United States
Environmental Protection
Agency

EPA Protocol for the Fourth Review of Existing National Primary Drinking Water Regulations

Office of Water (4607M)
EPA 815-R-24-018
February 2024
www.epa.gov/safewater

Table of Contents

Table of Exhibits

Abbreviations and Acronyms

ADWR	Aircraft Drinking Water Rule
ATSDR	Agency for Toxic Substances and Disease Registry
BAT	Best Available Technology
CalEPA	California Environmental Protection Agency
CSF	Cancer Slope Factor
DBP	Disinfection Byproduct
D/DBPR	Disinfectants/Disinfection Byproducts Rule
DWHSA	Drinking Water Standards and Health Advisory
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
EPA	U.S. Environmental Protection Agency
EQL	Estimated Quantitation Level
GDWQ	Guidelines for Drinking Water Quality
GWR	Ground Water Rule
HAA5	Haloacetic Acids (sum of five HAAs: monochloroacetic, dichloroacetic, trichloroacetic, monobromoacetic, and dibromoacetic acids)
HC	Health Canada
HED HHRA	Health Effects Division Human Health Risk Assessments
HESD	Health Effects Support Documents
ICR	Information Collection Request
IRIS	Integrated Risk Information System
LT2 ESWTR	Long-Term 2 Enhanced Surface Water Treatment Rule
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MDBP	Microbial and Disinfection Byproduct
MDL	Method Detection Limit
mg/L	Milligrams per Liter
MRDL	Maximum Residual Disinfectant Level
MRDLG	Maximum Residual Disinfectant Level Goal
MRL	Minimum Reporting Level
NAS	National Academy of Sciences
NAWQA	National Water Quality Assessment
NDWAC	National Drinking Water Advisory Council
NELAC	National Environmental Laboratory Accreditation Conference
NPDWR	National Primary Drinking Water Regulation
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
PHG	Public Health Goals
PPRTV	Provisional Peer-Reviewed Toxicity Value
PQL	Practical Quantitation Level
PT	Proficiency Testing
PWS	Public Water System

RED	Reregistration Eligibility Decision
RfD	Reference Dose
RTCR	Revised Total Coliform Rule
SDWA	Safe Drinking Water Act
SYR 4	Six-Year Review 4
SYR 3	Six-Year Review 3
SYR 2	Six-Year Review 2
SYR 1	Six-Year Review 1
TT	Treatment Technique
TCR	Total Coliform Rule
TTHM	Total Trihalomethanes (sum of four THMs: chloroform, bromodichloromethane, dibromochloromethane, and bromoform)
USGS	U.S. Geological Survey
WHO	World Health Organization

Executive Summary

The 1996 Safe Drinking Water Act (SDWA) Amendments require the U.S. Environmental Protection Agency (EPA or the agency) to periodically review the 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 identify those NPDWRs for which current health effects assessments, changes in technology, and/or other factors provide a health or technical basis to support a regulatory revision that will improve or strengthen public health protection. EPA completed and published the results of its first Six-Year Review on July 18, 2003 (USEPA, 2003a), after developing a systematic approach, or protocol, for the review of NPDWRs. EPA incorporated minor refinements into the protocol and completed the second review in December 2009 (published March 2010) (USEPA, 2009). EPA applied the same protocol with additional clarifications to its third Six-Year Review of NPDWRs and completed the review in December 2016 (USEPA, 2016). EPA made further clarifications to the protocol and applied it to the fourth Six-Year Review of NPDWRs (Six-Year Review 4 or SYR 4).

In the Six-Year Review 4, EPA addresses the following:

Maximum Contaminant Level Goals (MCLGs; the health goal) – For some contaminants, new health effects assessments, completed after the MCLG was promulgated or last revised, result in revisions to the reference doses (RfD) and/or cancer classification that could justify a revised MCLG.

Maximum Contaminant Levels (MCLs; the enforceable standard) – For some contaminants, the MCL is equal to the MCLG, and the health effects assessment indicates potential to revise the MCLG. For contaminants with an MCL greater than the MCLG, improvements in analytical or treatment feasibility may also indicate an opportunity to lower the MCL closer to the MCLG.

Maximum Residual Disinfectant Level Goal (MRDLG) – These goals, which are applicable to drinking water disinfectants, were reviewed in a manner similar to that noted above for MCLGs. For the purpose of the protocol, discussions of the review for MCLGs should be assumed to also incorporate the review of MRDLGs.

Maximum Residual Disinfectant Level (MRDL) – These levels, which are applicable to drinking water disinfectants, were reviewed in a manner similar to that noted above for MCLs. For the purpose of the protocol, discussions of the review for MCLs should be assumed to also incorporate the review of MRDLs.

Treatment Technique (TT; sometimes established in lieu of or in addition to an MCL) – Information on health effects, analytical feasibility, or treatment feasibility may suggest a possibility to revise a TT.

Other Treatment Technology (NPDWRs specify best available technologies (BATs) capable of achieving MCLs) – Changes to BAT recommendations may be appropriate for potential MCL revision.

Other Regulatory Requirements (e.g., monitoring) – Revisions to other regulatory requirements may be appropriate if information suggests that changes in requirements such as monitoring standards (e.g., frequency) could reduce health risks or costs while maintaining or improving the level of public health protection.

The regulatory review decision tree contains branches with a series of sequential questions that inform a decision about the appropriateness of revising an NPDWR. The order of the questions within the tree reflects the sequential relationships between the different NPDWR elements and thus avoids unnecessary analyses. As a part of Six Year 3, the EPA updated the regulatory review decision tree to include a risk-balancing branch which reflected some of the efforts of the microbial and disinfection byproduct (MDBP) rules. The decision tree contains 10 branches:

- Initial review,
- Health effects and MCLG,
- MCL,
- Treatment technique,
- Treatment technique analysis,
- Methods,
- Occurrence,
- Treatment,
- Risk-balancing, and
- Implementation.

SDWA [Section 1412(b)(4)(B)] requires that EPA generally set the MCL as close to the MCLG as feasible. Consequently, if the MCL is equal to the MCLG, EPA must make decisions regarding the availability and adequacy of information relevant to the potential to revise the MCLG before making decisions regarding the potential to revise the MCL. In addition, if there is no potential to revise the MCLG and the MCL is already equal to the MCLG, then there is no basis for revising the MCL. In this instance, the branch of the decision tree containing questions about revising the MCL is not reached, and it is not necessary to review information related to analytical feasibility.

The first branch of the decision tree is the Initial Review Branch, with the purpose of identifying NPDWRs for which further review of detailed technical data is premature (e.g., the NPDWR is the subject of a recent or ongoing rulemaking, an ongoing health effects assessment is pending, the MCL is already set equal to the MCLG). Excluding such NPDWRs from subsequent review prevents duplicative agency efforts.

The Six-Year Review 4 results identify which NPDWRs, if any, are candidates for revision. A recommendation to revise an NPDWR starts a regulatory process that involves more detailed analyses concerning health effects, costs, benefits, occurrence, and other matters relevant to deciding whether and how an NPDWR should be revised. At any point in this process, EPA may find that regulatory revisions are not appropriate and may discontinue regulatory revision efforts. Review of that NPDWR would, however, continue in future Six-Year Reviews.

Similarly, a recommendation to "take no action at this time" means that EPA does not believe that regulatory changes to a particular NPDWR are appropriate based on health effects, analytical methods, treatment data, ongoing scientific reviews, agency priorities, or other factors. The EPA Administrator has the discretion to determine which revisions are appropriate and may consider a variety of factors. These factors include, but are not limited to, the type of health effects on the general population and sensitive populations and life stages, including children; the geographical distribution of the affected systems and populations; the size of the affected populations; and competing agency priorities and resource constraints. However, reviews of these NPWDRs in future Six-Year Reviews may lead to a recommendation that regulatory changes are appropriate.

1 Introduction

The 1996 SDWA Amendments require the EPA to periodically review existing NPDWRs. Section 1412(b)(9) of the SDWA reads:

> ...[t]he Administrator shall, not less than every 6 years, review and revise, as appropriate, each 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 on July 18, 2003 (USEPA, 2003a), after developing a systematic approach, or protocol, for the review of NPDWRs (USEPA, 2003b). EPA incorporated minor refinements into the protocol and completed its second review in December 2009 (USEPA, 2009). In its third Six-Year Review of NPDWRs, EPA used the second Six-Year Review protocol, with minor clarifications. EPA updated the regulatory review decision tree as a part of SYR 3, including a review branch for risk balancing, which reflected some of the efforts related to microbial and disinfection byproducts (MDBP) rules (USEPA, 2016). For its fourth Six-Year Review, EPA updated the existing protocol with minor clarifications and updates. Section 2 in this document provides an overview of the protocol, and Section 3 provides a more detailed discussion of the decision tree and how it is implemented in the Six-Year Review process. The agency intends to continue to refine the protocol during subsequent Six-Year Reviews to address any changing circumstances.

This document does not summarize the review results from each branch of the Six-Year Review 4 protocol; please see the support documents for those results (USEPA, 2024a-j).

1.1 Basic Principles

The primary goal of the Six-Year Review process is to identify which NPDWRs, if any, are candidates for revision. Although the statute does not define when a revision is "appropriate," as a general benchmark, EPA considers a possible revision to be "appropriate" if, at a minimum, it 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.

EPA applies several basic principles in reviewing NPDWRs. First, the agency seeks to avoid redundant review efforts. Therefore, EPA classifies NPDWRs that are the subject of other rulemaking actions either ongoing or completed during this review period as having "ongoing actions" or "recent actions" and not subject to further technical review under the Six-Year Review 4.

Second, EPA evaluates the potential for new information to affect NPDWRs in a manner consistent with its existing policies and procedures for developing NPDWRs. For example, in determining whether a possible change in analytical feasibility exists, the agency applies the current policies and procedures for calculating the practical quantitation level (PQL) for NPDWRs.

Third, the agency does not believe it is appropriate to consider revisions to NPDWRs for contaminants with an ongoing health effect assessment and for which the Maximum Contaminant Level (MCL) is set equal to the Maximum Contaminant Level Goal (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 makes a "take no action" recommendation if the health effect assessment is not 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 provisions in the 1996 SDWA Amendments (SDWA §1412(b)(6)(A)).

Fourth, EPA addresses new information from health effect assessments completed after the information cutoff date for the Six-Year Review 3 (December 2015) and any new conclusions or additional information associated with the NPDWR during the next review cycle.

Fifth, EPA identifies areas of inadequate or unavailable data (data gaps) or emerging data that may be needed to determine whether revision to an NPDWR is appropriate. If EPA is able to fill such gaps or fully evaluate the emerging information after completing the Six-Year Review 4, the agency will consider the information as part of the next review cycle.

EPA may consider accelerating a review and possible revision for a particular NPDWR before the next review cycle if a review and possible revision is justified by new public health risk information.

Finally, EPA applies the agency's peer review policy (USEPA, 2015), where appropriate, to any new analyses.

1.2 Scope of Review

Consistent with the previous Six Year Reviews, the Six-Year Review 4 encompasses the individual elements of NPDWRs, as follows:

MCLG changes – EPA generally considers changes to the MCLG (i.e., the health goal) only in instances when a new health effects assessment, completed after the MCLG was promulgated or last revised, results in a revised RfD and/or cancer classification.

MCL changes – EPA generally considers changes to the MCL (i.e., the enforceable standard) whenever: (1) the health effects assessment justifies a possible change to the MCLG and the existing MCL is set at the MCLG or (2) the current MCL was limited by analytical or treatment feasibility and the review of these capabilities indicates that it may now be feasible to set the MCL closer to the MCLG.[1]

Maximum Residual Disinfectant Level Goal – EPA generally considers changes to the MRDLG (the health goal for disinfectants) in a manner similar to that noted above for MCLGs. For the purpose of the protocol, discussions of the review for MCLGs should be assumed to also incorporate the review of MRDLGs.

Maximum Residual Disinfectant Level – EPA generally considers changes to the MRDL (the enforceable standard for disinfectants) in a manner similar to that noted above for MCLs. For the purpose of the protocol, discussions of the review for MCLs should be assumed to also incorporate the review of MRDLs.

Treatment Technique[2] changes – Treatment techniques can improve to the point where more protective drinking water standards may be considered. EPA generally considers revisions to TT requirements whenever there is new information on health effects, analytical feasibility, or treatment feasibility that suggests a possibility to revise the TT.

Changes to Other Treatment Technology – When EPA sets an MCL, EPA does so based on the best technology, treatment techniques, and other means that are available (taking cost into consideration). The NPDWR also contains the best available technologies, treatment techniques, and other means the systems could use to meet the MCL, although no specific technology is required for compliance with the MCL. EPA generally limits review of BATs to those NPDWRs that are identified as candidates for revision.

Changes to Other Regulatory Requirements – EPA generally considers changes to other NPDWR requirements, such as monitoring provisions. This part of the review focuses on implementation-related issues that are not being addressed, or have not been addressed, through alternative mechanisms (e.g., as part of a recent or ongoing rulemaking). Where appropriate alternative mechanisms do not exist, EPA generally considers implementation-related concerns if the possible revision meets the following criteria:

- The possible revision would be a change to an NPDWR, as defined under section 1401 of SDWA;
- The possible revision is "ready" for rulemaking – that is, the problem to be resolved has been clearly identified and specific option(s) formulated to address the problem; and

[1] Although the 1996 SDWA Amendments allow EPA in certain circumstances to set the MCL at a level higher than the feasible level if the benefits do not justify the costs, SDWA precludes the agency from lessening the public health protection of an existing standard (SDWA §1412(b)(9)).

[2] A TT rule generally specifies a type of treatment (e.g., filtration, disinfection or other methods of control to limit contamination in drinking water) and means for ensuring adequate treatment performance (e.g., monitoring of water quality to ensure treatment performance).

- The possible revision could improve the level of public health protection or represents a cost savings, while maintaining or improving public health protection.

For the Six-Year Review 4, EPA reviewed the chemical, microbiological, and radiological NPDWRs shown in Exhibit 1.1.

Exhibit 1.1 NPDWRs Included in the Six-Year Review 4

Contaminants/ Parameters	MCLG (mg/L) [1,3]	MCL or TT (mg/L) [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	0.010	Glyphosate	0.7	0.7
Asbestos	7 (million fibers/L)	7 (million fibers/L)	Haloacetic acids (HAA5)	n/a [5]	0.060
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	0.010	*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

Contaminants/ Parameters	MCLG (mg/L) [1,3]	MCL or TT (mg/L) [2,3]	Contaminants/ Parameters	MCLG (mg/L) [1,3]	MCL or TT (mg/L) [2,3]
Chloramines	4	4.0	Monochlorobenzene (Chlorobenzene)	0.1	0.1
Chlordane (as Cl_2)	0	0.002	Nitrate (as N)	10	10
Chlorine (as Cl_2)	4	4.0	Nitrite (as N)	1	1
Chlorine dioxide (as ClO_2)	0.8	0.8	Oxamyl (Vydate)	0.2	0.2
Chlorite	0.8	1.0	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	3×10^{-8}
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 [7,8]	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

Contaminants/ Parameters	MCLG (mg/L) [1,3]	MCL or TT (mg/L) [2,3]	Contaminants/ Parameters	MCLG (mg/L) [1,3]	MCL or TT (mg/L) [2,3]
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], TT [8,11]	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

Notes:

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. Maximum contaminant level goals are non-enforceable health goals.
2. MCL: the maximum level allowed of a contaminant in water which is delivered to any user of a public water system. Treatment Technology (TT): any action, process, or procedure required of the water system that leads to the reduction of the level of a contaminant in tap water that reaches the consumer.
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 the Maximum Residual Disinfection Level Goal (MRDLG) and the Maximum Residual Disinfection Level (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 and *E. coli*.
8. Under the Revised Total Coliform Rule (RTCR), a Public Water System (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.40 CFR §141.859(c).

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.
11. Under the Ground Water Rule (GWR) in 40 CFR §141.402, a ground water system that does not provide at least 4-log treatment of viruses and has a distribution system RTCR sample that tests positive for total coliform is required to conduct triggered source water monitoring to evaluate whether the total coliform presence in the distribution system is due to fecal contamination in the ground water source. The system must monitor for one of three State-specified fecal indicators (i.e., *E. coli*, coliphage, or enterococci).

2 Overview of the Six-Year Review Protocol

During the Six-Year Review 1, the agency developed a systematic approach or protocol to review existing NPDWRs (USEPA, 2003b). The agency based this protocol on the recommendations of the National Drinking Water Advisory Council (NDWAC), through internal agency deliberations, and discussions with a diverse group of stakeholders involved in drinking water and its protection.

For the Six-Year Review 2, EPA assessed the protocol and determined that it remained appropriate and suitable for the second review. Thus, the information requirements and decision-making process of the Six-Year Review 2 protocol were essentially the same as those implemented during the Six-Year Review 1, with some minor refinements to enhance the agency's effectiveness in applying the protocol to the review of NPDWRs (USEPA, 2009).

For the Six-Year Review 3, EPA again assessed the protocol and determined that it remained generally appropriate and suitable for the third review. Thus, the decision-making processes of the Six-Year Review 3 protocol were essentially the same as those 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 for the MDBP rules.

For the Six-Year Review 4, EPA assessed the protocol and determined that it remained appropriate for the fourth review. The decision-making processes of the Six-Year Review 4 protocol are the same as those implemented during all previous Six-Year Reviews. However, as in previous Six-Year Reviews, EPA made some clarifications to review elements. These changes are described in Section 2.1.

The Six-Year Review 4 protocol addresses critical aspects of public health protection and the setting of standards under SDWA. The results of the Six-Year Review 4 will identify NPDWRs that are candidates for revision and those for which no action is recommended at this time.

The identification of NPDWRs that are candidates for revision pursuant to a Six-Year Review under Section 1412(b)(9) is not the end of a regulatory or decision-making process but rather a beginning; it is one step in a process that involves more detailed analyses concerning health effects, costs, benefits, occurrence, and other matters relevant to deciding whether and how an NPDWR should be revised. At any point in this process, EPA may find that regulatory revisions to the NPDWR are not appropriate and may discontinue regulatory revision efforts. The NPDWR would, however, be reviewed in future Six-Year Reviews.

Similarly, a recommendation to "take no action at this time" means that EPA does not believe that regulatory changes to a particular NPDWR are appropriate at this time due to a lack of new health effects, analytical methods or treatment data; lack of contaminant occurrence at levels of concern; ongoing scientific reviews; limited opportunity to reduce health risks; limited opportunity to reduce costs while maintaining the same or greater level of health protection; low agency priorities; or other factors. Reviews of these contaminants in future Six-Year Reviews may lead to a recommendation that regulatory changes are appropriate.

The agency will continue to refine the Six-Year Review protocol during subsequent reviews to address changing circumstances.

2.1 Protocol Clarifications for the Six-Year Review 4

During the Six-Year Review 2, EPA refined the protocol to implement a more detailed decision tree than it used during the Six-Year Review 1. The revised protocol was broken down into a series of questions that inform decisions about the appropriateness of revising an NPDWR. These questions were logically ordered into a decision tree that incorporated the sequential relationships between the different NPDWR elements.

During the Six-Year Review 3, EPA clarified the protocol to address concepts specific to the MDBP rules. While retaining the same branches as the Six-Year Review 2 protocol, clarifications were made to address situations such as 1) contaminants that have individual MCLGs (that might warrant a change) but only an MCL for the group (e.g., chloroform in TTHM, monochloroacetic acid in HAA5); 2) a treatment technique may be a candidate for revision (in addition to, or instead of, an MCL revision); and 3) the health risk for cancer and noncancer effects is identified in terms of the strength of the weight of evidence. In addition, the protocol was clarified to consider the use of indicators for groups of disinfection byproducts (DBPs), including regulated and unregulated DBPs, and to consider risk-balancing between MDBP requirements or among differing types of DBPs.

During the Six-Year Review 4, EPA further adjusted the protocol to clarify procedures in the Implementation Branch and the Health Effects and MCLG Branch. While retaining the same approach used in Six-Year Review 3, EPA updated the Implementation Branch decision tree to clarify that other NPDWR revisions (e.g., changes in monitoring) may be considered even if a meaningful opportunity to revise an MCL, MCLG, or TT is not identified. In the Health Effects and MCLG Branch, EPA modified the decision tree to clarify that relevant health effects assessments identified in prior SYR cycles would be reconsidered if no action had been taken to revise the MCLG, which is consistent with the approach taken in Six-Year Review 3. Finally, EPA updated the Health Effects and MCLG Branch decision tree to capture improvements made to the systematic search of peer-reviewed literature on relevant health effects.

2.2 Elements of the Six-Year Review 4 Decision Tree

The Six-Year Review decision tree contains branches with multiple questions for each review topic. Information flows between these branches and results in the NPDWR identified as either a candidate for revision or not a candidate for revision (i.e., “take no action at this time”). Exhibit 2.1 shows the flow of information between branches where the end result is whether an NPDWR is a candidate for revision or not. More details about the flow of information within each individual branch are found in exhibits within each section of the document. Each branch corresponds to a specific technical review of an NPDWR element that EPA conducted during the Six-Year Review 4. The following branches comprise the decision tree:

- Initial review,
- Health effects and MCLG,
- MCL,

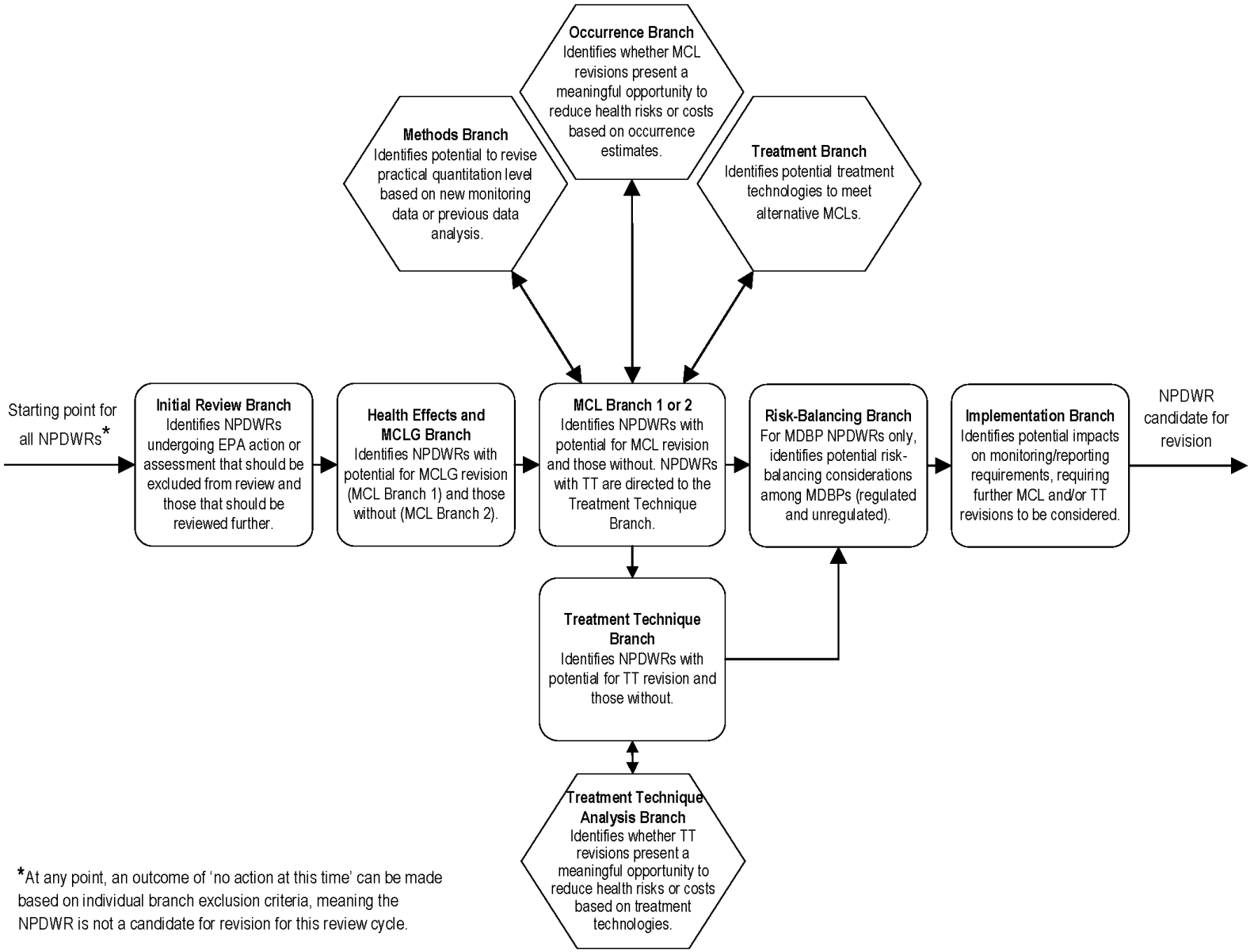
- Treatment technique,
- Treatment technique analysis,
- Methods,
- Occurrence,
- Treatment,
- Risk-balancing, and
- Implementation.

One of the key factors determining how an existing NPDWR moves through the Six-Year Review decision tree is whether an NPDWR involves an MCL or a TT requirement, since some of the branches are applicable to only one of those two types of NPDWRs. For example, NPDWRs with MCL-based requirements will complete all branches listed above except the Treatment Technique and Treatment Technique Analysis branches. Conversely, the NPDWRs that only involve a TT (e.g., NPDWRs related to microbial regulation) will complete all branches listed above except the MCL, Methods, Occurrence, and Treatment branches.

Another factor determining how an existing NPDWR moves through the Six-Year Review decision tree is whether an NPDWR regulates an MDBP. NPDWRs for MDBPs will complete the Risk-Balancing Branch. If an NPDWR is not an MDBP, most of the Risk-Balancing Branch will not be completed, as this branch is primarily applicable to MDBP NPDWRs.

The following sections describe each branch and provide detailed descriptions of EPA's data requirements, analyses, and decision-making process.

Exhibit 2.1 Process for Identifying NPDWRs that are Candidates for Revision



3 Detailed Discussion of Decision Tree Implementing the Protocol

This section describes the individual branches of the decision tree in detail, including the purpose, inputs, and outputs of each branch.

3.1 Initial Review Branch

The purpose of the Initial Review Branch (Exhibit 3.1) is to identify NPDWRs that meet one of three conditions for which further review is premature. The three conditions are:

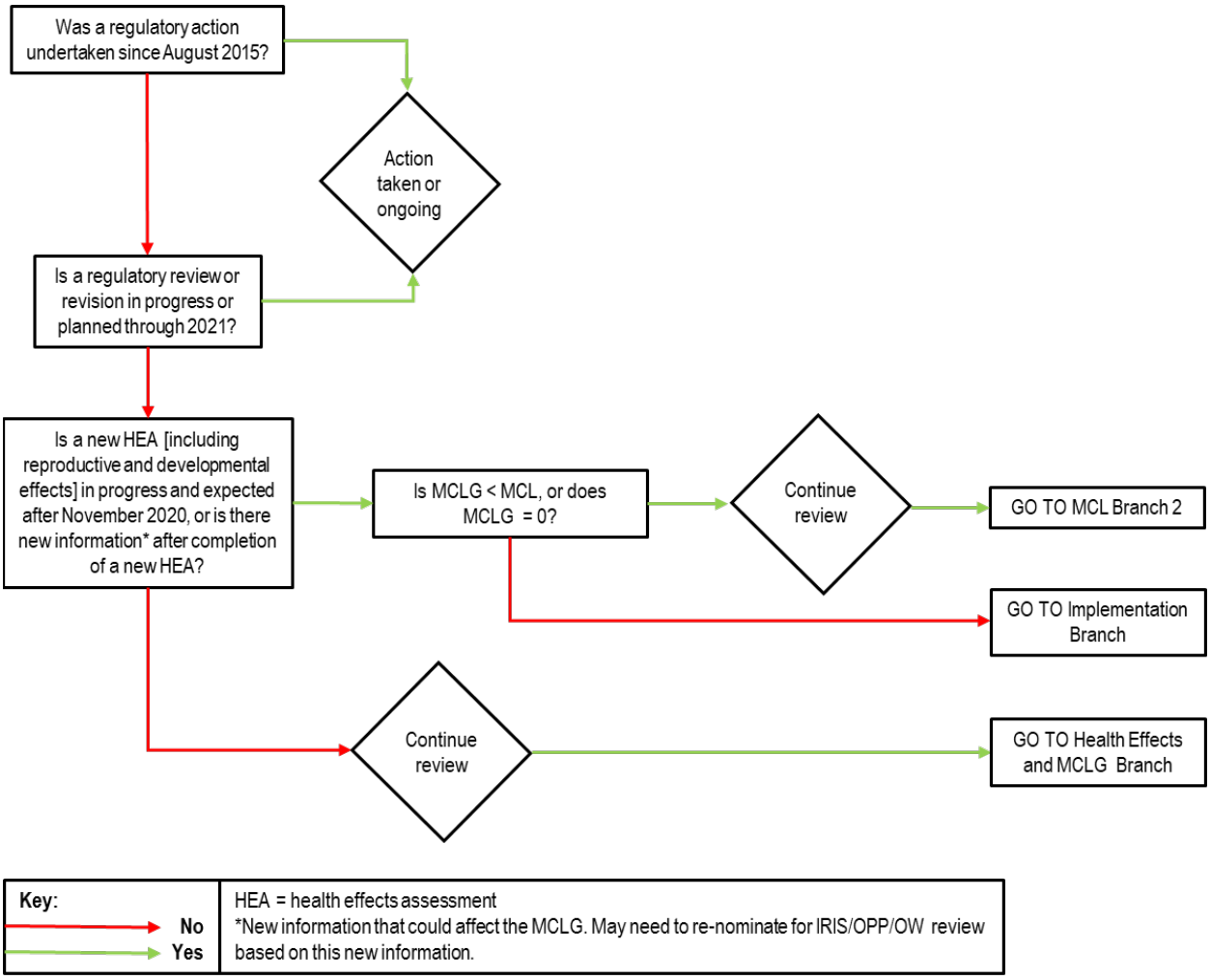
- The NPDWR was recently completed, reviewed, or revised (i.e., since August 2014);
- The NPDWR is part of an ongoing or pending regulatory action; or
- The NPDWR contaminant has an ongoing EPA health effects assessment that is due after the cutoff date for the review or EPA completed a health effects assessment but then identified new information with the potential to affect the MCLG and the MCL is set equal to the MCLG.

Excluding such NPDWRs from the review process prevents duplicative agency efforts associated with these three conditions.

3.1.1 Inputs to the Initial Review

The questions in the Initial Review Branch are screening-level questions that EPA answers for each NPDWR. The beginning questions in the branch require information regarding whether an NPDWR is the subject of recent, ongoing, or pending regulatory actions.

Exhibit 3.1 Initial Review Branch



If the contaminants are not part of recent, ongoing, or pending regulatory actions, a subsequent question in the decision tree (Exhibit 3.1) gathers information regarding whether a health effects assessment is in progress for the contaminant and if results will be available by the cutoff date for the health effects review (November 2020). Contaminants are placed in one of two lists for the purpose of tracking health effects information:

- Contaminants with ongoing EPA health effects assessments, or
- All other regulated drinking water contaminants that reached this decision tree point (i.e., all other contaminants except those that are the subject of recent, ongoing, or pending regulatory actions).

Health effects assessments used to develop NPDWRs are usually performed under the following EPA programs: Integrated Risk Information System (IRIS), Office of Pesticide Programs (OPP), the Office of Water (OW), and the National Academy of Sciences (NAS) when commissioned by EPA. The question expands this "take no action at this time" category to include any contaminant for which a health effects assessment was completed during the current review round but subsequent new information has the potential to affect its MCLG.

Health effects assessments are conducted outside the scope of the Six-Year Review process and follow EPA guidelines established to assess risks for different health effects, different exposure routes, and in different sensitive population groups and life stages including children. To inform the Six-Year Review process, EPA tracks the status of these health effect assessments and provides summaries that identify the contaminants with ongoing health effect assessments and their expected completion dates.

3.1.2 Outputs of Initial Review

The outputs of the initial review branch are: (1) a list of NPDWRs excluded from further review branches during the current cycle,[3] (2) a list of NPDWRs that proceed to the Health Effects and MCLG Branch for questions about the potential to revise the MCLG, and (3) a list of NPDWRs that proceed to the MCL Branch 2 (No MCLG Revision) despite ongoing health effects assessments because they have MCLs that are greater than their respective MCLGs.

3.2 Health Effects and MCLG Branch

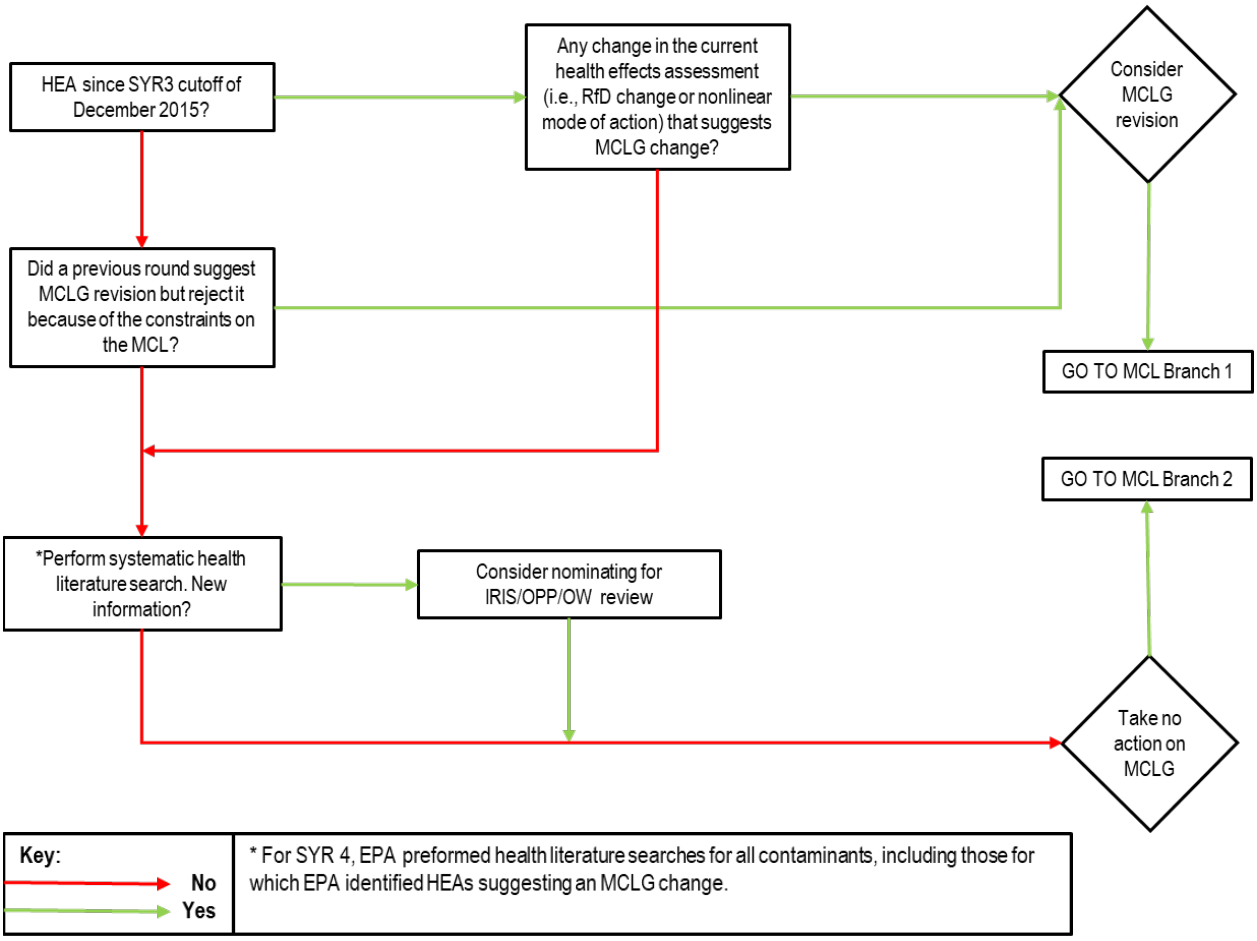
The primary purpose of the Health Effects and MCLG Branch (Exhibit 3.2) is to identify the NPDWRs for which potential exists to revise the MCLG. To do this, the protocol requires that:

- A revised or new health effects assessment be completed during the current cycle, after December 2015 and before November 2020; and,
- The assessment results in a change to the toxicity value (e.g., reference dose (RfD), cancer slope factor (CSF)) or cancer classification.

The protocol provides an option to revisit agency decisions to take no action for contaminants that had a new final, peer-reviewed health effects assessment that indicates the potential for an MCLG revision during the prior cycle.

[3] NPDWRs that have a "take no action at this time" result on the initial review may still be affected by a cross-cutting issue affecting multiple NPDWRs that qualifies for consideration under the conditions described for other regulatory revisions.

Exhibit 3.2 Health Effects and MCLG Branch



3.2.1 Inputs to Health Effects and MCLG Review

The first question in the Health Effects and MCLG Branch identifies the NPDWRs having a final, peer-reviewed health assessment completed during the current review cycle.

EPA determines whether new health effects assessments were published during the current cycle for each chemical except actively registered pesticides by searching the following sources:

- U.S. EPA OW Health Assessments: Drinking Water Standards and Health Advisory Documents (DWSHAs), Health Effects Support Documents (HESDs)
- U.S. EPA Office of Research and Development (ORD) Integrated Risk Information System (IRIS) Assessments
- U.S. EPA ORD Provisional Peer-Reviewed Toxicity Values (PPRTVs)
- U.S. EPA OPP Reregistration Eligibility Decisions (REDs), Health Effects Division Human Health Risk Assessments (HED HHRAs)
- U.S. EPA Office of Pollution Prevention and Toxics (OPPT) Toxic Substance Control Act (TSCA) Risk Evaluations

- Center for Disease Control and Prevention's Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles
- Health Canada (HC) Guidelines for Drinking Water Quality (GDWQ)
- World Health Organization (WHO) Drinking Water Guidelines
- California Environmental Protection Agency's (CalEPA) Public Health Goals (PHGs)
- Other publicly available state and federal assessments that have been externally peer-reviewed and are not derived from other Six-Year Review 4 assessment sources (e.g., The Institute of Medicine)

The most recent U.S. EPA OPP Human Health Risk Assessments and the corresponding toxicity values derived were selected for all pesticides with NPDWRs under SDWA as well as active registrations and tolerances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA follows a systematic process to select the final, peer-reviewed health assessments and corresponding toxicity values (e.g., RfD, CSF) and cancer classifications for each of the NPDWR contaminants. Assessments are reviewed for relevant information (e.g., toxicity values, cancer classifications) that could be used to derive screening MCLGs for noncarcinogenic and carcinogenic effects. Then, EPA evaluates whether a recent assessment results in a change to the RfD, CSF, or cancer classification. If there are changes to a toxicological parameter, EPA evaluates the potential impact to the MCLG.

This branch also identifies contaminants for which there is not a new health effects assessment in the current review cycle but there was one during the previous review cycle that included a change in the RfD. In the previous review cycle(s), EPA took no action to revise the NPDWR for some of these contaminants for one of the following reasons:

- The possible revision would not have provided a meaningful opportunity to reduce health risks;
- The possible revision would not have provided a meaningful opportunity to reduce costs while maintaining the same or greater level of health protection; or
- The possible revision would have been a low priority because of competing workload priorities, the administrative costs associated with rulemaking, and the burden on states and the regulated community to implement any regulatory change that resulted.

If a more recent health effects assessment is not available, EPA reconsiders the health effects assessment from the previous review cycle to evaluate potential changes to the MCLG.

After identifying new final, peer-reviewed health assessments, EPA conducts a systematic literature search of the peer-reviewed literature on relevant health effects, including general toxicity, reproductive and developmental toxicity, and cancer, via the oral route of exposure for the general population as well as sensitive subpopulations including children. Literature search results are not used to inform changes to the existing MCLG. Instead, the results of the literature searches for each NPDWR contaminant are used to survey the health effects literature that has become available since the previous review cycle, emerging issues for a contaminant, and data gaps to inform health assessment nominations. For more detailed information on the systematic process and individual contaminant literature search results refer to the Results of the Health

Effects Assessment Review and Literature Search for the Fourth Six-Year Review of Existing National Primary Drinking Water Standards (USEPA, 2024g).

3.2.2 Outputs from Health Effects and MCLG Review

Outputs from the Health Effects and MCLG Branch consist of the following lists of NPDWRs:

- NPDWRs for which potential exists to revise the MCLG based on the availability of a new final, peer-reviewed health effects assessment or contaminants for which there was a potential to revise the MCLG during a previous Six-Year Review but for which EPA took no action;
- NPDWRs for which a literature review indicates a potential change in health effects information and that should, therefore, be nominated for a formal health effects assessment through the OW, IRIS or OPP; and
- NPDWRs for which there is no potential to revise the MCLG during the current Six-Year Review.

The decision tree directs the first category of contaminants to the MCL branch that reflects potential for MCLG revision (MCL Branch 1 – Potential for MCLG Revision). It directs the second and third categories of contaminants to a second MCL branch that reflects no action will be taken regarding MCLG revision (MCL Branch 2 – No Potential for MCLG Revision).

3.3 Maximum Contaminant Level Branches

The purpose of each MCL branch is to identify NPDWRs for which new information indicates potential to revise the MCL. The SDWA requires that EPA generally set the MCL as close to the MCLG as feasible [Section 1412(b)(4)(B)]. Feasibility refers to both the ability to treat water to meet the MCL and the ability to monitor water quality at the MCL. For most contaminants for which the MCLG is greater than zero, the MCL equals the MCLG, which indicates that neither analytical method quantitation nor treatment capabilities limit the ability to achieve the MCLG. Conversely, when the MCLG equals zero, the MCL is usually set equal to the PQL, which is based on the detection capability that most laboratories can reliably and consistently achieve using approved analytical methods within specified limits of precision and accuracy. Thus, the PQL is the most common limiting factor with respect to feasibility. Consequently, the MCL branches address analytical feasibility before treatment feasibility. Additional considerations were included in development of MCLs for the disinfectants/disinfection byproducts rules (D/DBPRs), these details are described in later sections of the protocol.

The decision tree includes two MCL branches: one for contaminants with a possible MCLG revision (MCL Branch 1; Exhibit 3.3a), and the other for contaminants with no action regarding the MCLG (MCL Branch 2; Exhibit 3.3b).

Exhibit 3.3a Maximum Contaminant Level Branch 1 (Potential for MCLG Revision)

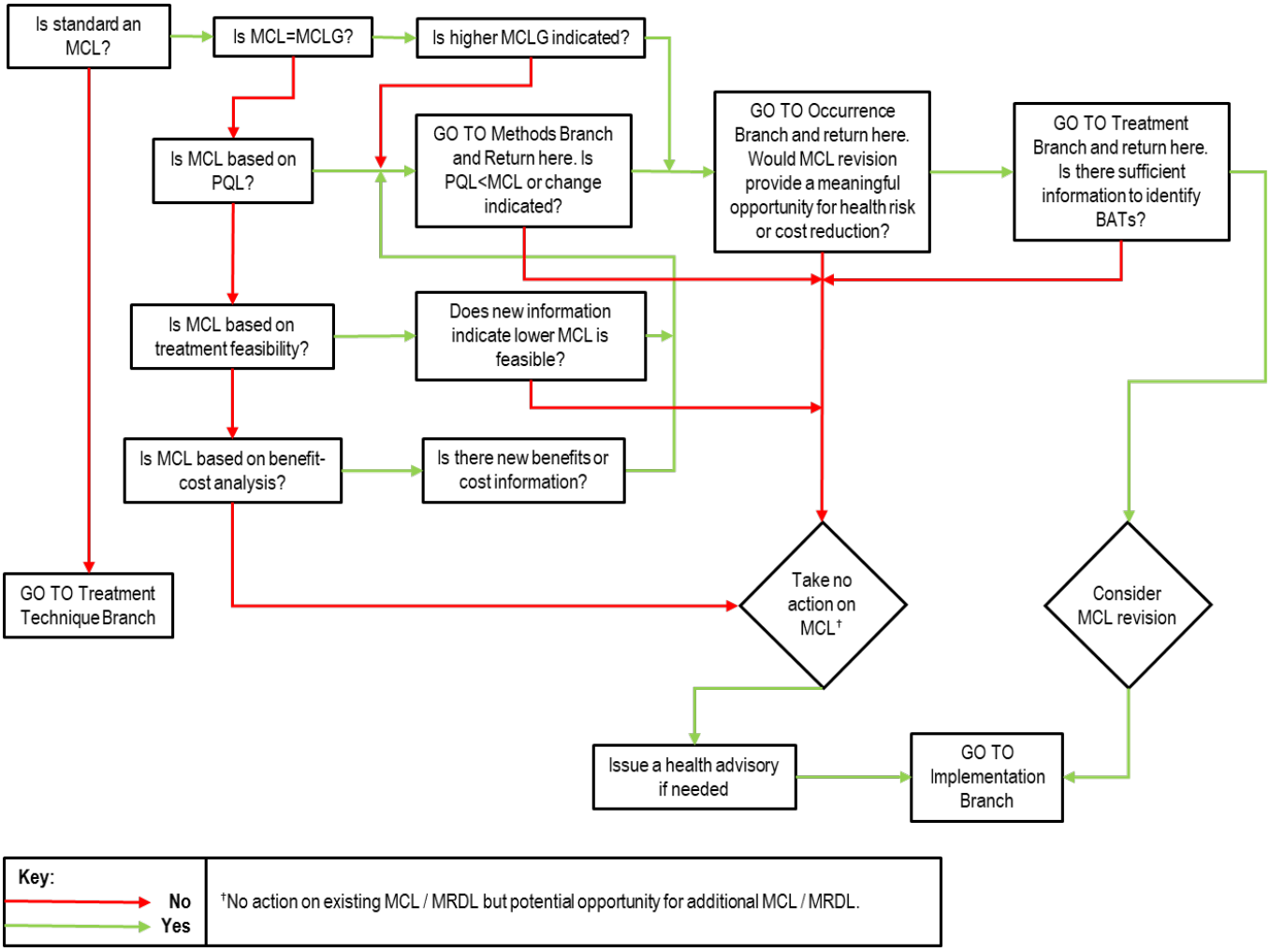
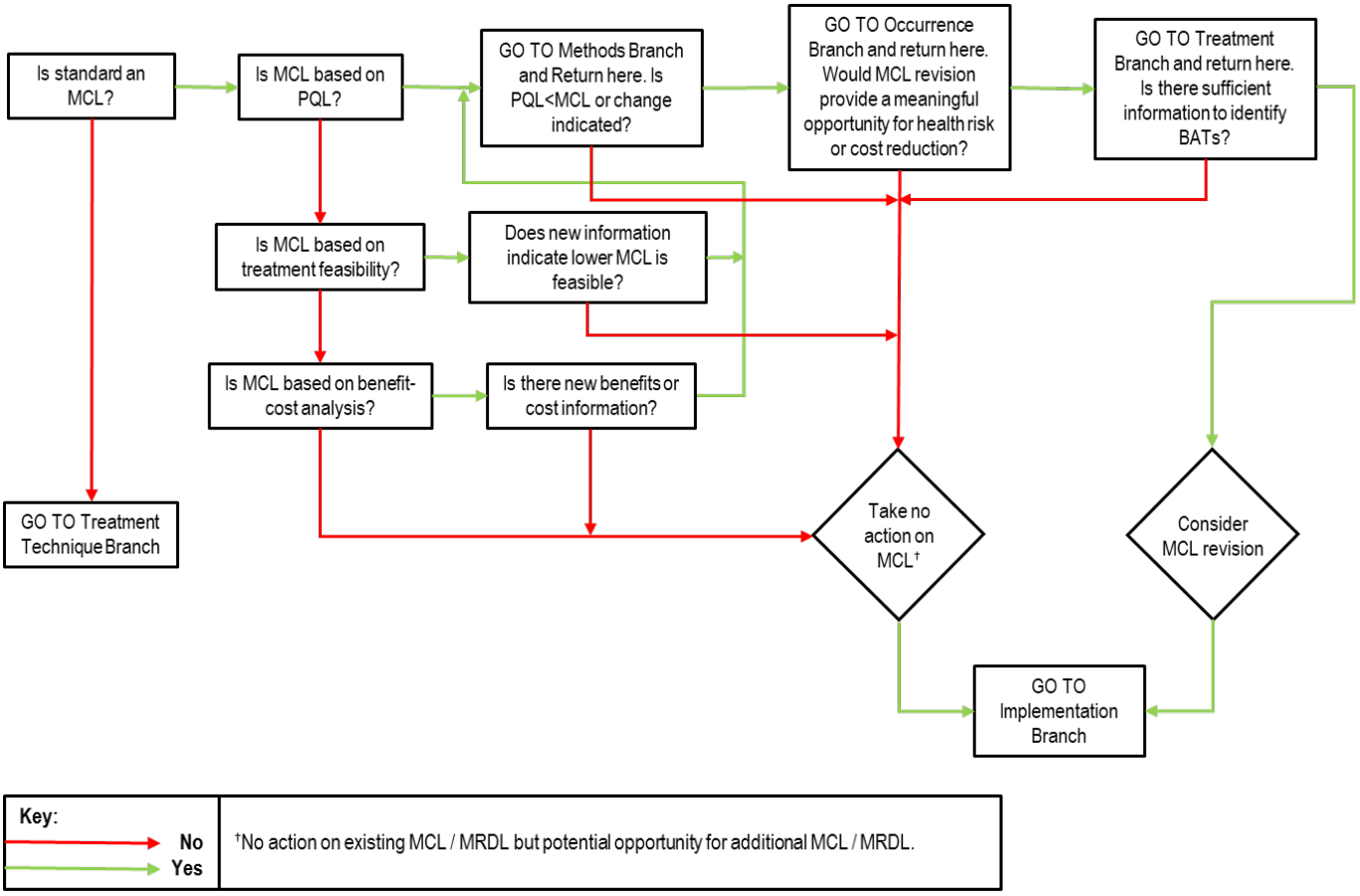


Exhibit 3.3b Maximum Contaminant Level Branch 2 (No Potential for MCLG Revision)



3.3.1 Inputs to Maximum Contaminant Level Review

The two MCL branches have similar questions but differ in that MCL Branch 1 is for contaminants with a possible MCLG revision, and MCL Branch 2 is for contaminants with no action regarding the MCLG. For example, MCL Branch 1 has an additional question to identify and address circumstances where the health effects information indicates potential to revise the MCLG upward, which would affect the MCL if the MCL is equal to the MCLG.

The initial questions on the MCL branches pertain to the following:

- Whether the standard is an MCL or a TT,
- Whether a higher or lower MCLG is indicated, if applicable (i.e., MCL Branch 1), and
- The basis for the current MCL.

The MDBP rules consist of both MCL and TT standards, including NPDWRs for a contaminant group that incorporates multiple MCLGs. For TTHM, the four individual contaminants each have their own MCLGs, with two that are zero and two non-zero. For HAA5, there are MCLGs for three of the five components; one is zero and the other two are non-zero.

Subsequent questions on the MCL branches involve subordinate branches for analytical methods, occurrence, and treatment analyses that explore the availability of new information that could affect EPA's recommendation regarding an MCL revision. Later sections of this document address the specific data requirements of these subordinate branches and describe the analyses that EPA conducted as part of these branches. The MCL branches combine the findings from these subordinate branches into an overall MCL recommendation.

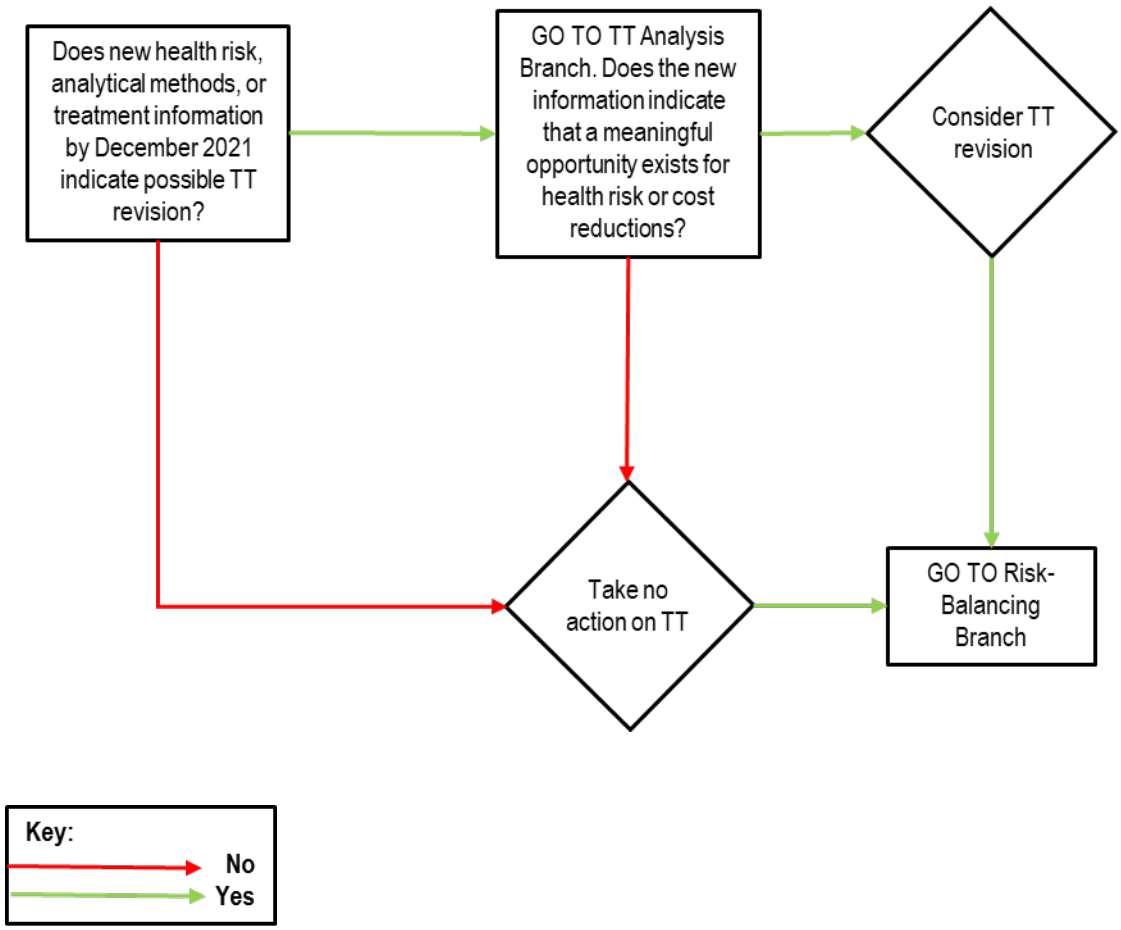
3.3.2 Outputs from Maximum Contaminant Level Review

The MCL branches identify contaminants for which the review did not identify any new information indicating potential for MCL revision and those for which new information indicates EPA should consider revising the MCL or adding complementary MCLs. After completing an MCL branch, the decision tree directs the review to the risk-balancing branch.

3.4 Treatment Technique Branch

When a contaminant has a TT standard instead of, or in addition to, an MCL, the protocol uses the Treatment Technique Branch of the decision tree (Exhibit 3.4), in addition to the MCL branches. The purpose of the Treatment Technique Branch is to identify whether potential exists to revise a TT standard.

Exhibit 3.4 Treatment Technique Branch



3.4.1 Inputs to Treatment Technique Review

The TT Branch includes the following questions:

- Does new information in the following areas indicate potential for TT revision: health risk, analytical methods, or TT?
- Based on the decisions on the Treatment Technique Analysis Branch, does a meaningful opportunity exist for health risk or cost reduction?

The following NPDWRs have a TT in lieu of an MCL: acrylamide, copper, *Cryptosporidium*, epichlorohydrin, *Giardia lamblia*, lead, *Legionella,* and viruses. In addition, the D/DBPRs include a TT for precursors in addition to the MCLs for contaminants.

3.4.2 Outputs from Treatment Technique Review

The Treatment Technique Branch identifies NPDWRs for which EPA should consider revisions to a TT standard because all of the following apply:

- New health, methods and/or treatment information are available that suggests revision; and
- There is a meaningful opportunity to lower health risks or costs.

The decision tree then directs the review to the Risk-Balancing Branch.

3.5 Treatment Technique Analysis Branch

The purpose of the Treatment Technique Analysis Branch (Exhibit 3.5) is to determine whether the new information that could affect the TT standard has the potential to present a meaningful opportunity to revise the TT standard.

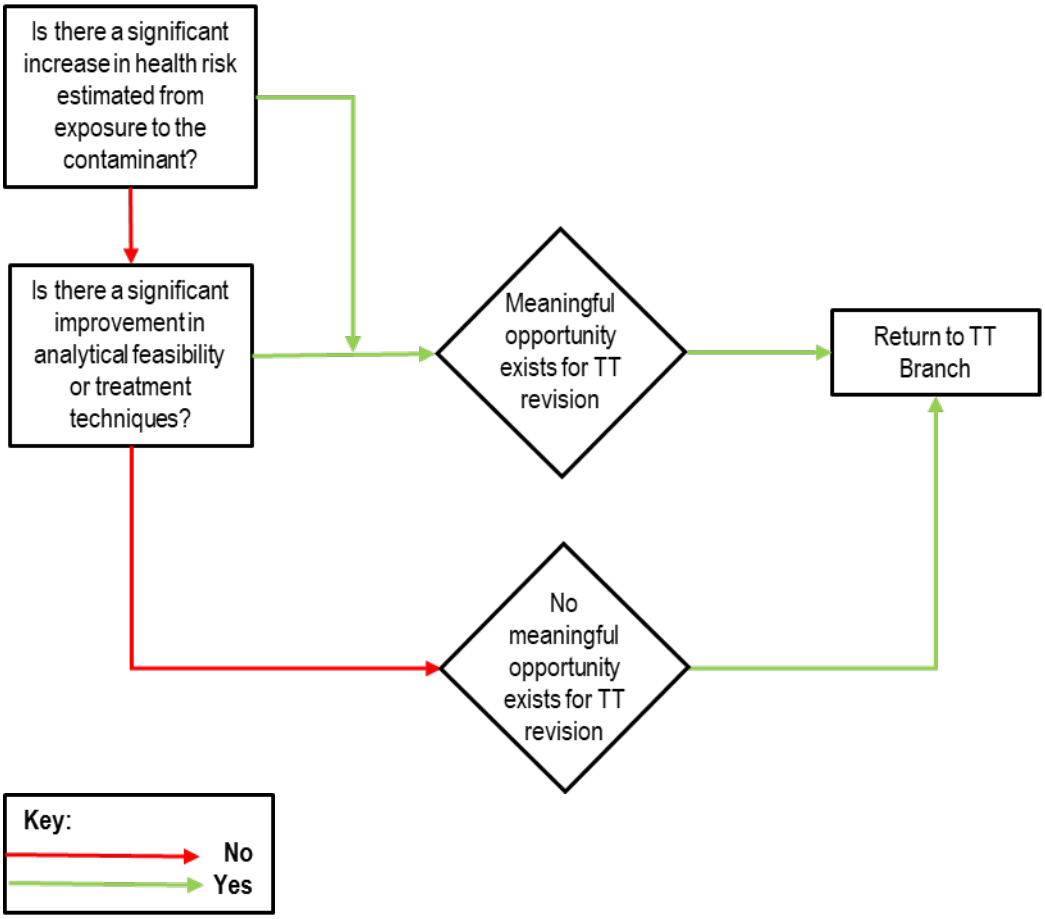
3.5.1 Inputs to Treatment Technique Analysis Review

The Treatment Technique Analysis Branch includes the following questions:

- Is there a significant increase in health risk estimated from exposure to the contaminant, or weight of evidence for health-related information on which the NPDWR was based?
- Is there a significant improvement in analytical or treatment feasibility?

The first question identifies whether new health effects information indicates health risks that are significantly different from those considered at the time EPA promulgated the NPDWR. The second question addresses whether there are significant changes in analytical feasibility constraints that might have originally led to a contaminant having a TT standard in lieu of an MCL. It also addresses whether significant changes in treatment feasibility indicate potential for revision to the TT standard.

Exhibit 3.5 Treatment Technique Analysis Branch



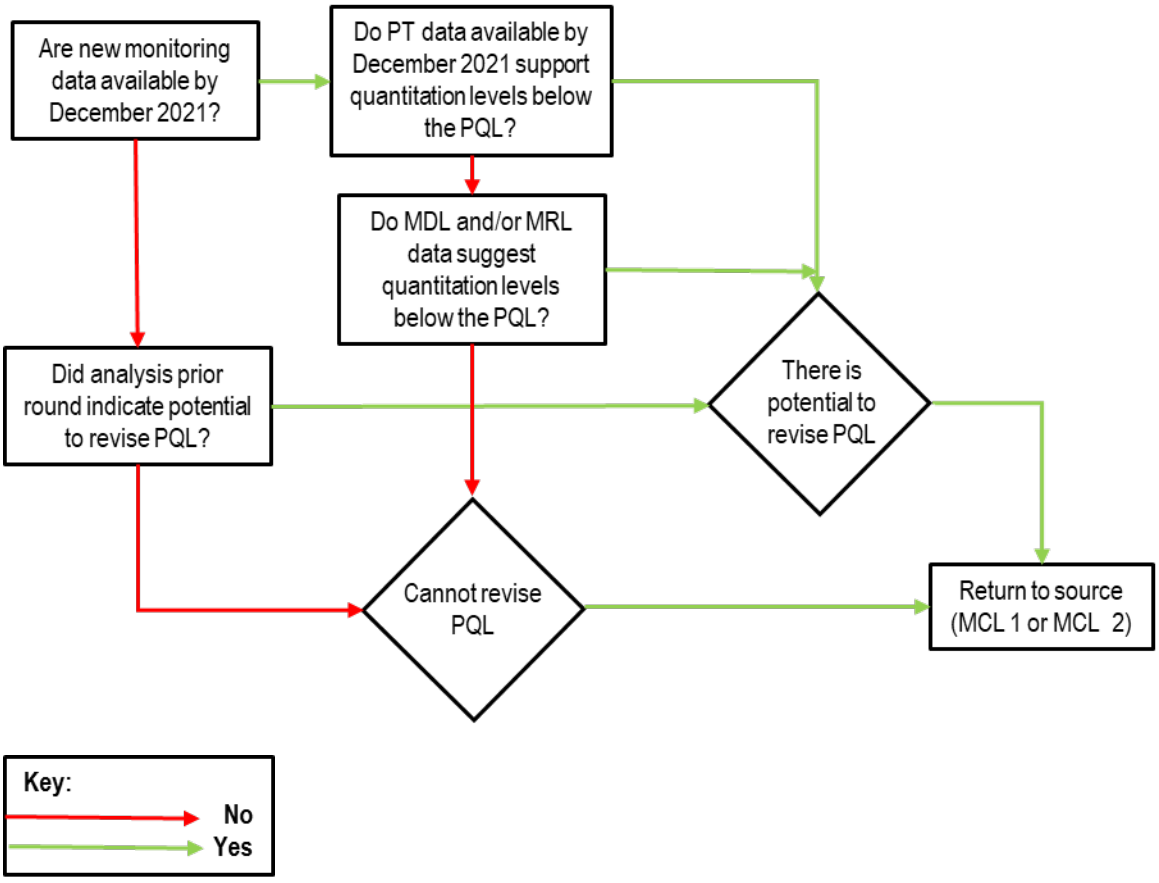
3.5.2 Outputs from Treatment Technique Analysis Review

The Treatment Technique Analysis Branch identifies contaminants for which new information may present a meaningful opportunity to lower health risks or costs through a TT revision. The decision tree then directs the review back to the main Treatment Technique Branch.

3.6 Methods Branch

The purpose of the Methods Branch (Exhibit 3.6) is to determine whether potential exists to revise the PQL for a regulated contaminant. The PQL is the level at which laboratories can reliably and consistently measure a chemical contaminant in drinking water. The PQL has typically been established as the analyte concentration at which 75 percent of laboratories can measure within the promulgated acceptance criteria (USEPA, 1989).

Exhibit 3.6 Methods Branch



The Methods Branch considers two categories of contaminants:

- Contaminants for which the MCL is limited by analytical feasibility (e.g., the MCL is set at the PQL), and the MCLG is still appropriate, and
- Contaminants for which the health effects review indicated potential to change the MCLG and the current PQL is above possible MCLG values.

EPA reviews and approves analytical methods under a separate regulatory process. Therefore, the Six-Year Review does not include a review to determine whether the approved analytical methods themselves can be revised. Historically, EPA has used two main approaches to determine a PQL for SDWA analytes during rule development: (1) analysis of multi-laboratory Performance Evaluation (PE) data, which is preferred when sufficiently available; or (2) a multiplier method, in which a method detection limit (MDL) from an EPA-approved laboratory method is multiplied by a factor of 5 or 10 (USEPA, 1985; USEPA, 1987; USEPA, 1989).

3.6.1 Inputs to Methods Review

The Methods Branch includes the following questions:

- Are new EPA-approved analytical methods or performance data available by the cutoff date of the Six-Year Review 4 (December 2021)?
- Do any new analytical methods indicate potential to revise the PQL?
- Does any new method performance information, such as a lower MDL or minimum reporting limit (MRL), indicate potential to revise the PQL?
- Do prior Six-Year Reviews indicate potential to revise the PQL?

The protocol developed for the Six-Year Review 1 (1996 – 2002) primarily used PE data from Water Supply studies, which EPA oversaw as part of a laboratory certification program (USEPA, 1993). In December 1999, the accreditation program was privatized, and the National Environmental Laboratory Accreditation Conference (NELAC) began oversight. Currently, the NELAC Institute oversees the Proficiency Testing (PT) program for drinking water laboratories. Since Six-Year Review 2 (2003 – 2009), EPA has requested PT results from NELAC-accredited PT providers on a voluntary basis. At that time, EPA also began incorporating analytical method performance data from the Six-Year Review Information Collection Request (ICR) dataset.

The method review process uses a variety of data. The primary data sources used to assess whether potential exists to achieve a lower quantitation level are:

- Laboratory passing rates based on PT data (i.e., the percent of laboratories passing a proficiency test for a given study) from 2012 through 2019,
- MDLs from published EPA-approved analytical method protocols, and
- Analytical method performance data (i.e., MRLs) collected by the Six-Year Review ICR.

The method review process includes both a PQL assessment and an estimated quantitation level (EQL) assessment. The PQL assessment involves 1) analysis of available PT data, and 2) review of MDLs of EPA-approved analytical methods published since the previous Six-Year Review. The PQL assessment produces qualitative conclusions regarding the potential to lower the current PQL. The EQL assessment includes 1) analysis of MRL data from the ICR dataset, and 2) derivation of thresholds by the MDL-multiplier method. The EQL assessment produces concentration thresholds that are applied in the occurrence analysis (Section 3.7).

For the PQL assessment, EPA first analyzes the PT passing rate results for tests conducted at and below the current PQL to indicate potential for PQL revision. Next, EPA compares analytical methods available for compliance monitoring at the time of promulgation to those currently available. EPA places contaminants into one of three categories based on whether the assessment supports, may support, or does not support a lower PQL. For example, EPA places contaminants with passing rates above 75 percent for PT studies with true values below the PQL in the "PQL reassessment supports reduction of the current PQL" category.

For the EQL assessment, when appropriate, EPA evaluates the distribution of MRL values for a particular contaminant to identify the mode, or value occurring most frequently. When 80 percent or more of the MRL values are less than or equal to the mode, the MRL value becomes a candidate EQL, if less than the PQL. If the MRL approach does not yield an EQL, EPA reviews

MDLs from analytical methods approved by EPA for drinking water. For a given contaminant, MDLs are multiplied by 10 and the highest resulting value that falls below the current PQL is chosen as the EQL.

3.6.2 Output from Methods Review

The Methods Branch produces the following outputs for each contaminant considered at this stage: 1) a conclusion regarding potential to lower the PQL, and 2) an EQL, expressed as a chemical concentration. The derived EQLs are used in the occurrence analysis to help the agency determine if there was a meaningful opportunity for risk reduction. An EQL does not, however, represent the agency's intent to revise the associated PQL at this time. The decision tree then returns the review to the MCL Branch for subsequent questions.

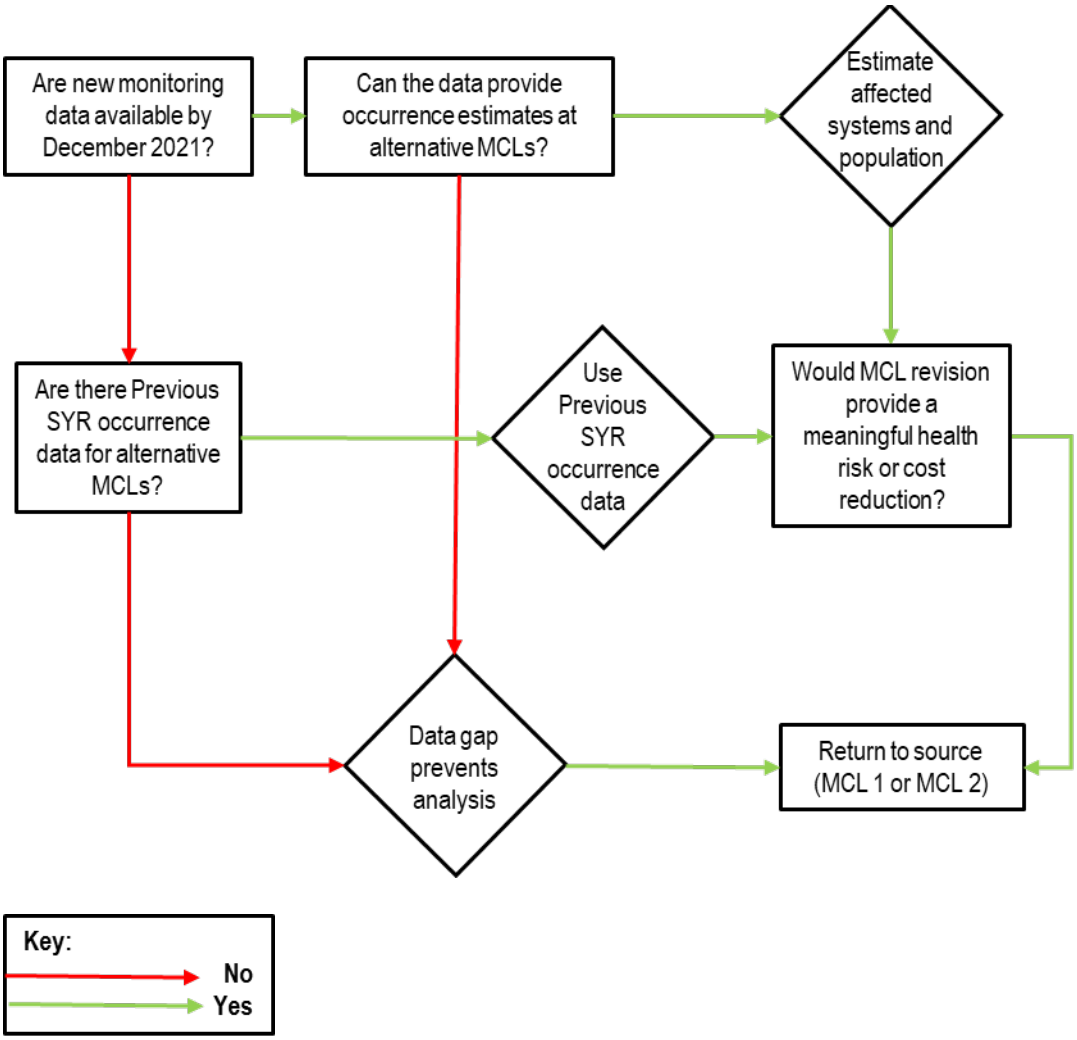
3.7 Occurrence Branch

The purpose of the Occurrence Branch (Exhibit 3.7) is to determine if a potentially meaningful opportunity exists to revise an MCL by:

- Estimating the number of PWSs in which contaminants occur at levels of interest based on health effects or analytical methods information, and
- Evaluating the number of people potentially exposed to these levels.

This occurrence and exposure information indicates how changing an MCL may affect health risks and compliance costs.

Exhibit 3.7 Occurrence Branch



3.7.1 Inputs to Occurrence Review

The initial questions elicit information regarding the availability of monitoring data for estimating occurrence at alternate benchmarks (e.g., MCLs, EQLs). For the Six-Year Review 4, the responses to these questions reflect new data that EPA received through its Six-Year Review ICR. EPA issued the ICR as a one-time voluntary request for states and other primacy agencies to submit historical monitoring data, covering the years 2012 through 2019, for regulated contaminants to EPA. A total of 59 states and primacy agencies provided compliance monitoring data that included all analytical detection and non-detection records. These data represent the national occurrence of regulated contaminants in public drinking water systems. For analysis, EPA uses the EQLs derived from the Methods Branch (Section 3.6) as screening thresholds.

EPA also reviews information on potential source water quality for the contaminants with possible MCLG increases. Because the ICR data represent water quality at entry points to the distribution system, the typical ICR occurrence analysis results are not adequate to evaluate the cost savings potential for contaminants with the potential for higher MCLG values. Therefore, EPA also evaluates source water quality information for these contaminants. For Six-Year Review 4, this information comes from two national data sources: the National Water Quality Assessment (NAWQA) program conducted by the U.S. Geological Survey (USGS) and the United States Department of Agriculture's Pesticide Data Program water monitoring survey.

Regardless of the occurrence data source and analysis method, EPA must determine whether the extent of occurrence represents a meaningful opportunity to reduce health risks or costs; no single benchmark exists for making this determination. The EPA Administrator has the discretion to determine which revisions are appropriate and may consider a variety of factors. These factors include but are not limited to the type of health effects on the general population and sensitive populations and life stages, including children; the geographical distribution of the affected systems and populations; the size of the affected populations; and competing agency priorities and resource constraints.

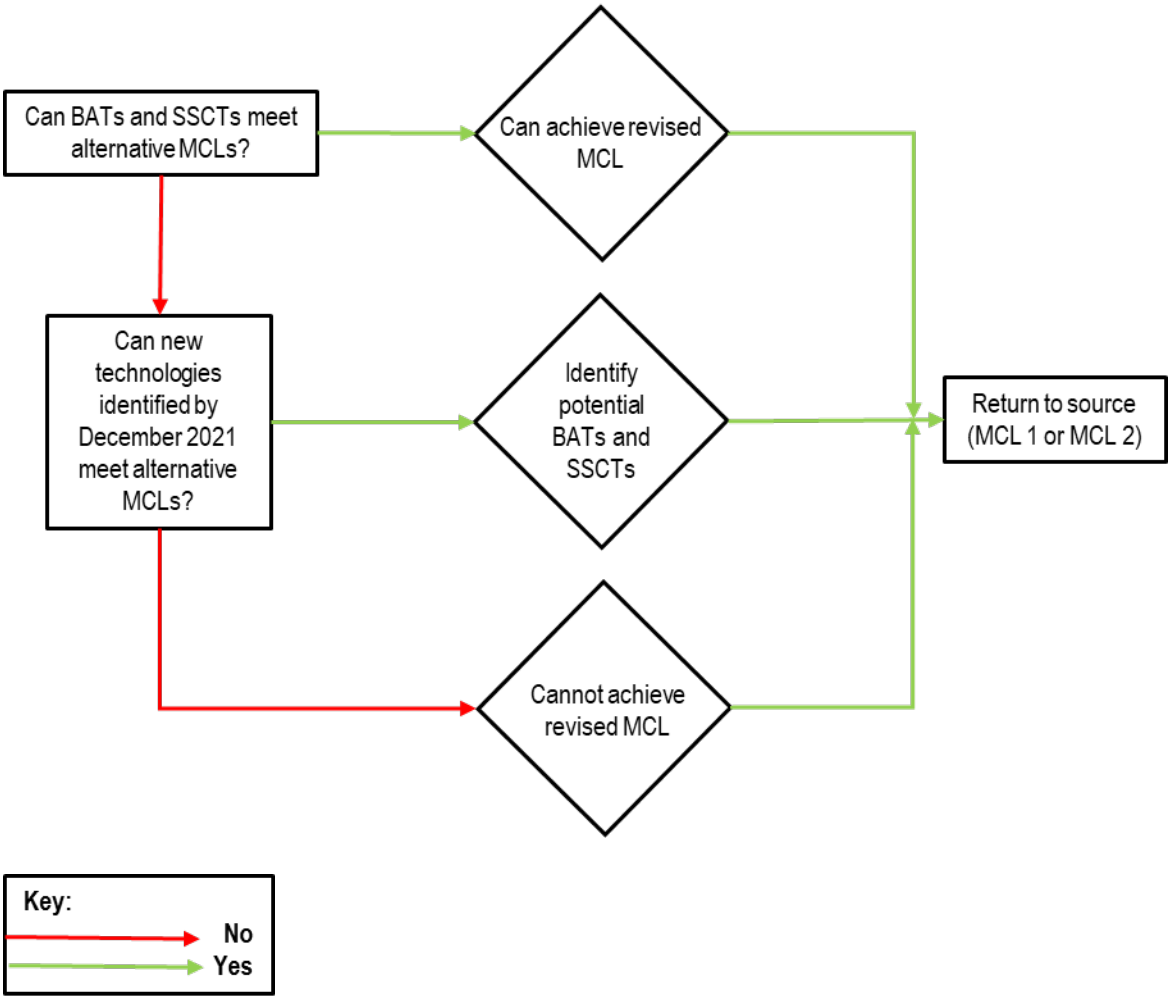
3.7.2 Output from Occurrence Review

The output of the Occurrence Branch is the identification of contaminants for which MCL revision would provide a meaningful opportunity for health risk reduction or cost savings, while maintaining or improving the level of public health protection. An additional result is the identification of contaminants for which data gaps prevent an occurrence review. The decision tree then returns the review to the MCL Branch for subsequent questions.

3.8 Treatment Branch

When EPA promulgates an MCL, the NPDWR also contains best available treatment (BAT) recommendations for drinking water treatment processes. 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. Thus, the purpose of the Treatment Branch (Exhibit 3.8) is to ascertain that there are technologies that meet BAT criteria when an MCL can be lowered and by doing so presents a meaningful opportunity to reduce health risks.

Exhibit 3.8 Treatment Branch



3.8.1 Inputs to Treatment Review

The Treatment Branch includes the following questions:

- Can the BATs and small system compliance technologies (SSCTs) meet alternative MCLs?
- Can new technologies identified by the cutoff date (December 2021) meet alternative MCLs?

For the Six-Year Review, EPA limits its review of BATs to those NPDWRs for which it was considering possible revisions to the MCL based on the health effects, analytical feasibility, and occurrence analyses. To address both questions, EPA conducts a review of treatment performance studies for all applicable technologies for the contaminant in question. EPA uses the same sources that it has relied on in the past to develop regulations and guidance, including published EPA treatment reports, peer-reviewed journals, other sources of technology performance (e.g., pilot and demonstration project reports), and information received from EPA stakeholders. EPA evaluated whether these treatment studies indicate that current BATs can achieve possibly lower MCLs and whether newer treatment technologies potentially meet BAT criteria.

3.8.2 Output of Treatment Review

The output of the Treatment Branch is a determination of whether treatment feasibility would pose a limitation to revising an MCL. The decision tree then returns the review to one of the MCL branches for subsequent questions.

3.9 Risk-Balancing Branch

The Risk-Balancing Branch (Exhibit 3.9) is applicable only to the review of the MDBP rules, which were promulgated to address balancing between microbial and DBP requirements, and among differing types of DBPs. This effort was based on the SDWA requirement that EPA "minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants the concentration of which may be affected by the use of a treatment technique or process that would be employed to attain the maximum contaminant level."

The purpose of the Risk-Balancing Branch is to address tradeoffs in risks for regulated and unregulated contaminants. Under this branch, EPA considers whether a change to an MCL and/or TT will affect the risk from one or more other contaminants and, if so, considers revisions that will balance these overall risks. For example, EPA considers the potential impact on DBP concentrations should an increase in the stringency of microbial protection rules be considered. This approach was used in the development of several NPDWRs, such as those for the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2 ESWTR) and the Stage 2 D/DBPR, promulgated in January 2006.

3.9.1 Inputs to Risk-Balancing Branch

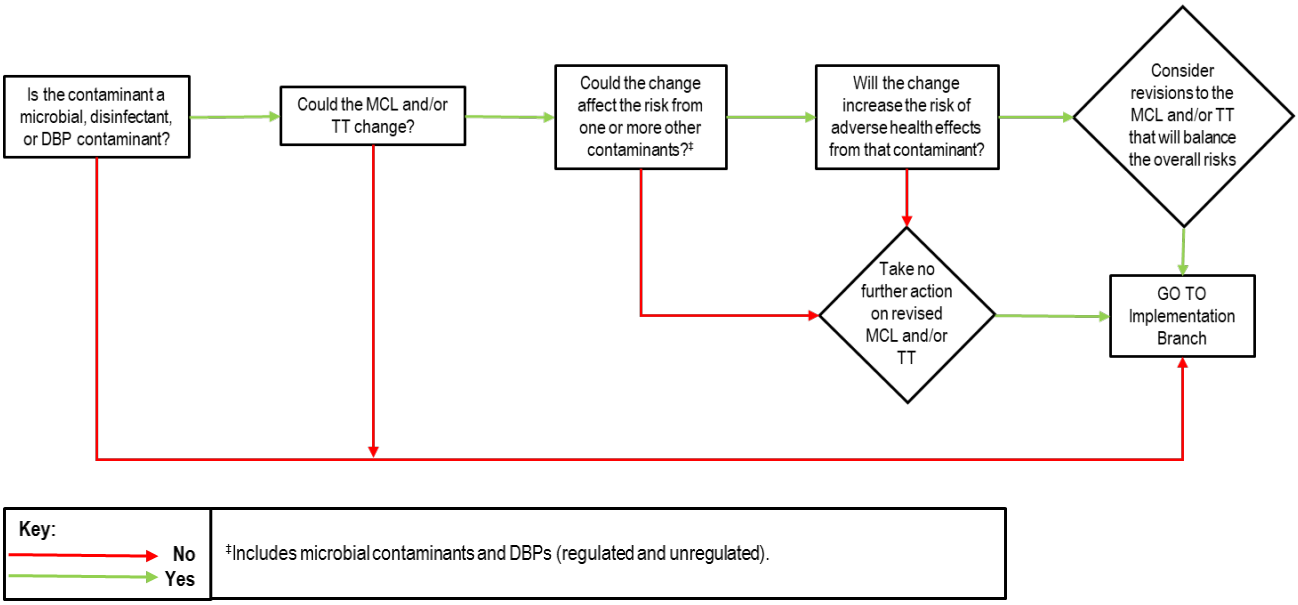
The Risk-Balancing Branch includes the following questions:

- Could the change to an NPDWR affect the risk from one or more contaminants?
- If so, will the change increase the risks of adverse health effects from that contaminant?

3.9.2 Outputs from Risk-Balancing Branch

The output of the Risk-Balancing Branch is a determination of whether additional revisions to the MCL and/or TT are appropriate to help balance the overall risks from potential changes. Following this determination, the decision tree then transitions to the Implementation Branch for subsequent questions.

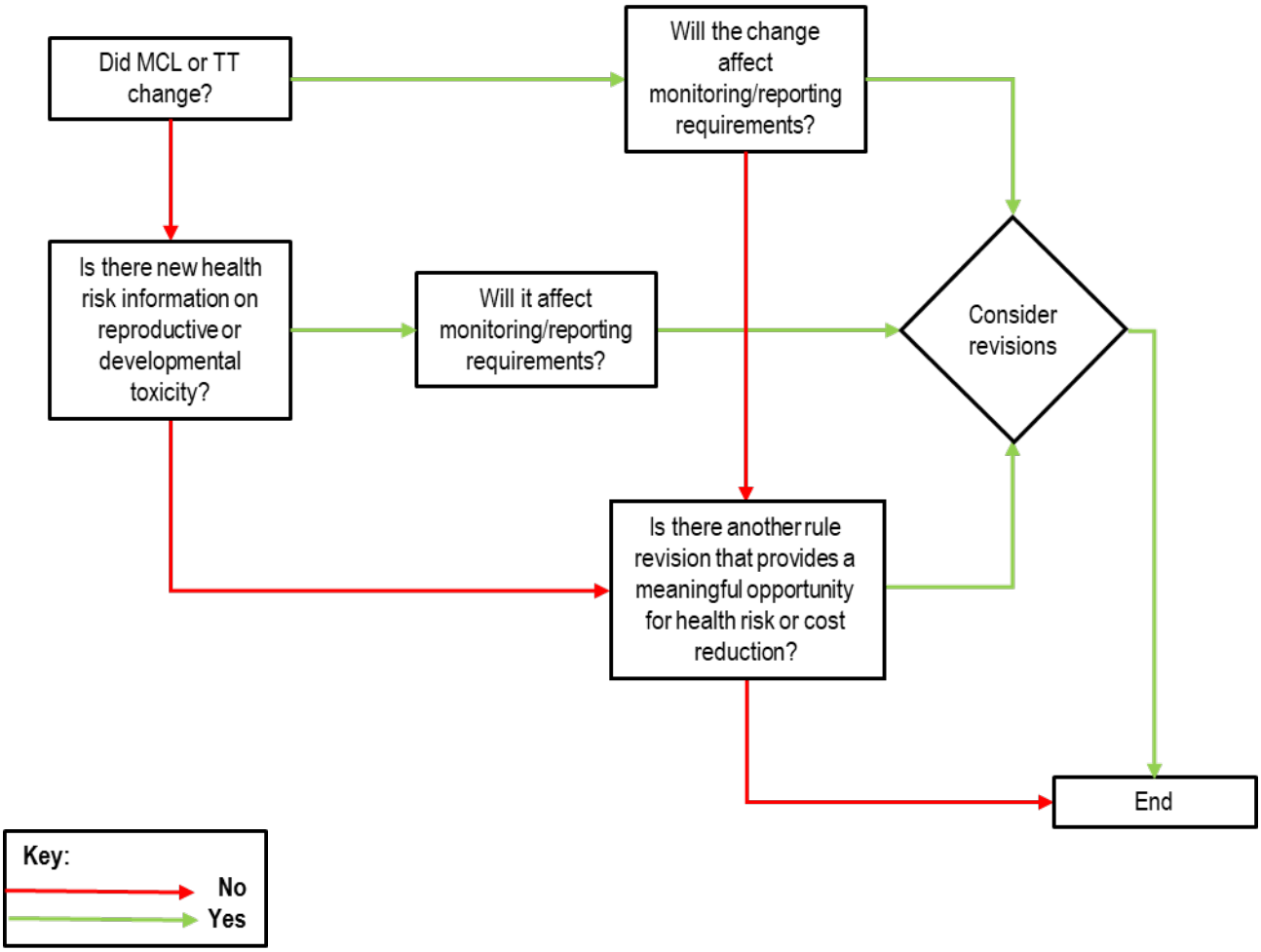
Exhibit 3.9 Risk-Balancing Branch



3.10 Implementation Branch

The purpose of the Implementation Branch (Exhibit 3.10) is to evaluate potential revisions pertaining to "other" NPDWR requirements, such as monitoring provisions and system reporting. Regulatory revisions to MCLs or TTs may affect the monitoring and system reporting requirements for a contaminant and new health risk information may also warrant revisions.

Exhibit 3.10 Implementation Branch



3.10.1 Inputs to Implementation Review

The Implementation Branch requires information regarding whether a change in a contaminant's MCL or TT or new health effects information will affect the monitoring and system reporting requirements for a particular contaminant. EPA focuses this review on issues that are not already being addressed through other efforts, such as through a recent or ongoing rulemaking. EPA also reviewed implementation-related NPDWR concerns that were "ready" for rulemaking – that is, the problem to be resolved has been clearly identified, along with specific options to address the problem, and shown to either clearly improve the level of public health protection or represent a meaningful opportunity for cost savings while maintaining the same level of public health protection.

3.10.2 Outputs from Implementation Review

The output of the Implementation Branch is a determination regarding whether EPA should consider revisions to the monitoring and system reporting requirements of an NPDWR. It is the final branch of the decision tree.

4 References

USEPA. 1985. National Primary Drinking Water Regulations: Volatile Synthetic Organic Chemicals; Final Rule and Proposed Rule. 50 FR 46880. November 13, 1985.

USEPA. 1987. National Primary Drinking Water Regulations–Synthetic Organic Chemicals; Monitoring for Unregulated Contaminants; Final Rule. 52 FR 25690. July 8, 1987.

USEPA. 1989. National Primary and Secondary Drinking Water Regulations: Proposed Rule. 54 FR 22062. May 22, 1989.

USEPA. 1993. Office of Water Performance Evaluation Study Project Final Report. May 1993. Available online at: https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=20001QGR.txt

USEPA. 2003a. National Primary Drinking Water Regulations; Announcement of Completion of EPA's Review of Existing Drinking Water Standards; Notice. 68 FR 42908. July 18, 2003.

USEPA. 2003b. EPA Protocol for Review of Existing National Primary Drinking Water Regulations. Washington, DC: Office of Ground Water and Drinking Water. EPA 815-R-03-002. June 2003. Available online at: http://nepis.epa.gov/Exe/ZyPDF.cgi/20001ZLT.PDF?Dockey=20001ZLT.PDF

USEPA. 2009. EPA Protocol for the Second Review of Existing National Primary Drinking Water Regulations (Updated). Washington, DC: Office of Ground Water and Drinking Water. EPA 815-B-09-002. October 2009. Available online at: https://www.epa.gov/sites/production/files/2014-12/documents/815b09002.pdf

USEPA. 2015. Science Policy Council Handbook: Peer Review, 4th Edition. Washington, DC. EPA 100-B-15-001. October 2015. Available online at: https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf

USEPA. 2016. EPA Protocol for the Third Review of Existing National Primary Drinking Water Regulations. Washington, DC: Office of Ground Water and Drinking Water. EPA 810-R-16-007. December 2016. Available online at: https://www.epa.gov/sites/default/files/2016-12/documents/810r16007.pdf

USEPA. 2024a. Analysis of Regulated Contaminant Occurrence Data from Public Water Systems in Support of the Fourth Six-Year Review of National Primary Drinking Water Regulations: Chemical Phase and Radionuclides Rules. EPA-815-R-24-014.

USEPA. 2024b. Analytical Feasibility Support Document for the Fourth Six-Year Review of National Primary Drinking Water Regulations. EPA-815-R-24-015.

USEPA. 2024c. Chemical Contaminant Summaries for the Fourth Six-Year Review of Existing National Primary Drinking Water Regulations. EPA-815-S-24-002.

USEPA. 2024d. Consideration of Other Regulatory Revisions in Support of the Fourth Six-Year Review of the National Primary Drinking Water Regulations: Chemical Phase Rules and Radionuclides Rules. EPA-815-R-24-016.

USEPA. 2024e. Data Management and Quality Assurance/Quality Control Process for the Fourth Six-Year Review Information Collection Request Dataset. EPA-815-R-24-017.

USEPA. 2024f. Occurrence Analysis for Potential Source Waters for the Fourth Six-Year Review of National Primary Drinking Water Regulations. EPA-815-R-24-019.

USEPA 2024g. Results of the Health Effects Assessment for the Fourth Six-Year Review of Existing Chemical and Radionuclide National Primary Drinking Water Standards. EPA-815-R-24-020.

USEPA. 2024h. Review of Fluoride Occurrence for the Fourth Six-Year Review. EPA-815-R-24-021.

USEPA. 2024i. Six-Year Review 4 Technical Support Document for Microbial Contaminant Regulations. EPA-815-R24-022.

USEPA. 2024j. Support Document for Fourth Six-Year Review of Drinking Water Regulations for Acrylamide and Epichlorohydrin. EPA 815-R-24-023.