United States
Environmental Protection
Agency

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

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Abbreviations and Acronyms

BAT	best available technology
DBP	disinfection byproduct
D/DBPR	Disinfectants/Disinfection Byproducts Rule
EPA	U.S. Environmental Protection Agency
EQL	estimated quantitation level
HAA5	Haloacetic Acids (five) (sum of monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid and dibromoacetic acid)
HEA	health effects assessment
HSDB	Hazardous Substances Data Bank
IARC	International Agency for Research on Cancer
ICR	information collection request
IRIS	Integrated Risk Information System
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
NPDWR	national primary drinking water regulation
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
PQL	practical quantitation level
PE	performance evaluation
PT	proficiency testing
PWS	public water system
RfD	reference dose
SDWA	Safe Drinking Water Act
SSCT	small system compliance technology
SYR1	Six-Year Review 1
SYR2	Six-Year Review 2
SYR3	Six-Year Review 3
TT	treatment technique
TTHM	total trihalomethanes (sum of four THMs: chloroform, bromodichloromethane, dibromochloromethane, and bromoform)
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 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 ("Six-Year Review 1 (SYR1)") 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 its second review ("Six-Year Review 2 (SYR2)") in December 2009 (published March 2010) (USEPA, 2010). As described in this document, EPA applies the same protocol with additional clarifications to its third Six-Year Review of NPDWRs ("Six-Year Review 3 (SYR3)").

In the Six-Year Review 3, 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. Improvements in analytical or treatment feasibility may also indicate it is feasible to set 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, or BATs, capable of achieving MCLs) – Changes to BAT recommendations may be appropriate for revised MCLs.
- **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 EPA updated the regulatory review decision tree as part of the Six-Year Review 3. The 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. The decision tree contains ten branches, including a new branch for risk-balancing, which reflects some of the efforts related to the microbial and disinfection byproduct (MDBP) rules.

For example, EPA must 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 an Initial Review Branch, with the purpose of identifying NPDWRs for which further review of detailed technical data is premature (for example, the NPDWR is the subject of recent or ongoing rulemaking, or there is an ongoing health effects assessment and the MCL is already set equal to the MCLG). Excluding such NPDWRs from subsequent review prevents duplicative agency efforts.

The branches of the decision tree are:

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

The Six-Year Review 3 results identify which NPDWRs, if any, are candidates for revision and specify those NPDWRs for which no action is to be taken at this time. A recommendation to revise a 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 a 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 only 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, priority or other reasons. 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.

Reviews of these NPDWRs 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. EPA incorporated minor refinements into the protocol and completed its second review in December 2009 (USEPA 2010). In its third Six-Year Review of NPDWRs, EPA uses the same protocol as was used in the SYR2, with minor clarifications. Section 2 provides an overview of the protocol and Section 3 provides a more detailed discussion of the decision tree implementing the protocol as used for the Six-Year Review 3. The Agency intends to continue to refine the protocol during subsequent Six-Year Reviews to address changing circumstances.

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.

Toward this end, EPA applied a number of basic principles in reviewing NPDWRs. First, the Agency sought to avoid redundant review efforts. Therefore, EPA classified NPDWRs that were 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 3.

Second, EPA evaluated 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 existed, the Agency applied the current policies and procedures for calculating the practical quantitation level 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 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 made a "take no action" recommendation if the health effect 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 provisions in the 1996 SDWA Amendments (SDWA §1412(b)(6)(A)).

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

Fifth, EPA identified areas of inadequate or unavailable data (data gaps) or emerging data that are 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 3, 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 applied the Agency's peer review policy (USEPA, 2015), where appropriate, to any new analyses.

1.2 Scope of Review

Consistent with the Six-Year Review 1 and the Six-Year Review 2, the Six-Year Review 3 encompasses the individual elements of NPDWRs, as follows:

- **MCLG changes –** EPA generally considers changes to the MCLG (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 (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.

[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, the SDWA precludes the Agency from lessening the public health protection of an existing standard (SDWA §1412(b)(9)).

- **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, the NPDWR also contains BAT recommendations that address drinking water treatment processes. Although not required for compliance purposes, EPA sets BATs that have the capability to meet MCLs. EPA generally limits review of BAT recommendations to those NPDWRs with possible MCL revisions.
- **Changes to Other Regulatory Requirements –** EPA generally considers changes to other regulatory requirements, such as changes to monitoring requirements, if other possible NPDWR revisions or health effects information suggest that such changes (e.g., increased frequency in monitoring) could reduce health risks or costs while maintaining or improving the level of public health protection. 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 considered implementation-related concerns if the possible revision meets the following criteria:

    - The possible revision indicates a change to an NPDWR, as defined under section 1401 of the SDWA;
    - The possible revision was "ready" for rulemaking – that is, the problem to be resolved has been clearly identified and specific option(s) formulated to address the problem; and
    - 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 3, EPA reviewed the 88 chemical, microbiological and radiological NPDWRs shown in Exhibit 1.1.

Exhibit 1.1 NPDWRs Included in the 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

[2] A TT 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).

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]
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

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]
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.

1.3 Organization and Contents of this Document

This document describes the review process for the Six-Year Review 3:

- Section 2 provides an overview of the Six-Year Review protocol and the decision tree EPA developed to implement it for the Six-Year Review 3; and
- Section 3 provides detailed description of the individual branches of the decision tree implementing the Six-Year Review 3 protocol.

This document does not summarize the review results from each branch of the Six-Year Review 3; please see support documents for results (USEPA, 2016[3]).

[3] EPA developed multiple support documents to support the SYR3—see references USEPA, 2016a to USEPA, 2016r in the reference section.

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, 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.

The Six-Year Review 3 protocol addresses critical aspects of health protection and the setting of standards under the SDWA. The results of the Six-Year Review 3 identify NPDWRs that are candidates for revision and those for which no action is recommended at this time.

The publication of candidates for revision pursuant to a Six-Year Review under Section 1412(b)(9) is not the end of the regulatory process, but rather the beginning; it 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, resume 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 priority; or other reasons. 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 3

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 informs a decision 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 were used in the Six-Year Review 2, clarifications were made to the protocol to address situations such as: where there are MCLGs for individual contaminants in a group (that might warrant a change) but only an MCL for the group (such as with TTHM or HAA5); where there is a potential for a treatment technique revision (in addition to, or instead of, an MCL revision); and where the health risk 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.

2.2 Elements of the Six-Year Review 3 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 ("no action at this time"). Exhibit 2.1 shows the flow of information between branches where the result is a NPDWR as a candidate for revision. 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 3. The following branches comprise the decision tree:

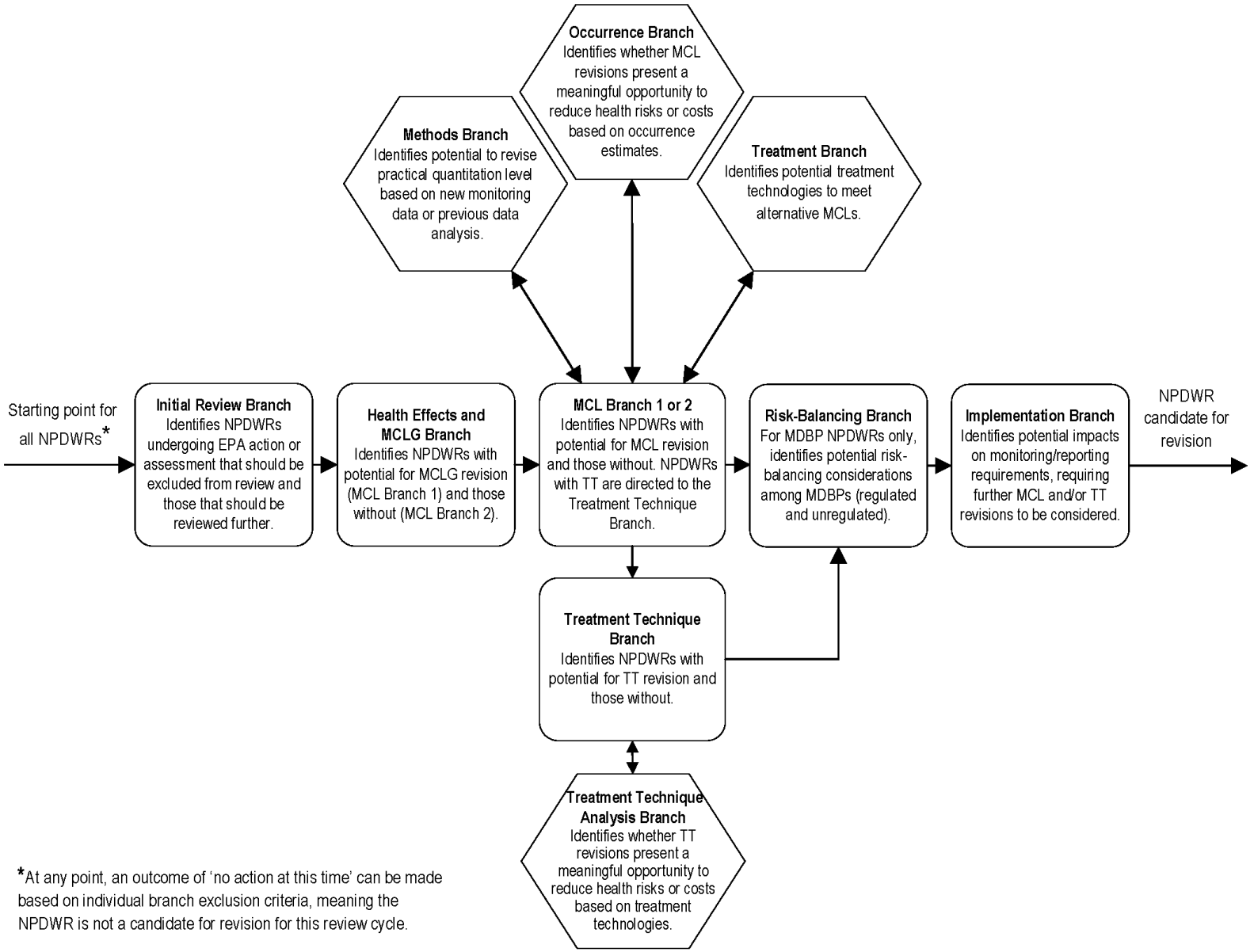
- Initial review,
- Health effects and MCLG,
- MCL,
- Treatment technique,
- Treatment technique analysis,
- Methods,
- Occurrence,
- Treatment,
- Risk-balancing, and
- Implementation.

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 requirements. For example, those NPDWRs that only involve an MCL will complete all branches mentioned in the list above including the MCL-related branches of MCL, Methods, Occurrence and Treatment but excluding the TT-related branches of Treatment Technique and Treatment Technique Analysis. Conversely, the NPDWRs that only involve a TT (e.g., NPDWRs related to microbial regulation) will complete all branches mentioned in the list above including the TT-related branches of Treatment Technique and Treatment Technique Analysis but excluding the MCL-related branches of Methods, Occurrence and Treatment. NPDWRs that only involve a TT will also not complete a large majority of the MCL Branch.

Another factor determining how an existing NPDWR moves through the Six-Year Review decision tree is whether an NPDWR is an MDBP. If an NPDWR is an MDBP it will complete the Risk-balancing Branch in its entirety. If an NPDWR is not an MDBP, a majority of the Risk-balancing Branch will not be completed, as this branch is applicable only to the review of the 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:

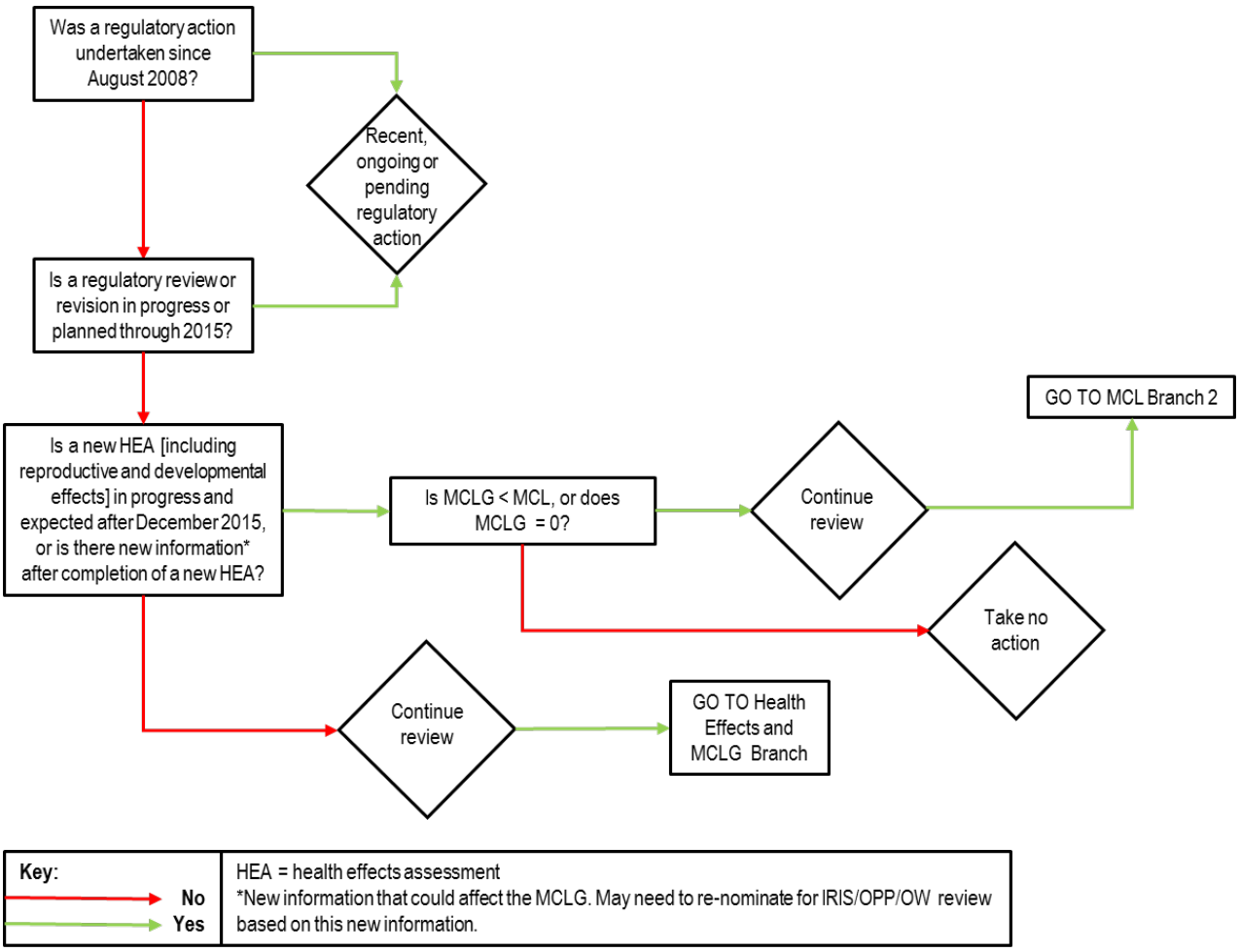
- The NPDWR was recently completed, reviewed or revised (i.e., since August 2008);
- The NPDWR is part of an ongoing or pending regulatory action; or
- The NPDWR contaminants has an ongoing EPA health effects assessments that is due after the cutoff date for the review or EPA completed a health effects 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 answered 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 were not part of recent, ongoing or pending regulatory actions, a subsequent question 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 review (December 2015). Contaminants were placed in one of two lists for the purpose of tracking health effects information:

- Contaminants with ongoing formal 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 and the National Academy of Sciences when commissioned by EPA. The question expands this "No Action" 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 Output 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,[4] (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 there is potential to revise the MCLG. To do this, the protocol requires that:

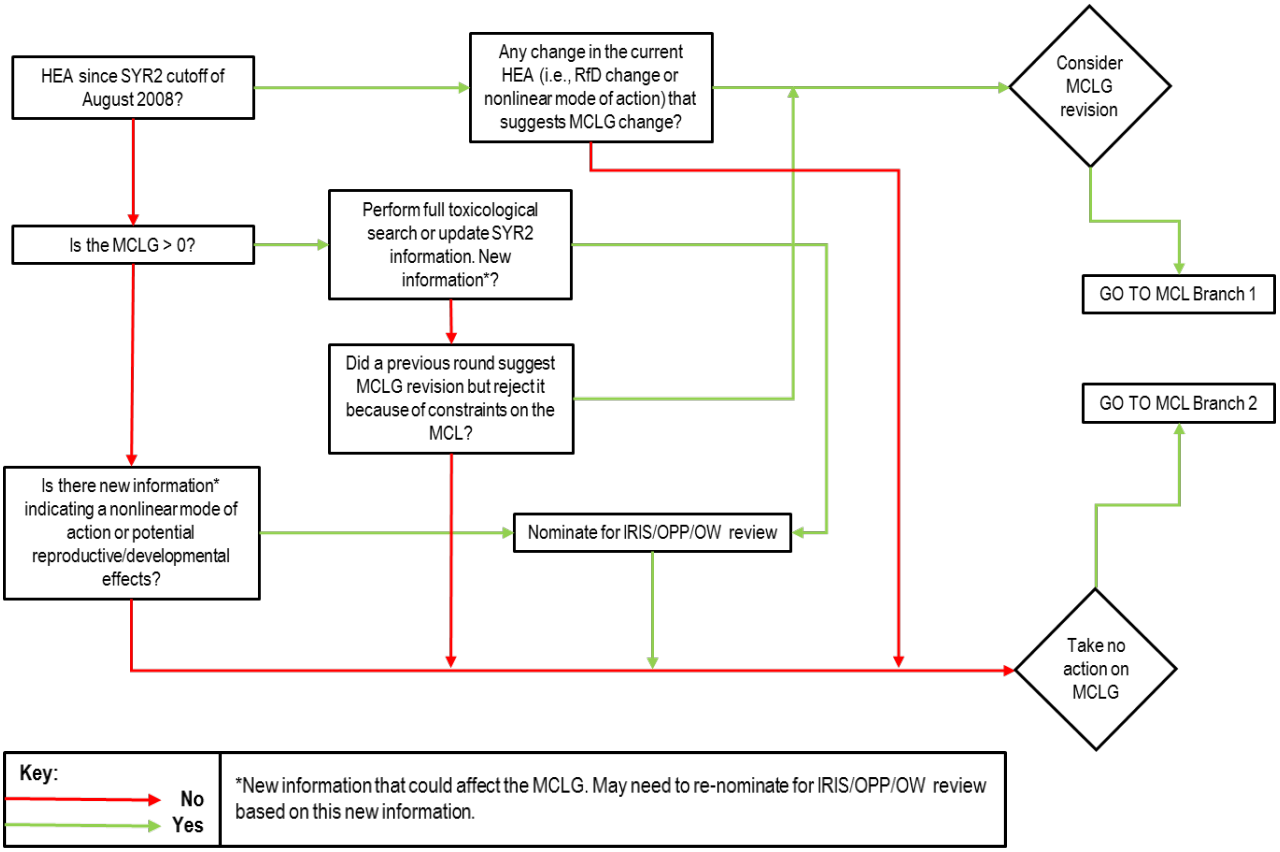
- A revised or new health effects assessment be completed during the current cycle, after August 2008 and before December 2015, and
- The assessment results in a change to the RfD or cancer risk.

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

The Health Effects and MCLG Branch also identifies whether there is new health effects information identified during a review of peer-reviewed literature that leads to a nomination for a new health effects assessment for those contaminants for which there are no recent or ongoing assessments. This would also address situations where there is new health-related information associated with the data on which the MCL or TT was based, such as the weight of evidence information used to support the development of MDBP rules.

[4] 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 formal health effects and toxicological assessment completed during the current review cycle.

For regulated contaminants that have a new health effects assessment, this branch asks whether there was a change in toxicological parameters that affect the MCLG, including conditions such as:

- Whether the assessment resulted in changes to the RfD or cancer classification, and
- Whether these changes would potentially affect the MCLG.

EPA obtained RfD and cancer classification information from its own formal health effects assessments such as IRIS and OPP. EPA also evaluated relevant non-EPA assessments such as the Agency for Toxic Substances and Disease Registry, California Environmental Protection Agency, Health Canada, World Health Organization (WHO), National Toxicology Program and International Agency for Research on Cancer.

If there were no new cancer data or studies for the SYR3 evaluation, EPA retained the cancer classification of the NPDWR based on 1986 cancer risk classifications (USEPA, 1986): Category I (Human carcinogen or Probable human carcinogen), Category II (Possible human carcinogen) and Category III (Not classifiable as to human carcinogenicity or evidence of non-carcinogenicity for humans). In some instances, a combination of the 1986 classification and the

draft 1999 classification (USEPA, 1999) was used (e.g., for the MDBP rules, depending on whether the regulation was part of the Stage 1 and Stage 2 Disinfectants and Disinfection Byproducts Rules (D/DBPR)). If there were new cancer data or studies, EPA could recommend a cancer risk evaluation following the 2005 cancer guidelines and the supplemental guidelines, where appropriate (USEPA, 2005).

Another question in this branch divides NPDWRs that did not have a recent health effects assessment into two categories:

- Those with nonzero MCLGs, including non-carcinogens or carcinogens with threshold, and
- Those with MCLGs of zero, e.g., linear low-dose carcinogens.

Subsequent questions address whether literature searches indicate a need for a new formal health effects assessment. For the Six-Year Review 3, EPA conducted a review of the peer-reviewed literature on relevant health effects (i.e., general toxicity, reproductive and developmental toxicity, and cancer risk via an oral route for the general population and sensitive subpopulation groups including children). This review searched for new health effects information indicating that the current RfD values or cancer risk categories might not adequately represent health risks.

EPA's review for each chemical began with reviews or assessments using the following sources: IRIS, OPP, the Office of Radiation and Indoor Air, National Academy of Sciences, Agency for Toxic Substances and Disease, National Toxicology Program, National Institute of Environmental Health Sciences, California Environmental Protection Agency, WHO, European Commission Concise International Chemical Assessment Documents, International Programme on Chemical Safety/Environmental Health Criteria, International Agency for Research on Cancer, Health Canada, Joint Expert Committee on Food Additives, and Joint Food and Agriculture Organization of the United States/WHO Meeting on Pesticide Residues. EPA obtained each organization's most recent assessment available. EPA also conducted literature searches to identify primary literature to supplement the information in the authoritative reviews. The searches utilized the following databases: TOXLINE, MEDLINE®, Developmental and Reproductive Toxicology, Chemical Carcinogenesis Research Information System and Hazardous Substances Data Bank.

The review identified two categories of contaminants, those with:

- New health effects information indicating a nonlinear mode of action or potential reproductive/developmental or other toxicological effects for contaminants at concentrations at or below the MCL when the MCLG is zero, and
- New cancer data or toxicological information in the literature that potentially affects the RfDs for contaminants without a recent health effects assessment and a nonzero MCLG.

Another question in this branch identifies contaminants for which there was 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. During the Six-Year Review 2, 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.

For MDBP NPDWRs, EPA examined new health-related information about epidemiological and toxicological effects (in a manner similar to the review completed during the development of the D/DBPRs). As discussed in the preamble to the final rule for the Stage 2 D/DBPR, EPA promulgated the rule to provide for increased protection against the potential risks of cancer and reproductive and developmental health effects associated with DBPs. The rule was designed to reduce the level of exposure to DBPs without undermining the control of microbial pathogens. It was based, in part, on the weight of evidence from epidemiological and toxicological studies linking bladder, colon and rectal cancers to DBP exposure, as well as epidemiological and toxicological studies showing possible associations between chlorinated drinking water and adverse reproductive and developmental endpoints. During the Six-Year Review 3, EPA evaluated the weight of evidence from health-related information related to those effects, for both cancer and reproductive and developmental endpoints. EPA also examined toxicological data for individual contaminants such as specific DBPs that are included in a group MCL (TTHM or HAA5).

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 there is potential to revise the MCLG based on the availability of new Agency health effects information or recent non-EPA assessments that include new scientific information consistent with EPA guidelines and policies, 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 Office of Water, IRIS or OPP; and
- NPDWRs for which there is no potential to revise the MCLG during the Six-Year Review 3.

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 practical quantitation limit (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 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)

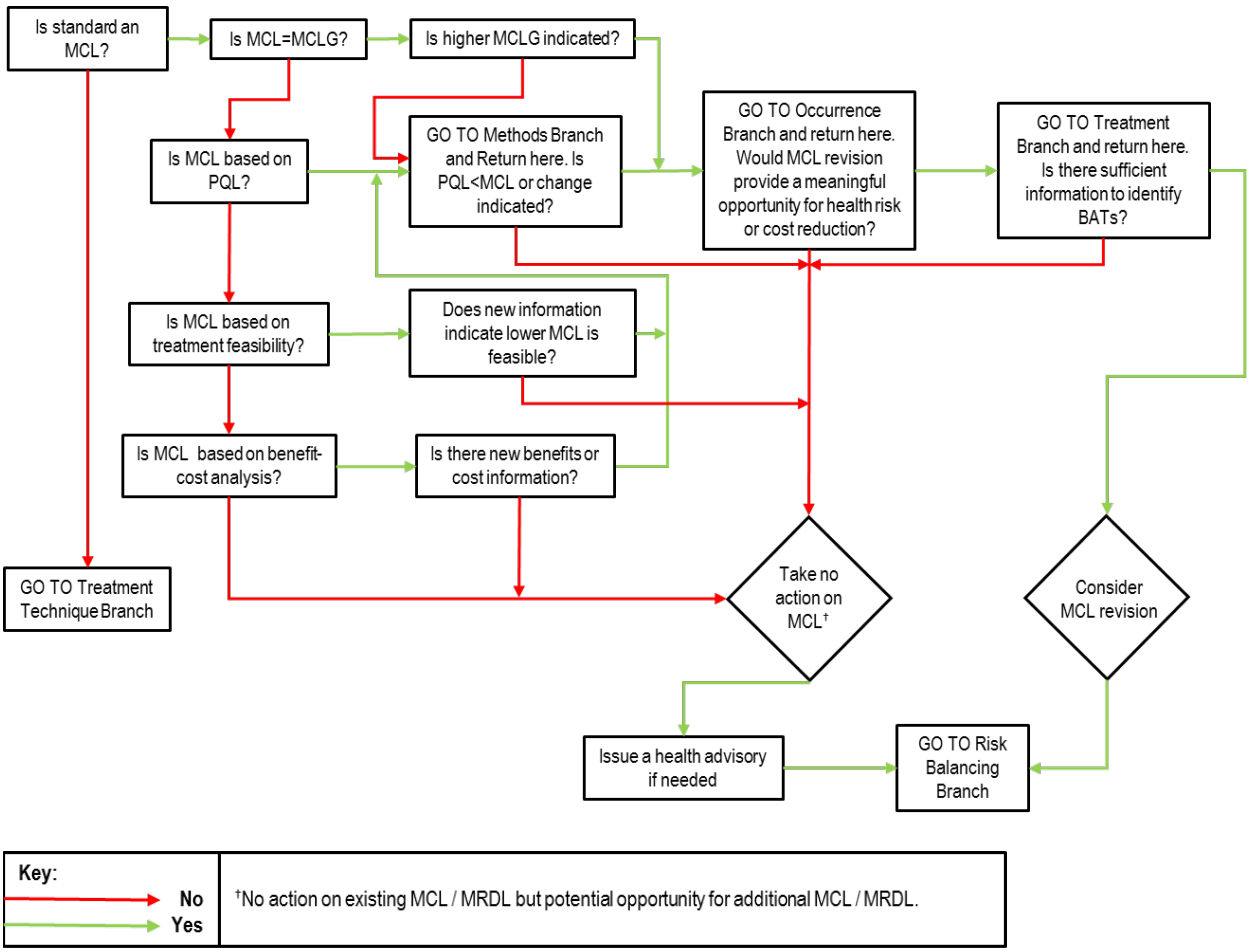
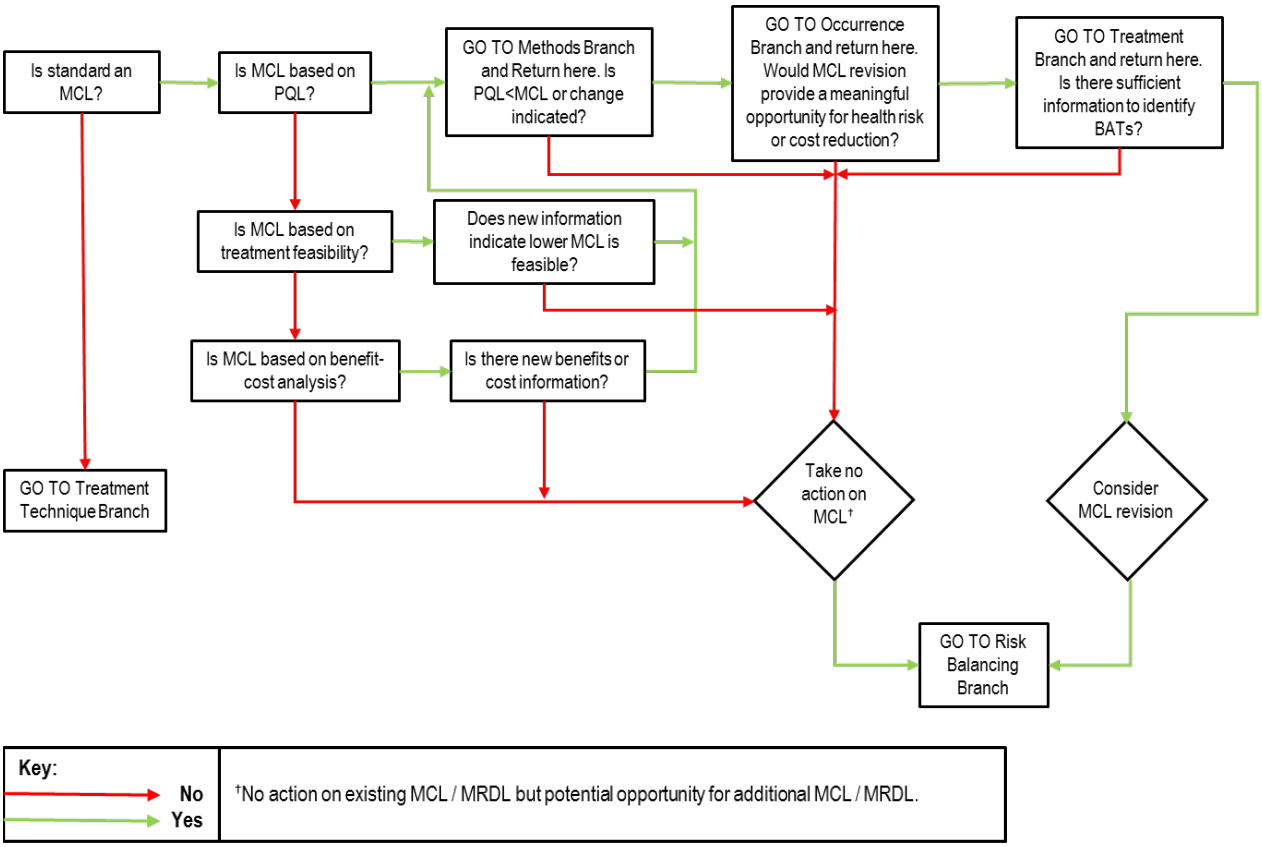


Exhibit 3.3b Maximum Contaminant Level Branch 2 (No Potential for MCLG Revision)



3.3.1 Inputs to Maximum Contaminant Level Review

The two MCL branches have similar questions and differ in that one poses the questions for contaminants with a possible MCLG revision (MCL Branch 1), and the other poses the questions for contaminants with no action regarding the MCLG (MCL Branch 2). 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 situations where there are multiple MCLGs for a given NPDWR. For TTHM, the four individual components 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. For the Six-Year Review 3, EPA examined these MCLGs on an individual component basis, and completed an overall health effects review. As discussed earlier for these rules, it should be noted that the treatment techniques were reviewed in addition to the MCLs.

Subsequent questions on the MCL branches involve subordinate branches for analytical methods, occurrence and treatment analysis 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.

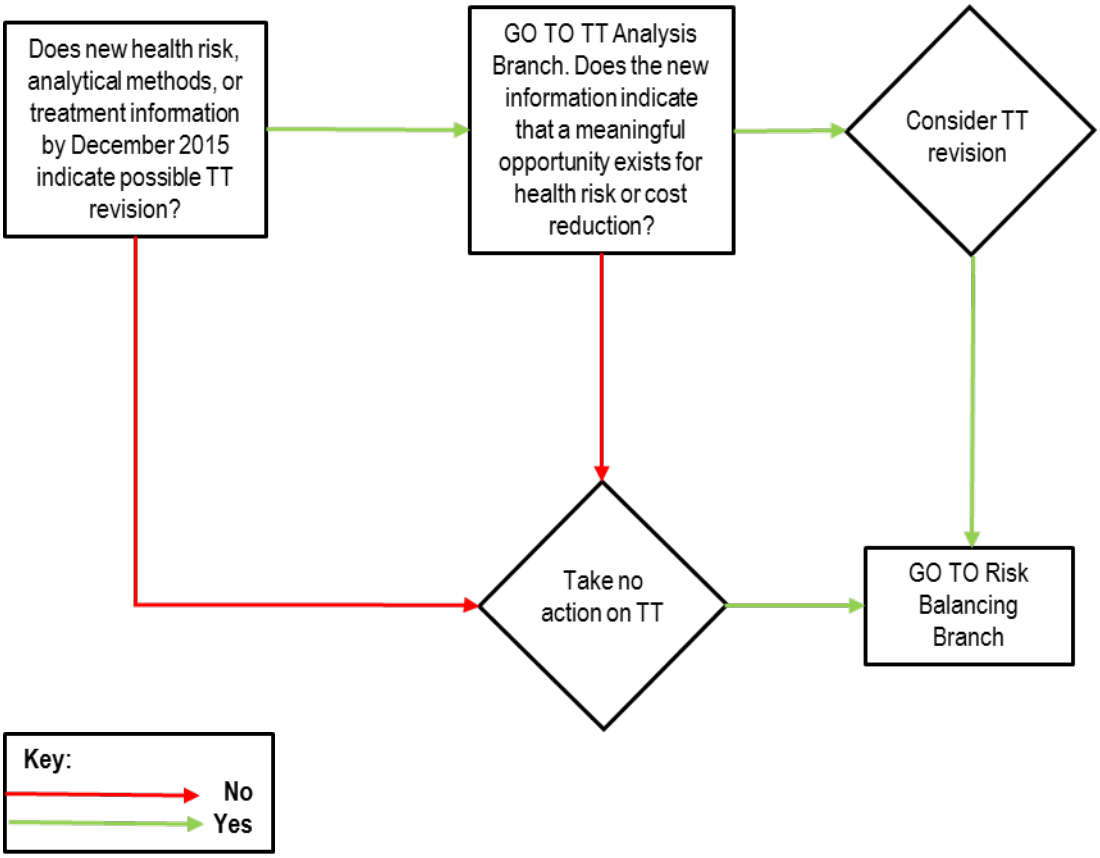
3.3.2 Outputs from Maximum Contaminant Level Review

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 there is potential 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 treatment technique?
- 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.

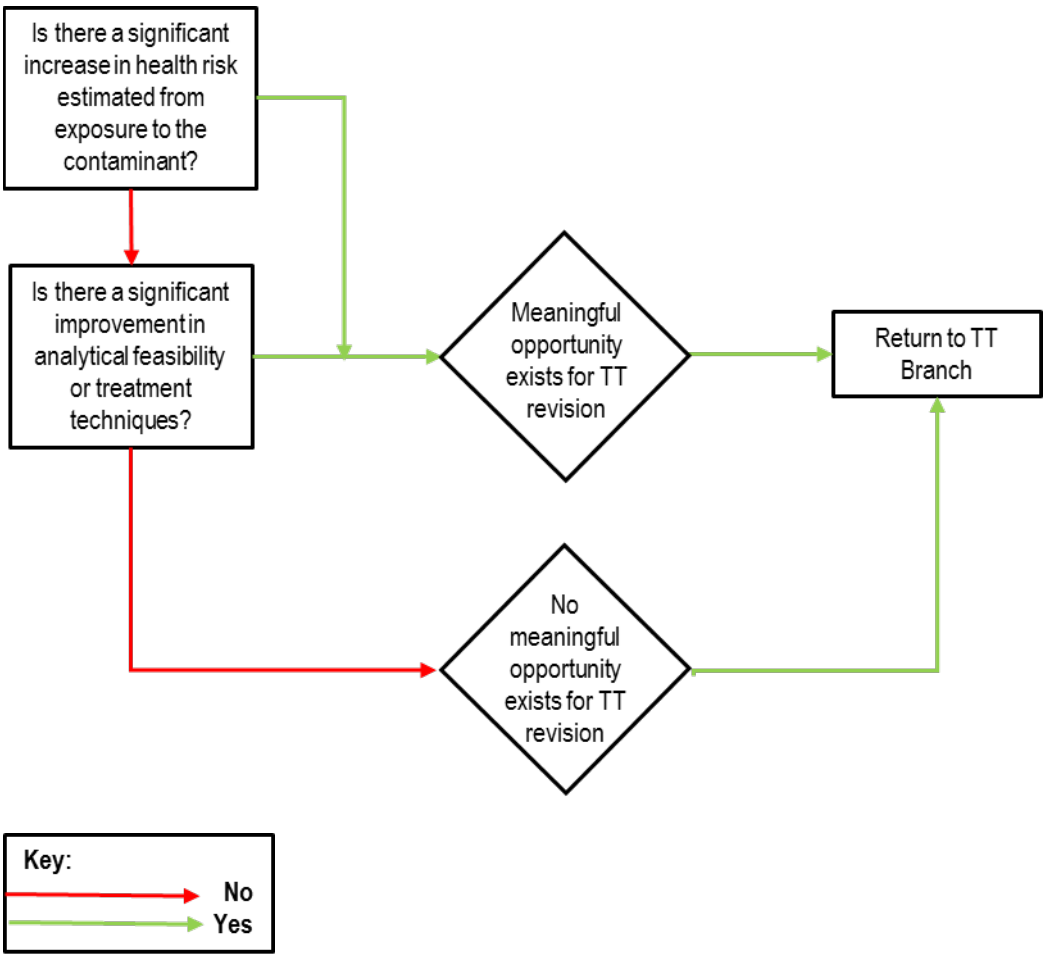
3.5.1 Inputs to Treatment Technique Analysis Review

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



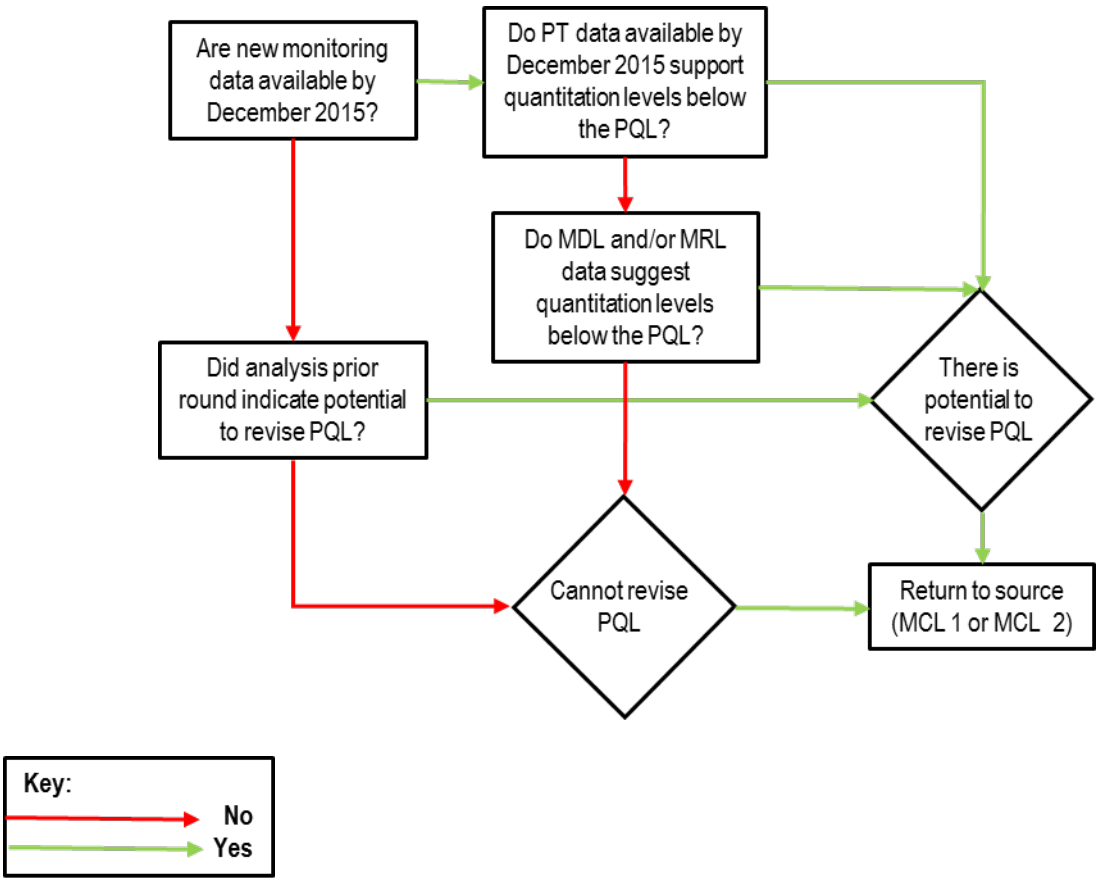
3.5.2 Outputs from Treatment Technique Analysis Review

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 there is potential 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. This is usually interpreted as the analyte concentration at which 75 percent of laboratories can measure concentration within the promulgated acceptance criteria.

Exhibit 3.6 Methods Branch



The 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 3 did 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 the SDWA analytes: (1) Performance Evaluation (PE) data from Water Supply studies is the preferred alternative when sufficient data are available; or (2) a multiplier method, in which the PQL is calculated by multiplying the EPA-derived method detection limit (MDL) by a factor of 5 or 10 (USEPA, 1985; USEPA, 1987; USEPA, 1989). Using PE data to derive the PQL for chemical NPDWRs involves determining the concentration of an analyte at which 75 percent of EPA Regional and state laboratories achieve results within a specified acceptance window (USEPA, 1989).

3.6.1 Inputs to Methods Review

The Methods Branch includes the following questions:

- Are new monitoring data available by the cutoff date (December 2015) that EPA selected for the Six-Year Review 3?
- Do the new analytical methods data indicate potential to revise the PQL?
- Do other new data such as MDL and/or minimum reporting level (MRL) information indicate potential to revise the PQL?
- Do previous data or analyses (i.e., the Six-Year Review 1, the Six-Year Review 2) indicate potential to revise the PQL?

The protocol developed for the Six-Year Review 1 primarily used PE data from Water Supply studies. These were laboratory accreditation studies conducted under EPA oversight until 1999, when the program was privatized. The National Environmental Laboratory Accreditation Conference currently conducts the accreditation program via Proficiency Testing (PT) studies. For the Six-Year Review 2, EPA could not obtain actual PT study analytical results from the National Environmental Laboratory Accreditation Conference or any PT providers. Given that PE data and comparable PT data were not available for the Six-Year Review 2, EPA modified the review process, as described below.

The PQL reassessments for the Six-Year Review 3 use a variety of data. The primary data sources were:

- Laboratory passing rates based on PT data (i.e., the percent of laboratories passing a proficiency test for a given study) from 2008 through 2014, and
- Analytical method feasibility data (i.e., MRLs and MDLs) collected as part of the Six-Year Review information collection request (ICR).

EPA first reviewed the PT passing rate results for tests conducted at and below the current PQL to indicate potential for PQL revision. EPA placed contaminants into one of three categories based on whether the PT and PE data supported, may support, or did not support a lower PQL. For example, EPA placed 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.

When the analysis of PT and PE data did not provide conclusive indications regarding whether there was potential to revise a PQL, EPA reviewed two other sources of information. The first source was the MRLs in the SYR3 ICR database (USEPA, 2016a). 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 (USEPA, 2016b). Through the SYR3 ICR, EPA received voluntary submissions of compliance monitoring data for public water systems (PWSs) from 54 states and entities. The data contain a large number of analytical non-detection records with accompanying MRLs for regulated contaminants (see Section 3.7.1). When appropriate, EPA evaluated the distribution of MRL values for contaminants to identify the mode, or value occurring most frequently for that contaminant ("modal MRL"). The use of modal MRLs to provide additional insight into whether there is potential to revise a PQL is another refinement of the protocol, necessitated by limited

availability of PT and PE data below the current PQL and made possible by the extensive amount of information included in the ICR database.

The second type of information that EPA reviewed to evaluate the potential for a change in the PQL was the MDLs for analytical methods approved by EPA for drinking water. In using MDLs, EPA followed the multiplier approach used to derive some PQLs. This approach was also used to identify possible analytical feasibility levels for the Six-Year Review 1 (USEPA, 2003b) and the Six-Year Review 2 (USEPA, 2009). Based on these MDL values, EPA used an MDL multiplier to estimate where the possible lower limit of quantitation may currently lie. The multiplier is 10 for most contaminants; the exception is contaminants for which EPA developed a PQL using a multiplier of 5 (e.g., dioxin).

EPA also used the modal MRL and MDL-based estimates when it derived estimated quantitation levels (EQLs) for the occurrence analysis to help the Agency determine if there was a meaningful opportunity for health risk reduction. The EQL does not, however, represent the Agency's intent to calculate new PQL at this time. Because of lack of data, EPA did not recalculate PQLs during the Six-Year Review 2 or the Six-Year Review 3.

3.6.2 Output from Methods Review

The output of the Methods Branch is a decision regarding whether new information or information from an earlier cycle indicates a potential to lower the PQL for a contaminant. The decision tree then returns the review to the MCL Branch for subsequent questions.

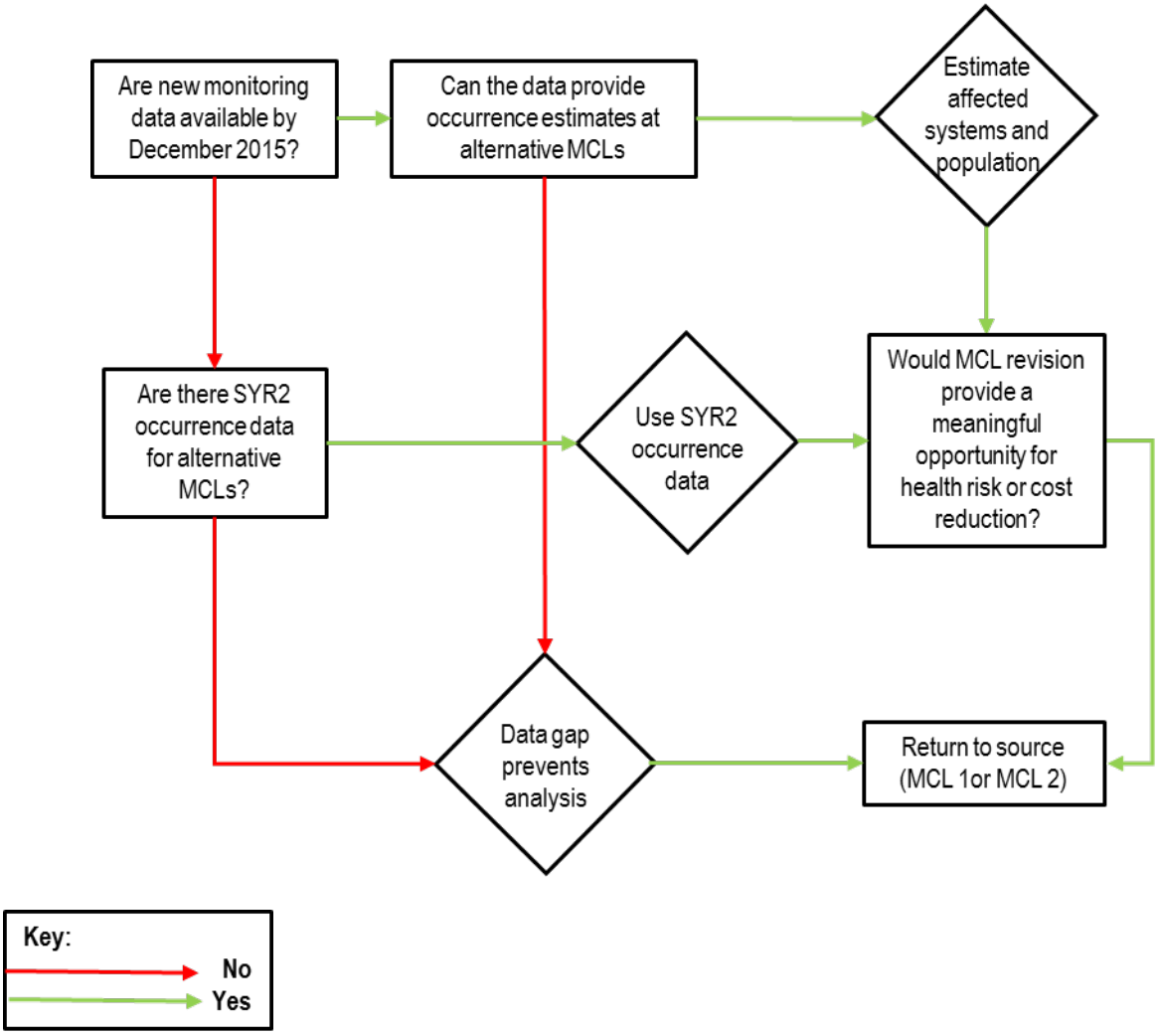
3.7 Occurrence Branch

The purpose of the Occurrence Branch (Exhibit 3.7) is to determine if there is a potential meaningful opportunity 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 and EQLs). For the Six-Year Review 3, the responses to these questions reflected new data that EPA received through its Six-Year Review ICR. EPA issued the ICR as a one-time voluntary request for states to submit historical monitoring data (covering the years 2006 through 2011) for regulated contaminants to EPA. A total of 54 states and entities 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. If new monitoring data were not available from the latest ICR data request, EPA would have reviewed monitoring data from the previous Six-Year Review, in this case SYR2.

Similar to the Six-Year Review 2 protocol, EPA also reviewed 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 were not adequate to evaluate the cost savings potential for contaminants with the potential for higher MCLG values. Therefore, EPA also evaluated source water quality information for these contaminants. This information came from two national data sources: the National Water Quality Assessment program conducted by the U.S. Geological Survey, and EPA's STORET (short for STOrage and RETrieval) data system, which are part of OGWDW's National Contaminant Occurrence Database.

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; there is no single benchmark 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.

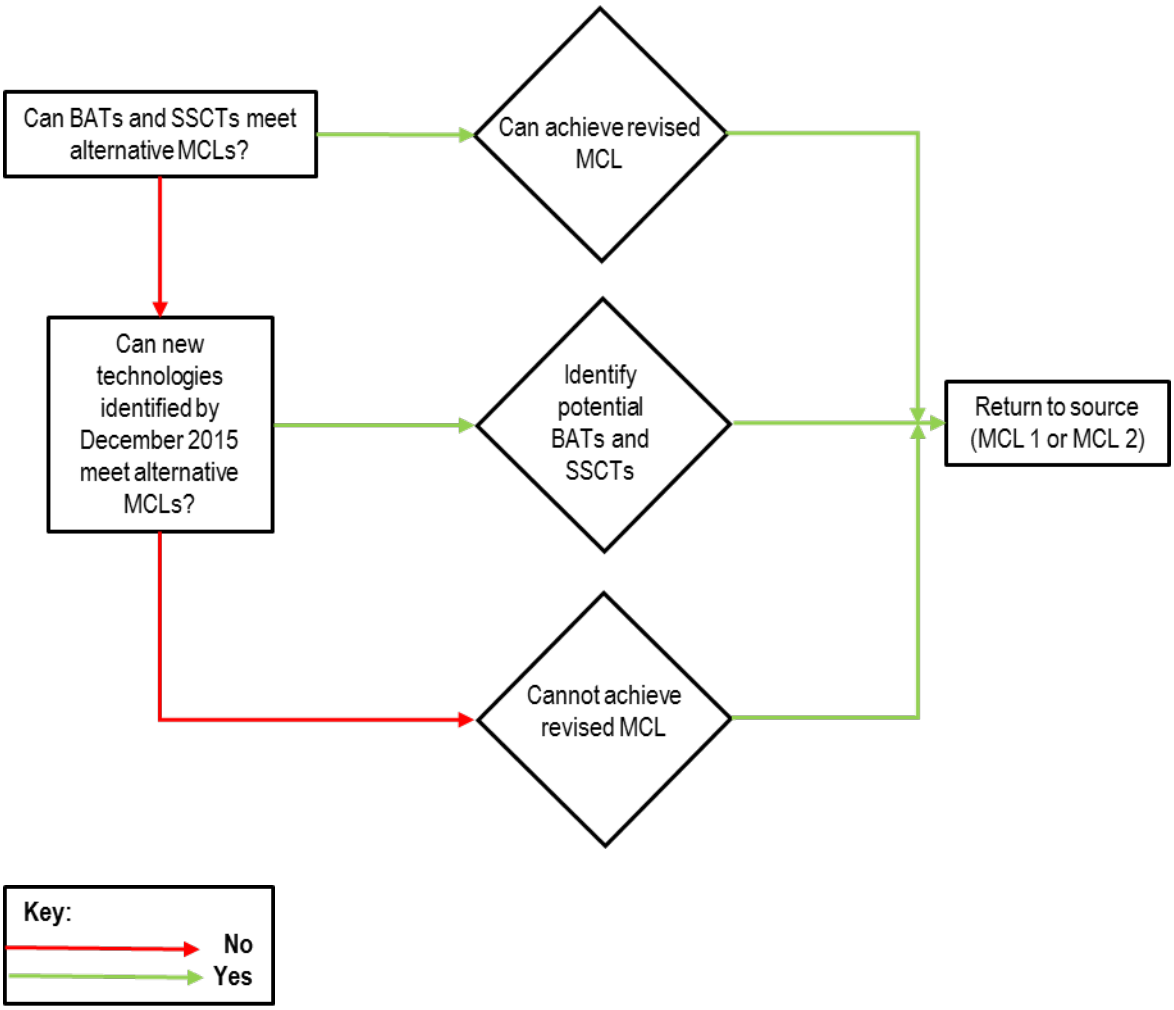
3.7.2 Output from Occurrence Review

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 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 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 2015) meet alternative MCLs?

For the Six-Year Review 3, EPA limited its review of BATs to those NPDWRs for which it was considering possible revisions to the MCL based on the health effects or analytical feasibility reviews. To address both questions, EPA conducted a review of treatment performance studies for all applicable technologies for the contaminant in question. EPA used the same sources that it has relied on in the past to develop regulations and guidance, including published EPA treatment reports, peer-reviewed journals and other sources of technology performance (e.g., pilot and demonstration project reports), as well as information received from EPA stakeholders. EPA evaluated whether these treatment studies indicate that current BATs are capable of achieving 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 identify how the Six-Year Review addresses 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. This approach was used in the development of several NPDWRs, such as those for the Long-Term 2 Enhanced Surface Water Treatment Rule 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 question:

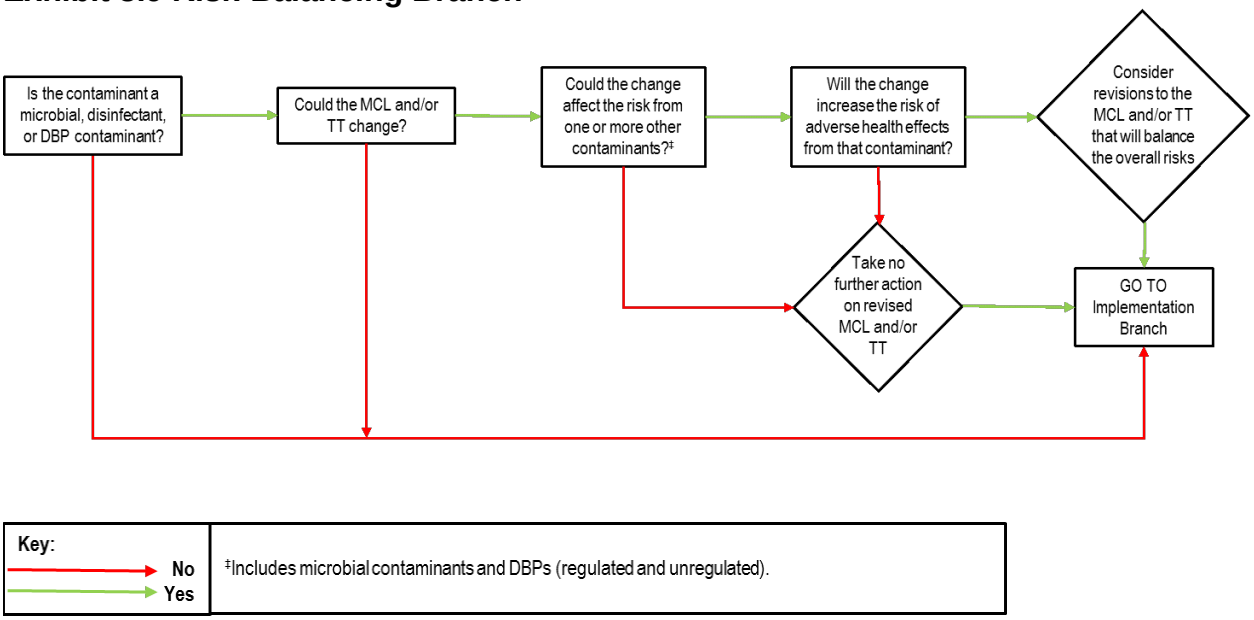
- Could the change to an NPDWR affect the risk from one or more contaminants, and, if so, will the change increase the risks of adverse health effects from that contaminant?

For the Six-Year Review 3, 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 protection rules. In addition, EPA reviewed risk-balancing between different types of DBP contaminants. Depending on the stringency of potential DBP regulations, there may be response strategies used by the regulated community that might have the effect of increasing the concentrations of other types of contaminants (regulated and unregulated). EPA considered these potential response strategies, with a goal of balancing the overall risks.

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 needed to help balance the overall risks from potential changes. Following this determination, the decision tree then transitions to the Implementation Branch for subsequent questions.

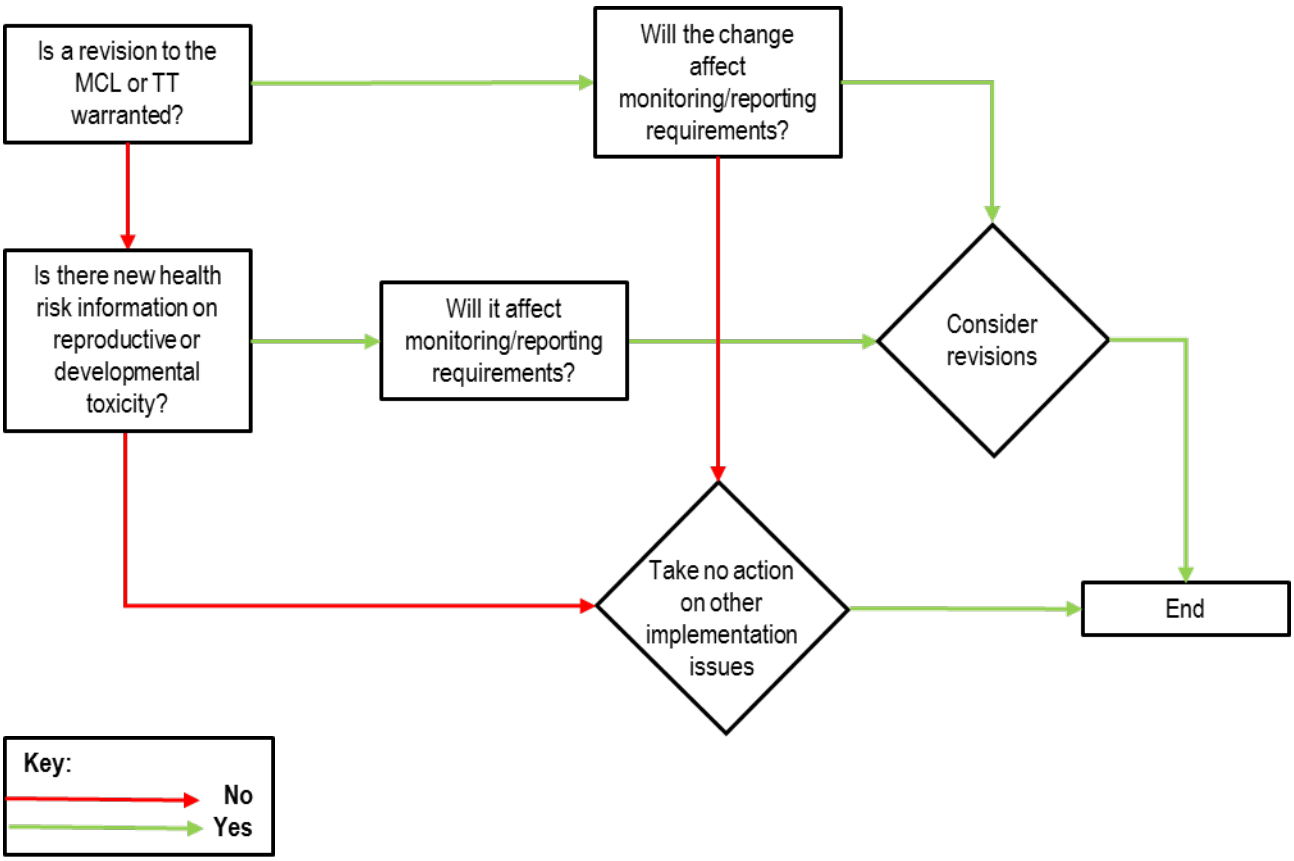
Exhibit 3.9 Risk-Balancing Branch



3.10 Implementation Branch

The purpose of the Implementation Branch (Exhibit 3.10) is to evaluate potential revisions pertaining to "other" regulatory requirements, such as monitoring 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. For the Six-Year Review 3, EPA focused this review on issues that were not already being addressed through alternative mechanisms, 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 had 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.

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