that can result in hydraulic dead-ends, and possibly installing re-chlorination stations) when low chlorine residuals are observed during hot summer months. They also noted that this storage tank had been cleaned subsequent to the outbreak (Cohn et al, 2014; Ashbolt, 2015).

To help address concerns about *Legionella*, EPA developed a document entitled "Technology for Legionella Control in Premise Plumbing Systems: Scientific Literature Review" (USEPA, 2016r). The document summarizes information about the effectiveness of different approaches to control *Legionella* in a building's premise plumbing system. EPA expects that use of this document will further improve public health by helping primacy agencies, facility maintenance operators, and facility owners make science-based risk management decisions regarding treatment and control of *Legionella* in buildings.

EPA also reviewed the scientific literature on the effectiveness of disinfectant residuals at controlling biofilm growth. Many factors influence the concentration of the disinfectant residual in the distribution system; and therefore, the ability of the residual to control microbial growth and biofilm formation. These factors include the

level of assimilable organic carbon (AOC), the type and concentration of disinfectant, water temperature, pipe materials, and system hydraulics.

Problems associated with biofilms in distribution systems include enhanced corrosion of pipes and deterioration of water quality. Biofilms can provide ecological niches that are suited to the potential survival of pathogens (Walker and Morales, 1997; Baribeau et al., 2005; Behnke et al., 2011; Wang et al., 2012; Biyela et al., 2012; Revetta et al., 2013; Ashbolt, 2015). The biofilm can protect microorganisms from disinfectants and can enhance nutrient accumulation and transport (Baribeau et al., 2005).

HPC Alternative to Detectable Residual Measurement

Under the SWTR, a system may demonstrate that its HPC levels are less than 500 per mL, at any sampling locations, in lieu of demonstrating the presence of a detectable disinfectant residual at that location, per primacy agency approval. EPA reviewed new information that suggests development of criteria which may be more protective than the HPC criterion. For example, criteria used in the Netherlands for systems operating without a distribution system disinfectant residual provides an example of an alternative criteria than the HPC criterion. In the Netherlands, chlorine is not used routinely

for primary or secondary disinfection. Dutch water systems use the following general approach to control microbial activity in the distribution system without a disinfectant residual (Smeets et al., 2009): produce a biologically stable drinking water; use distribution system materials that are non-reactive and biologically stable; and optimize distribution system operations and maintenance practices to prevent stagnation and sediment accumulation. For the determination of a biologically stable water they use AOC as an indicator.

CT Criteria for Virus Disinfection

EPA reviewed new disinfection studies published since the release of the original CT tables. Collectively, the data in the recent literature indicate that EPA CT values for free chlorine disinfection are sufficient to inactivate most enteric viruses in drinking water, except for Coxsackie virus B5 at a pH higher than 7.5 (Black et al., 2009; Cromeans et al., 2010; Keegan et al., 2012).

EPA's CT values for chlorine incorporate a safety factor of three to account for differences between dispersed and aggregated hepatitis A virus and between buffered, demand-free water and environmental water. In light of new information about the hepatitis A virus and the effects of source water quality on chlorine disinfection, EPA concludes that the safety factor of three should be re-evaluated to ensure its

adequacy. A larger safety factor (thus higher EPA CT values) is expected to enhance waterborne pathogen control but could lead to higher DBP formation and warrants further examination in any rulemaking activity.

Adenovirus is the virus that is most resistant to chloramines, through it is very susceptible to free chlorine disinfection. Several studies revealed that monochloramine disinfection might not provide adequate control of adenovirus in drinking water, particularly in waters with relatively high pH and at low temperature (Sirikanchana et al., 2008; Hill and Cromeans, 2010).

Research and Information Collection Partnership Findings

The RICP partners are EPA and Water Research Foundation. EPA examined information from the 10 high priority RICP areas in the context of the Six-Year Review, particularly information related to the effectiveness of sanitary survey and corrective action requirements under the IESWTR. However, EPA found limited information that would shed light on the frequency and magnitude of distribution system vulnerability events (e.g., backflow events, storage tank breeches), associated risk implication, and costs for preventing such events from occurring. The RICP report identifies potential follow-up

research areas that could help to address these gaps (USEPA and Water Research Foundation, 2016).

Risk-Balancing

The Agency has considered the risk-balancing aspects of the MDBP rules and has determined that potential revisions to the SWTRs could provide improved health protection. The risk-balancing activities considered by the Agency include those between the microbial and disinfection by-product rules, as well as those between different groups of DBPs. This includes balancing the reduction in risks from microbial pathogens should there be additional requirements to maintain a disinfectant residual with the increased risk from D/DBPs resulting from such requirements. EPA also considered the potential impact of further constraints on DBP precursors on the reduction of demand for disinfectant residual. The risk-balancing review was based on a preliminary, qualitative assessment of unintended consequences; it is important to note that further assessment of such consequences would be an important component of any further rulemaking activities.

b. LT2

Background

EPA promulgated the LT2 on January 5, 2006 (71 FR 654, USEPA, 2006c). The LT2 applies to all PWSs that use surface water or ground

water under the direct influence of surface water as drinking water. The LT2 builds upon the IESWTR and the LT1 by improving control of microbial pathogens, specifically the contaminant *Cryptosporidium*. The purpose of the LT2 is to reduce illness linked with the contaminant *Cryptosporidium* and other disease-causing microorganisms in drinking water. The LT2 supplements the IESWTR and the LT1 regulations by establishing additional *Cryptosporidium* treatment requirements for higher-risk systems. The LT2 requires source water occurrence monitoring which is used to determine additional treatment requirements. The LT2 rule provides for additional CT credits for *Cryptosporidium* inactivation by ozone and chlorine dioxide. The LT2 also provides UV treatment credits for *Cryptosporidium*, *Giardia* and virus inactivation. EPA recognized that research in the field of *Cryptosporidium* inactivation is ongoing and included a provision in the rule that allows unfiltered systems using a disinfectant other than chlorine to demonstrate the log inactivation that can be achieved.

The LT2 also contains provisions to reduce risks from uncovered finished water reservoirs (UCFWRs).[5] The rule ensures that systems maintain microbial protection when they take steps to decrease the formation of disinfection byproducts in systems that add a chemical

[5] LT2 uses the term ‘facilities” instead of ‘reservoirs’. The term ‘reservoirs’ is used in this document.

disinfectant (i.e., other than UV light) or receive a chemically disinfected water. Storage of treated drinking water in open reservoirs can lead to significant water quality degradation and health risks to consumers (USEPA, 1999). Examples of such water quality degradation include increases in algal cells, coliform bacteria, heterotrophic bacteria, particulates, disinfection byproducts, metals, taste and odor, insect larvae, *Giardia*, *Cryptosporidium* and nitrate (USEPA, 1999). Contamination of reservoirs occurs through surface water runoff, bird and animal wastes, human activity, algal growth, airborne deposition and insects and fish.

The LT2 requires PWSs using uncovered finished water storage facilities to either cover the storage facility or treat the storage facility discharge (i.e., prior to entering the distribution system) to achieve inactivation and/or removal of 4-log virus, 3-log *G. lamblia*, and 2-log *Cryptosporidium* spp. on a state-approved schedule.

Under the LT2, PWSs were required to notify their state/primacy agency by April 1, 2008, if they used UCFWRs. Additionally, the LT2 required all PWSs to either meet the requirement to cover the UCFWR, or treat the UCFWR discharge to the distribution system or be in compliance with a state-approved schedule for meeting these requirements no later than April 1, 2009. Under this review, EPA evaluated published

information to assess whether allowing a state-approved risk management plan would justify revisions to the LT2.

Summary of Review Results

Information available since promulgation of the LT2 either supports the current regulatory requirements or does not justify a revision. EPA determined that no regulatory revisions to the UCFWR requirements of the LT2 are warranted at this time based on the review of available information.

Health Effects

EPA reassessed the health risks resulting from exposure to *Cryptosporidium* spp., *Giardia lamblia* and viruses, as well as other potential microbiological risks to human health. The Agency also reviewed new information on other pathogens of potential concern to determine whether additional measures are warranted to provide greater public health protection from these pathogens, particularly in the context of the UCFWR provisions of the LT2.

The principal objectives of this health effects review were to: (1) evaluate whether there are new or additional ways to estimate risks from *Cryptosporidium* and other pathogenic microorganisms in drinking water and (2) evaluate surveillance and outbreak data on *Cryptosporidium* and other contaminants of potential concern. Based on the review, the new

information does not justify a revision to the health basis for the LT2 at this time. For more information regarding EPA's review of health effects, see the "Six-Year Review 3 Technical Support Document for Long-Term 2 Enhanced Surface Water Treatment Rule" (USEPA, 2016m).

Analytical Feasibility

The LT2 specifies approved analytical methods to determine the levels of *Cryptosporidium* in source waters for the identification of additional treatment needs. The LT2 requires systems and/or laboratories to use either "Method 1622: *Cryptosporidium* in Water by Filtration/IMS/FA" (EPA 815–R–05–001, USEPA, 2005d) or "Method 1623: *Cryptosporidium* and *Giardia* in Water by Filtration/IMS/FA" (EPA 815–R–05–002, USEPA, 2005e). EPA Methods 1622 or 1623 is used in monitoring programs to characterize *Cryptosporidium* levels in the source water of PWSs for the purposes of risk-targeted treatment requirements under the LT2. Method recoveries of more than 3,000 matrix spiked samples from the first round of monitoring for the LT2 indicated an average recovery of oocysts with Methods 1622 and 1623 to be 40 percent. In addition to evaluating the results from the first round of monitoring, EPA gathered new information on *Cryptosporidium* analytical methods by investigating improvements to Methods 1622 and 1623. EPA evaluated whether the required use of a revised method (Method 1623.1)

would be justified for Round 2 monitoring under the LT2. Though new information is available that indicates the potential for a regulatory revision, the Agency does not believe it is appropriate to revise the rule to require the use of Method 1623.1, since the Agency believes such a change would not provide substantially greater protection of public health at the national level. The use of Method 1623.1 during the LT2 Round 2 monitoring is optional, and not required. Since EPA is not planning changes to the methods required under the LT2, the schedule for the LT2 Round 2 monitoring remains the same as described in the final LT2, which is scheduled to be completed no later than 2021 for all PWSs.

Occurrence and Exposure

The LT2 requires PWSs using surface water or ground water under the direct influence of surface water to monitor their source waters for *Cryptosporidium* spp. (and/or *E. coli*) to identify additional treatment requirements. PWSs must monitor their source water (i.e., the influent water entering the treatment plant) over two different timeframes (Round 1 and Round 2) to determine the *Cryptosporidium* level. Monitoring results determine the extent of *Cryptosporidium* treatment requirements under the LT2.

Under the LT2, the date for PWSs to begin monitoring is staggered by PWS size, with smaller PWSs starting at a later time than larger systems.

According to the LT2 rule requirements, all PWSs were expected to complete Round 1 in 2012.

To reduce monitoring costs, small filtered PWSs (serving fewer than 10,000 people) initially monitor for *E. coli* for one year as a screening analysis and are required to monitor for *Cryptosporidium* only if their *E. coli* levels exceed specified trigger values. Small filtered PWSs that exceed the *E. coli* trigger, as well as small unfiltered PWSs, must monitor for *Cryptosporidium* for one or two years, depending on the sampling frequency.

Based on the source water monitoring results, filtered systems were classified in one of four risk categories to determine additional treatment needed (Bins 1-4). Systems in Bin 1 are required to provide no additional *Cryptosporidium* treatment. Filtered systems in Bins 2-4 must achieve 1.0-2.5 log of treatment (i.e., 90 to 99.7 percent reduction) for *Cryptosporidium* over and above that provided by conventional treatment, depending on the *Cryptosporidium* concentrations. Filtered PWSs must meet the additional *Cryptosporidium* treatment requirements in Bins 2, 3, or 4 by selecting one or more technologies from the microbial toolbox of options for ensuring source water protection and management, and/or *Cryptosporidium* removal or inactivation. All unfiltered water systems must provide at least 99 or 99.9 percent (2 or 3-log) inactivation of

Cryptosporidium, depending on the results of their monitoring. Additionally, all filtered systems that provide, or will provide, 5.5 log treatment for *Cryptosporidium* are exempt from monitoring and subsequent bin classification. Systems providing 5.5 log *Cryptosporidium* treatment must notify the state no later than the date by which the system must submit a sampling plan.

Six years after the initial bin classification, filtered systems must conduct a second round of monitoring. Round 2 monitoring is in place to understand year-to-year occurrence variability. The difference observed between occurrence at the time of the ICR Supplemental Surveys (USEPA, 2000c) and the LT2 Round 1 monitoring indicates year-to-year variability. Round 2 monitoring began in 2015. Under this review, EPA considered whether a third round of monitoring would be justified at this time, in particular, requiring the use of Method 1623.1. EPA also considered whether a modification to the action bin boundaries should be made based on requiring Method 1623.1.

Because of the relatively modest gains in public health protection predicted by the Round 2 monitoring EPA does not believe a third round of monitoring is justified at this time, even if the Agency were to require the use of Method 1623.1 for this monitoring. Round 1 *Cryptosporidium* occurrence was lower than expected (3.3-5.3 percent of Bin 1 systems

from Round 1 would be moved to a higher bin). As mentioned earlier, EPA will not require the use of Method 1623.1 for *Cryptosporidium* monitoring. Therefore, EPA will not make changes to the action bin boundaries at this time.

Treatment Feasibility

LT2 includes a variety of treatment and control options, collectively termed the "microbial toolbox," that PWSs can implement to comply with the LT2's additional *Cryptosporidium* treatment requirements. Most options in the microbial toolbox carry prescribed credits toward *Cryptosporidium* treatment and control requirements. The LT2 Toolbox Guidance Manual (USEPA, 2010f) provides guidance on how to apply the toolbox options.

The LT2 also requires all unfiltered PWSs to provide at least 2 to 3-log (i.e., 99 to 99.9 percent) inactivation of *Cryptosporidium*. Further, under the LT2, unfiltered PWSs must achieve their overall inactivation requirements (including *Giardia* and virus inactivation as established by earlier regulations) using a minimum of two disinfectants.

EPA reviewed information available since the promulgation of the LT2 on the use of the microbial toolbox to determine if the information would support a potential change to the prescribed credits or the associated design and operational criteria. In addition, EPA searched for

information on new and emerging tools that would support their potential addition to the toolbox. The Agency also received input on the use and effectiveness of the microbial toolbox tools through public meetings, research of publicly available information and by actively communicating with some systems. EPA also considered benefits and/or difficulties observed by the PWSs when using the available tools.

EPA also examined information from some PWSs with UCFWRs to evaluate the potential effectiveness of risk management measures taken by those PWSs for protecting the finished water in the UCFWRs from contamination. The New York City Department of Environmental Protection (NYC DEP) has undertaken more activities than any other PWS to protect their Hillview Reservoir from contamination. These activities include wildlife management (e.g., bird harassment and deterrents, mammal relocation), security measures, runoff control, public health surveillance, microbial monitoring (e.g., *Cryptosporidium*, *E. coli*) and a *Cryptosporidium* and *Giardia* action plan[6]. EPA reviewed information pertaining to these activities and concluded that the information is inadequate to support regulatory changes at the national level. The data is also insufficient to demonstrate that risk management activities provide

[6] http://www.nyc.gov/html/dep/pdf/reports/fad_4.1_waterfowl_management_program_annual_report_07-12.pdf

equivalent public health protection compared to covering the reservoir or treating the outflow from the reservoir.

The LT2 includes disinfection profile and benchmark requirements to ensure that any significant change in disinfection, whether for disinfection byproducts control under the Stage 2 D/DBPR, improved *Cryptosporidium* control under the LT2, or both, does not significantly compromise existing *Giardia* and virus protection. The profiling and benchmarking requirements under the LT2 are similar to those promulgated under the IESWTR and the LT1 (USEPA, 2002c) and are applicable to systems that make a significant change to their disinfection practices.

EPA did not identify information that would support a potential change to the methodology and calculations for developing the disinfection profile and benchmark under the LT2. However, EPA identified information that would support a potential change to the CT values required for virus disinfection (as discussed in the Section VI.B.4.a. "SWTRs"). EPA is considering this information in the review of the overall filtration and disinfection requirements in the SWTR.

Based on the outcome of this review, EPA determined that no regulatory revisions to the microbial toolbox options are warranted at this time. Any new information available to the Agency either supports the

current regulatory requirements or does not justify a revision. For more information regarding EPA's review of treatment feasibility see the "Six-Year Review 3 Technical Support Document for Long-Term 2 Enhanced Surface Water Treatment Rule" (USEPA, 2016m).

c. FBRR

Background

EPA promulgated the FBRR in 2001 (66 FR 31086, USEPA, 2001b). It requires PWSs to review their backwash water recycling practices to ensure microbial control is not compromised, and it requires PWSs to recycle filter backwash water.

Summary of Review Results

EPA reviewed this rule as part of the Six-Year Review 3, and the result is to take no action on the basis that EPA did not identify any relevant information that indicate changes to the NPDWR.

d. GWR

Background

EPA promulgated the GWR in 2006 (71 FR 65573, USEPA, 2006b) to provide protection against microbial pathogens in PWSs using ground water sources. The rule establishes a risk-based approach to target undisinfected ground water systems that are vulnerable to fecal contamination. If a system has an initial total coliform positive in the

distribution system (based on routine coliform monitoring under the RTCR), followed by a fecal indicator positive (*E. coli*, enterococci or coliphage) in a follow-up source water sample, it is considered to be at risk of fecal contamination. Systems at risk of fecal contamination must take corrective action to reduce potential illness from exposure to microbial pathogens. Disinfecting systems that can demonstrate 4-log virus inactivation are not subject to the monitoring requirements.

In addition to the protection provided by the Revised Total Coliform Rule (RTCR) and GWR monitoring requirements, systems that do not disinfect are also protected by the sanitary survey provisions of the GWR and the Level 1 assessment provisions of the RTCR.

Summary of Review Results

EPA has not identified the GWR as a candidate for revision under the Six-Year Review 3 because EPA needs to evaluate emerging information from full implementation of the GWR (71 FR 65573, USEPA, 2006b) and the RTCR (78 FR 10270, USEPA, 2013a) before determining if there is an opportunity to improve public health protection. Implementation of the GWR was not yet completed for the period of time covered by the SYR3 ICR. The RTCR was promulgated in 2013 and became effective on April 1, 2016. EPA expects that implementation on the RTCR may impact the percent of ground water systems that will be triggered into source water

monitoring and taking any corrective actions under the GWR. Therefore, the effects of the GWR and the RTCR implementation in addressing vulnerable ground water systems are not yet known. EPA notes that the GWR was also recently reviewed under Section 610 of the Regulatory Flexibility Act, which required federal agencies to review regulations that have significant economic impact on a substantial number of small entities within 10 years after their adoption as final rules. The 610 Review of the GWR was recently completed; three comments were received. A report is available discussing the 610 Review, comments received, and EPA's response to major comments (USEPA, 2016g).

Health Effects

Borchardt et al. (2012) studied the health effects associated with enteric virus occurrence in undisinfected PWS wells in 14 communities in Wisconsin. Drinking water samples were assayed for a suite of viral pathogens using quantitative polymerase chain reaction (qPCR). Community members kept daily diaries to self-report AGI. The study found a statistically significant association between enteric virus occurrence in the drinking water and AGI incidences in the communities.

Using the 2005 data, EPA estimated a national average TC detection rate of 2.4 percent for routine samples from undisinfected CWSs with populations less than 4,100 people (USEPA, 2012). The 14 communities

(with undisinfected PWS wells) studied by Borchardt et al. (2012) had TC detections of 2.3 percent. These data suggest that the 14 communities studied by Borchardt et al. (2012) had TC detection rates no different from an average undisinfected community PWS in the U.S.

Analytical Methods

Since the promulgation of the GWR in 2006, EPA has approved several new methods for the analysis of TC samples used as a trigger for GWR source water monitoring, or for source water fecal indicators used under the GWR. These methods can be found on the EPA website (https://www.epa.gov/dwanalyticalmethods/approved-drinking-water-analytical-methods). However, PWSs are not required to use these new methods. Additionally, EPA did eliminate the use of fecal coliforms from the RTCR as an indicator of fecal contamination.

Occurrence and Exposure

New information suggests that total coliform occurrence varies among small undisinfected ground water systems, depending upon whether the system is a community, non-transient non-community or transient non-community PWS (USEPA, 2016n). Statistical modeling of 2011 data (about 60,000 systems based on occurrence data collected from undisinfected ground water systems) shows that undisinfected transient non-community ground water systems have the highest occurrence, at

approximately four percent median routine TC positive occurrence as compared with three percent for undisinfected non-transient non-community ground water systems and two percent for undisinfected community ground water systems (USEPA, 2016n). These occurrence levels are similar to those estimated during the development of the RTCR using 2005 data (USEPA, 2012). Additionally, according to the 2005 and 2011 datasets, the smaller systems had higher median TC occurrence than the larger systems. All positive total coliform samples were assayed for *E. coli*; about one in 20 were *E. coli* positive.

A small percentage of undisinfected ground water systems have higher TC detection rates. For example, of the 52,000 undisinfected transient, non-community ground water systems serving populations less than 101 people (the total count is from USEPA, 2006b), EPA (2012) estimated that about 2,600 (five percent) of those systems (4.6 percent for the 2005 data set) had TC detection rates of 20 percent or more.

Under the third monitoring cycle of the Unregulated Contaminant Monitoring Rule (UCMR3), EPA sampled about 800 randomly selected undisinfected ground water systems serving fewer than 100 people for virus and virus indicators. These data show that only a small number of samples were virus positive by qPCR (16 out of 1,044 or two percent) USEPA, 2016j). This result contrasts significantly with the virus positive

sample rate from Borchardt et al. (2012) (287 out of 1,204 or 24 percent). One difference is that Borchardt et al. (2012) sampled prior to any treatment in the undisinfected wells (e.g., softening, iron/manganese removal). In contrast, many wells in the UCMR3 virus study were sampled after softening or other treatment. The UCMR3 monitoring results are available online at: https://www.epa.gov/dwucmr/data-summary-third-unregulated-contaminant-monitoring-rule.

VII. EPA's Request for Comments and Next Steps

EPA invites commenters to submit any relevant data or information pertaining to the NPDWRs identified in this action as candidates for revision, as well as other relevant comments. EPA will consider the public comments and/or any new, relevant data submitted for the eight NPDWRs listed as candidates for revision as the Agency moves forward in determining whether regulatory revisions for these NPDWRs are necessary. The announcement whether or not the Agency intends to revise an NPDWR (pursuant to SDWA §1412(b)(9)) is not a regulatory decision.

Relevant data include studies/analyses pertaining to health effects, analytical feasibility, treatment feasibility and occurrence/exposure. This information will inform EPA's evaluation as the Agency moves forward determining whether regulatory revisions for these NPDWRs are necessary. The data and information requested by EPA include peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the review justifies use of the data).

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 the documentation that supports them (USEPA, 2015a).

Specifically, EPA is requesting comment and/or information related to the following aspects of potential revisions to the MDBP NPDWRs:

- Potential approaches that could enhance protection from DBPs, including both those that are regulated and those currently unregulated (e.g., nitrosamines). Specifically, commenters are requested to provide information about requiring greater removal of precursors (e.g., TOC), and/or more targeted constraints on precursors (e.g., based on watershed vulnerabilities) that could provide for an improvement in health protection from mixtures of DBPs while considering risk-balancing. For example, commenters are requested to provide information about an approach that provides for an option to either control source water vulnerabilities (e.g., de facto reuse) or to further constrain precursors associated with unregulated DBPs. In addition, commenters are requested to provide information that considers a comprehensive analysis of source waters for the formation of a wide variety of byproducts (e.g., TTHM, HAA5, and unregulated DBPs such as nitrosamines, brominated and iodinated compounds).

- Potential approaches that could enhance protection from chlorite, chlorate, and chlorine dioxide. Specifically, commenters are requested to provide information about approaches that could involve, for example: setting standards for systems using hypochlorite that address combined exposure to chlorite and chlorate; and setting standards for systems using chlorine dioxide (alone or in combination with other disinfectants) that address combined exposure from chlorite, chlorate, and chlorine dioxide.
- Potential approaches that could provide increased protection from microbial pathogens and that take into consideration the issues noted about disinfection residual requirements, while considering the risk-balancing aspects of the MDBP rules. In addition, commenters are requested to provide information about approaches that could offer enhanced protection without the use of a chlorine-based disinfectant residual in the distribution system, including technology and management systems associated with those approaches.
- Information about how frequently PWS monitor for DBPs during chlorine burn periods, including revised monitoring schedules for DBPs, taking into account occurrence and exposure to DBPs during chlorine burn periods, and related short-term health effects on sensitive populations.

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