



**EPA Protocol for the  
Second Review of Existing National Primary  
Drinking Water Regulations (Updated)**

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## Abbreviations and Acronyms

2,4-D	2,4-dichlorophenoxyacetic acid
ATSDR	Agency for Toxic Substances and Disease Registry
BAT	best available technology
CalEPA	California Environmental Protection Agency
CCRIS	Chemical Carcinogenesis Research Information System
CICADS	European Commission Concise International Chemical Assessment Documents
DART	Developmental and Reproductive Toxicology
DBCP	1,2-dibromo-3-chloropropane
DBPR	Disinfectants and Disinfection Byproducts Rule
DEHA	di(2-ethylhexyl)adipate
DEHP	di(2-ethylhexyl)phthalate
EDB	ethylene dibromide
EPA	U.S. Environmental Protection Agency
EQL	estimated quantitation level
FAO	Food and Agriculture Organization of the United Nations
GWR	Ground Water Rule
HAA5	haloacetic acids
HSDB	Hazardous Substances Data Bank
IARC	International Agency for Research on Cancer
ICR	Information Collection Request
IPCS/EHC	International Programme on Chemical Safety/Environmental Health Criteria
IRIS	Integrated Risk Information System
JECFA	Health Canada, Joint Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LCR	Lead and Copper Rule
LT2	Long-Term 2 Enhanced Surface Water Treatment Rule
MCL	maximum contaminant level
MCLG	maximum contaminant level goal
MDL	method detection limit
mg/L	milligrams per liter
MRL	minimum reporting level
N	nitrogen
NAS	National Academy of Sciences
NAWQA	National Water Quality Assessment
NCOD	National Drinking Water Contaminant Occurrence Database
NDWAC	National Drinking Water Advisory Council
NELAC	National Environmental Laboratory Accreditation Conference
NIEHS	National Institute of Environmental Health Sciences
NPDWR	National Primary Drinking Water Regulation
NTP	National Toxicology Program

OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
OW	Office of Water
OST	Office of Science and Technology
PCBs	polychlorinated biphenyls
PQL	practical quantitation level
PE	performance evaluation
PT	proficiency testing
PWS	public water system
R2S2	Regulatory Review Support Spreadsheet
RfD	reference dose
SDWA	Safe Drinking Water Act
SSCT	small system compliance technology
TT	treatment technique
TTHM	total trihalomethanes
WHO	World Health Organization
WS	water supply

## Executive Summary

The 1996 Safe Drinking Water Act (SDWA) Amendments require the U.S. Environmental Protection Agency (EPA or the Agency) to review and revise National Primary Drinking Water Regulations (NPDWRs) at least once every six years as appropriate to maintain or improve human health protection. EPA completed and published the results of its first Six-Year Review (Six-Year Review 1) July 18, 2003 (68 *FR* 42908) after developing a systematic approach, or protocol, for the review of NPDWRs. As described in this document, EPA has applied the same protocol with minor refinements (revised protocol) to its second Six-Year Review of NPDWRs (Six-Year Review 2).

In Six-Year Review 2, EPA addressed the following:

- **Maximum Contaminant Level Goals (MCLGs; the health goal)** – for some contaminants new health effects assessments completed since the MCLG was promulgated or last revised include revised reference doses (RfD) and/or cancer classification.
- **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 feasibility to set the MCL closer to the MCLG.
- **Treatment Technique (TT; sometimes established in lieu of an MCL)** – new information on health effects, analytical feasibility, or treatment feasibility may suggest a possibility to revise TT.
- **Other Treatment Technology** (NPDWRs contain Best Available Technologies, or BATs, capable of achieving MCLs) – Changes to BAT recommendations may be appropriate for revised MCLs.
- **Other Regulatory Requirements (Monitoring)** – Other regulatory revisions may be appropriate if information suggest that changes in monitoring standards (e.g., frequency) could reduce health risks or costs while maintaining or improving the level of public health protection.

This comprehensive review comprised 85 NPDWRs. To facilitate the process, EPA developed a Six-Year Review 2 decision tree that structures a series of questions about whether there is new information suggesting that it is possible to revise one or more NPDWR elements in a logical order. The order of the questions within the tree reflects the sequential relationships between the different NPDWR elements and thus avoids unnecessary analyses.

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 new information relevant to the potential to revise the MCLG before decisions regarding the potential to revise the MCL. Also, 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 contaminants for which further review of detailed technical data is premature (the contaminant is the subject of recent or ongoing rulemaking, or there is an ongoing health effects assessment). Excluding such contaminants from subsequent review prevents duplicative Agency efforts. For contaminants for which there is an ongoing health effects assessment and the MCL is above the MCLG, the review proceeds to branches that evaluate whether there is potential to lower the MCL. The Agency's review of new information that may affect the MCL for these contaminants is one of several refinements of the protocol. During Six-Year Review 1, EPA took no further action on any contaminants with ongoing health effects assessments. This refinement addresses the SDWA requirement that EPA set each MCL as close to the MCLG as feasible.

The additional branches of the decision tree are:

- Health effects and MCLG
- MCL
- Treatment technique
- Analytical methods
- Occurrence and exposure
- Treatment feasibility.

A series of technical support documents (U.S. EPA, 2009a-g) provide data and analysis to support EPA's decisions in each branch. EPA also developed an automated tool called the Regulatory Review Support Spreadsheet (R2S2) to track the review results. This tool enhances transparency, automates the decision process, and facilitates the Agency's reporting of its recommendations. The Agency will continue to refine the Six-Year Review protocol during subsequent reviews to address changing circumstances.

As for Six-Year Review 1, Six-Year Review 2 results consist of recommendations to revise some NPDWRs, and to take no action at this time for the remaining NPDWRs. 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 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. Reviews of these contaminants in future Six-Year Reviews may lead to a recommendation that regulatory changes are appropriate.



# 1 Introduction

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). Section 1412(b)(9) of 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 (Six-Year Review 1) July 18, 2003 (68 *FR* 42908) after developing a systematic approach, or protocol, for the review of NPDWRs. EPA has applied the same protocol with minor refinements (revised protocol) to the second Six-Year Review of NPDWRs (Six-Year Review 2). Section 2 provides an overview of the protocol and Section 3 describes the protocol and the minor refinements used for the Six-Year Review 2. The Agency will 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 NPDWRs for possible regulatory revision. Although the statute does not define when a revision is “appropriate,” as a general benchmark, EPA considered 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 Six-Year Review 2.

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 policy and procedures for calculating the practical quantitation level for drinking water contaminants.

Third, the Agency does not believe it is appropriate to consider revisions to NPDWRs for contaminants with an ongoing health effect assessment 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 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 1996 SDWA Amendments’ cost-benefit provision.

Fourth, EPA will address new information from health effect assessments completed after the information cutoff date (March 1, 2009) for the Six-Year Review 2 and any new conclusions or additional information associated with the contaminant during the next review cycle. The Agency may consider accelerating a review and possible revision for a particular NPDWR before the next review cycle when justified by new public health risk information.

Fifth, EPA identified areas of inadequate or unavailable data (data gaps) or emerging data that is 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 Six-Year Review 2, 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 if a review and possible revision is justified by new public health risk information.

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

## 1.2 Scope of Review

As for Six-Year Review 1, Six-Year Review 2 encompassed the individual elements of NPDWRs, as follows:

- MCLG changes – EPA generally considered changes to the MCLG (the health goal) only in instances of a new health effects assessment completed since the MCLG was promulgated or last revised, which resulted in a revised reference dose (RfD) and/or cancer classification justifying a revised MCLG.
- MCL changes – EPA generally considered 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.<sup>1</sup>
- Treatment Technique (TT)<sup>2</sup> changes – Treatment techniques can improve to the point where more protective drinking water standards may be considered. EPA generally considered revisions to TT requirements whenever there was 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 Best Available Technology (BAT) recommendations that address drinking water

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<sup>1</sup> 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 also precludes the Agency from making an existing standard less stringent solely on economic considerations.

<sup>2</sup> 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).

treatment processes. Although not required for compliance purposes, EPA sets BATs that have the capability to meet MCLs. EPA generally limited review of BAT recommendations for those NPDWRs with possible MCL revisions.

- Changes to Other Regulatory Requirements – EPA generally considered other regulatory revisions, such as changes to monitoring requirements, if other possible NPDWR revisions or health effects information suggest that changes in monitoring standards (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 focused 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 met the following criteria:
  - The possible revision indicates a possible change to an NPDWR, as defined under section 1401 of 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.
  - The possible revision could improve the level of public health protection or represent a cost savings while maintaining or improving public health protection.

For Six-Year Review 2, EPA reviewed the chemical, microbiological, and radiological NPDWRs for the 85 contaminants shown in **Exhibit 1-1**. Of the 85 NPDWRs, EPA is reviewing or has revised 14 through recent or ongoing rulemakings (see **Exhibit 1-2**).

**Exhibit 1-1. NPDWR Contaminants Included in Six-Year Review 2**

Contaminants	MCLG (mg/L) <sup>1</sup>	MCL (mg/L) <sup>1</sup>	Contaminants	MCLG (mg/L) <sup>1</sup>	MCL (mg/L) <sup>1</sup>
Acrylamide	0	TT	Epichlorohydrin	0	TT
Alachlor	0	0.002	Ethylbenzene	0.7	0.7
Alpha particles	0 (pCi/L)	15 (pCi/L)	Ethylene dibromide (EDB)	0	0.00005
Antimony	0.006	0.006	Fluoride	4	4
Arsenic	0	0.01	<i>Giardia lamblia</i>	0	TT
Asbestos	7 (million fibers/L)	7 (million fibers/L)	Glyphosate	0.7	0.7
Atrazine	0.003	0.003	Haloacetic acids (HAA5)	n/a <sup>3</sup>	0.06
Barium	2	2	Heptachlor	0	0.0004
Benzene	0	0.005	Heptachlor epoxide	0	0.0002
Benzo[a]pyrene	0	0.0002	Hexachlorobenzene	0	0.001
Beryllium	0.004	0.004	Hexachlorocyclopentadiene	0.05	0.05
Beta particles	0 (millirems/yr)	4 (millirems/yr)	Lead	0	TT
Bromate	0	0.01	<i>Legionella</i>	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

**Exhibit 1-1. NPDWR Contaminants Included in Six-Year Review 2**

Contaminants	MCLG (mg/L) <sup>1</sup>	MCL (mg/L) <sup>1</sup>	Contaminants	MCLG (mg/L) <sup>1</sup>	MCL (mg/L) <sup>1</sup>
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
Coliform	0% <sup>2</sup>	5% <sup>2</sup>	Polychlorinated biphenyls (PCBs)	0	0.0005
Copper	1.3	TT	Radium	0 (pCi/L)	5 (pCi/L)
<i>Cryptosporidium</i>	0	TT	Selenium	0.05	0.05
Cyanide	0.2	0.2	Simazine	0.004	0.004
2,4-D	0.07	0.07	Styrene	0.1	0.1
Dalapon	0.2	0.2	2,3,7,8-TCDD (Dioxin)	0	3.00E-08
Di(2-ethylhexyl)adipate (DEHA)	0.4	0.4	Tetrachloroethylene	0	0.005
Di(2-ethylhexyl)phthalate (DEHP)	0	0.006	Thallium	0.0005	0.002
1,2-Dibromo-3-chloropropane (DBCP)	0	0.0002	Toluene	1	1
1,2-Dichlorobenzene (o-Dichlorobenzene)	0.6	0.6	Total Trihalomethanes (TTHMs)	n/a <sup>4</sup>	0.08
1,4-Dichlorobenzene (p-Dichlorobenzene)	0.075	0.075	Toxaphene	0	0.003
1,2-Dichloroethane (Ethylene dichloride)	0	0.005	2,4,5-TP (Silvex)	0.05	0.05
1,1-Dichloroethylene	0.007	0.007	1,2,4-Trichlorobenzene	0.07	0.07
cis-1,2-Dichloroethylene	0.07	0.07	1,1,1-Trichloroethane	0.2	0.2
trans-1,2-Dichloroethylene	0.1	0.1	1,1,2-Trichloroethane	0.003	0.005
Dichloromethane (Methylene chloride)	0	0.005	Trichloroethylene	0	0.005
1,2-Dichloropropane	0	0.005	Uranium	0 (µg/L)	30 (µg/L)
Dinoseb	0.007	0.007	Vinyl Chloride	0	0.002
Diquat	0.02	0.02	Viruses	0	TT
Endothall	0.1	0.1	Xylenes (total)	10	10
Endrin	0.002	0.002			

1. Units are in milligrams per liter (mg/L) unless otherwise noted. Milligrams per liter are equivalent to parts per million.

2. No more than 5.0% samples total coliform-positive in a month.

3. 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.

4. There is no MCLG for total trihalomethanes. MCLGs for some of the individual contaminants are: bromodichloromethane (zero), bromoform (zero), dibromochloromethane (0.06 mg/L), and chloroform (0.07 mg/L).

**Exhibit 1-2. NPDWR Contaminants with Recent or Ongoing Actions**

Contaminant/Indicator	Recent or Ongoing Action
<b>Disinfection Byproducts</b>	
Bromate	Stage 2 DBPR (January 4, 2006)
Chlorite	Stage 2 DBPR (January 4, 2006)
TTHMs: chloroform, bromodichloromethane, dibromochloromethane, bromoform	Stage 2 DBPR (January 4, 2006)
HAA5: monochloroacetic acid, dichloroacetic acid trichloroacetic acid, monobromoacetic acid dibromoacetic acid	Stage 2 DBPR (January 4, 2006)
<b>Disinfectant Residuals</b>	
Chlorine	GWR (November 8, 2006)
Chloramines	GWR (November 8, 2006)
Chlorine dioxide	Stage 2 DBPR (January 4, 2006)
<b>Inorganics</b>	
Lead	Short-Term Revisions (October 10, 2007) Long-Term Revisions currently underway
Copper	Long-Term Revisions currently underway
<b>Microorganisms</b>	
<i>Cryptosporidium</i>	LT2 (January 5, 2006)
<i>Giardia lamblia</i>	LT2 (January 5, 2006)
<i>Legionella</i>	GWR (November 8, 2006)
Viruses (enteric)	LT2 (January 5, 2006) GWR (November 8, 2006)
Coliform	Total Coliform Rule-making currently underway

Dates of promulgation are as follows:

Stage 2 DBPR: 71 *FR* 388 (January 4, 2006)

LT2 Rule: 71 *FR* 654 (January 5, 2006)

GWR: 71 *FR* 65574 (November 8, 2006)

LCR Short-Term Regulatory Revisions: 72 *FR* 57782 (October 10, 2007)

**1.3 Organization and Contents of this Document**

This document describes the review process for Six-Year Review 2:

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

EPA has developed additional technical support documents, noted in the text, to provide detailed discussion of each element of the review.

## 2 Overview of Six-Year Review Protocol

During Six-Year Review 1, the Agency developed a systematic approach or protocol to review existing NPDWRs (USEPA, 2003c). 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 Six-Year Review 2, EPA assessed this 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 are essentially the same as those implemented during Six-Year Review 1, with some minor refinements to enhance the Agency's effectiveness in applying the protocol to the review of NPDWRs.

The Six-Year Review 2 protocol addresses critical aspects of health protection and the setting of standards under the SDWA. Similar to the Six-Year Review 1, the results of the Six-Year Review 2 protocol are recommendations to revise some NPDWRs, and to take no action at this time for the remaining NPDWRs.

The publication of a recommendation to revise pursuant to a Six-Year Review under Section 1412(b)(9) is not the end of the regulatory process, but is the beginning of one. A recommendation to revise 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 only that EPA does not believe that regulatory changes to a particular NPDWR are appropriate due to: a lack of new health effects, analytical methods, or treatment data; ongoing scientific reviews; 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 Refinements for Six-Year Review 2

During Six-Year Review 2, EPA refined the protocol to implement a more detailed "decision tree" than it used during Six-Year Review 1. The revised protocol can be broken down into a series of questions about whether there is new information for a contaminant that suggests it is possible to revise one or more of the NPDWR elements. These questions can be logically ordered into a decision tree that incorporates the sequential relationships between the different NPDWR elements. 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 new information relevant to the potential to revise the MCLG

before decisions regarding the potential to revise the MCL. Also, 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 MCL branch of the decision tree is not reached, and it is not necessary to make related decisions such as whether the practical quantitation level (PQL) can be revised.

EPA developed an automated tool called the Regulatory Review Support Spreadsheet (R2S2) to track the review process for each contaminant that leads to the revise/take no action recommendations. This tool enhances transparency of the review results. The automation also streamlines the decision process and facilitates the Agency's reporting of its recommendations. **Exhibit 2-1** shows the decision tree structure for the revised protocol.

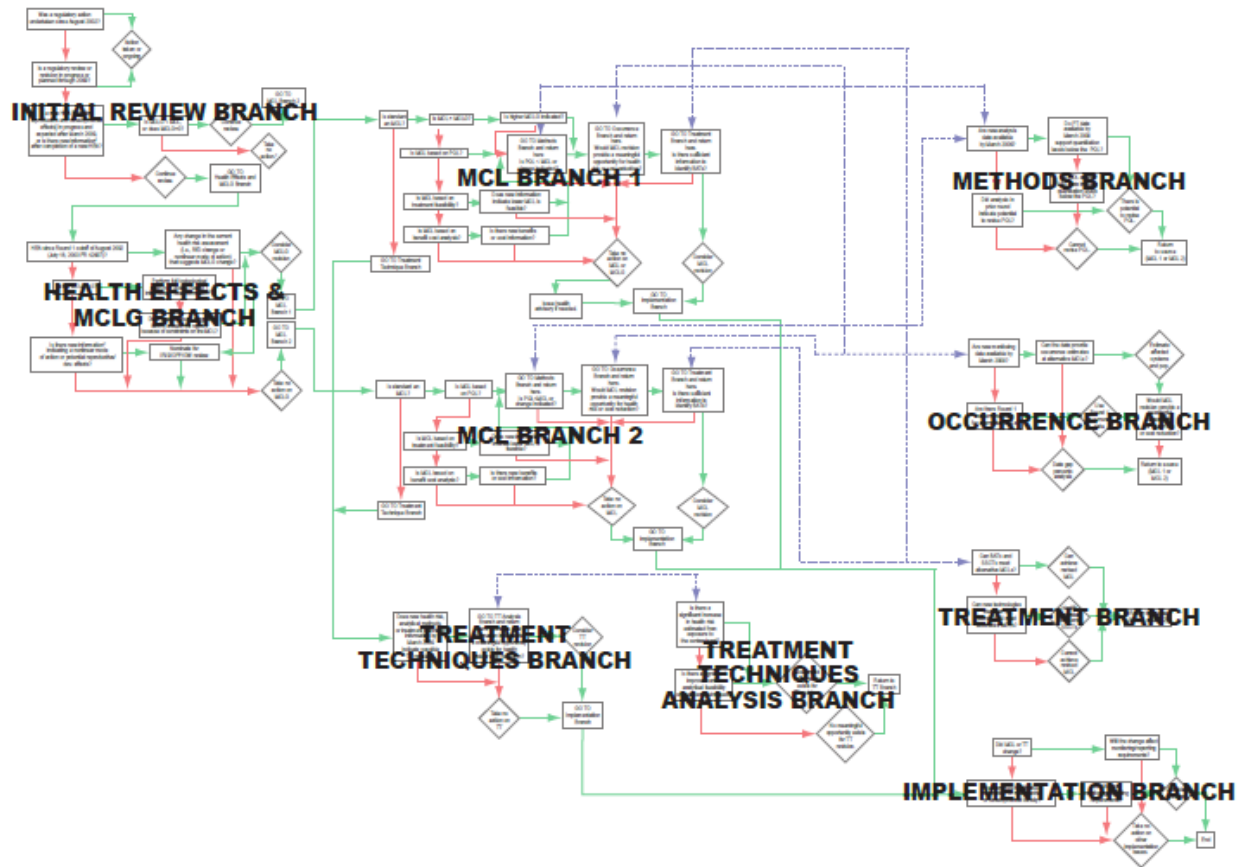
## 2.2 Elements of the Six-Year Review 2 Decision Tree

The Six-Year Review decision tree contains a "branch" with multiple questions for each review topic. Information flows between these branches as shown in Exhibit 2-1. Each branch corresponds to a specific technical review of an NPDWR element that EPA conducted during Six-Year Review 2. These branches include:

- Initial review
- Health effects and MCLG
- MCL
- Treatment technique
- Analytical methods
- Occurrence and exposure
- Treatment feasibility
- Implementation.

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

**Exhibit 2-1. Overview of Six-Year Review Decision Tree**





## 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

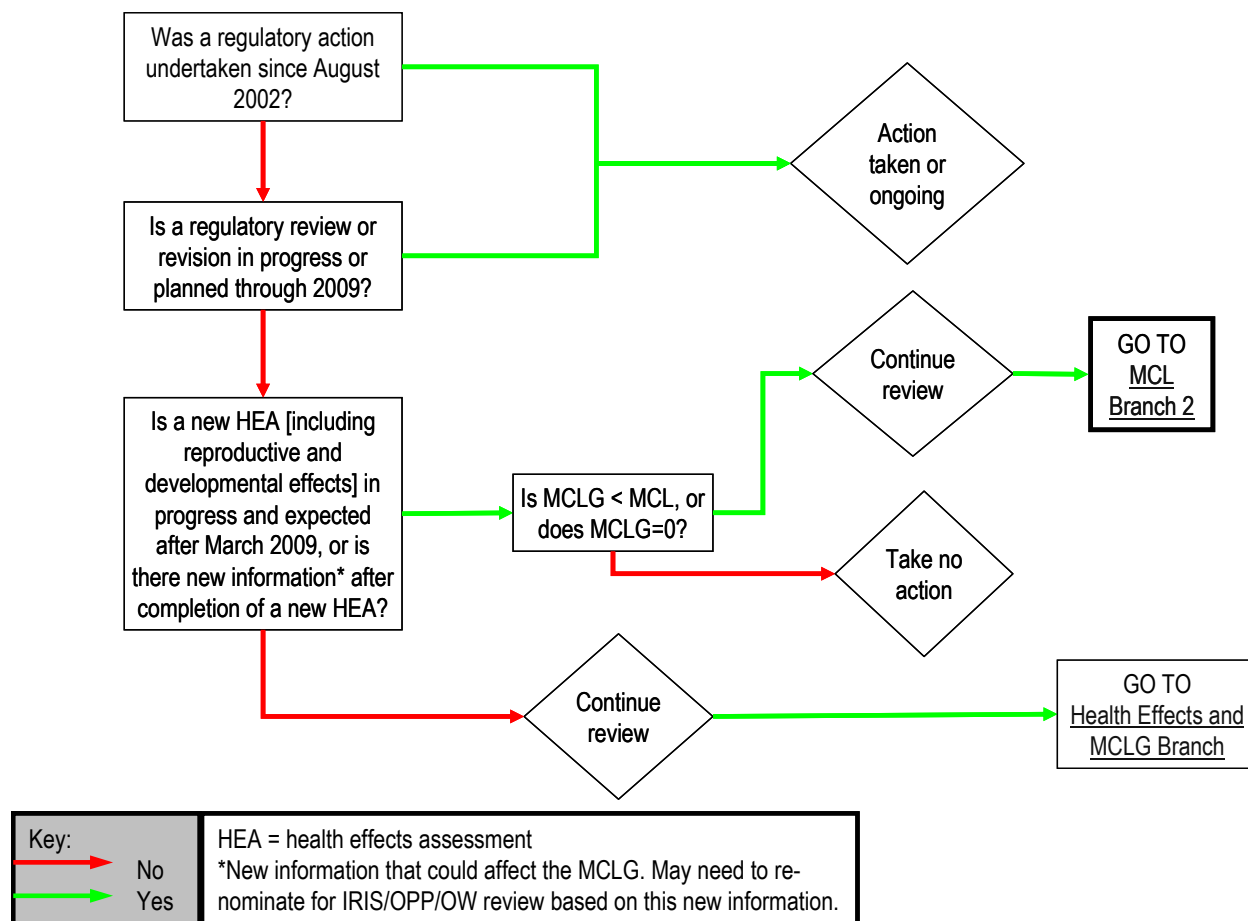
The first branch of the decision tree is an Initial Review Branch (**Exhibit 3-1**), with the purpose of identifying contaminants meeting one of three conditions for which there is a recent or ongoing action or for which further review of detailed technical data is premature. The three conditions are:

- EPA has recently reviewed and revised the NPDWR (i.e., since August 2002)
- EPA is conducting an ongoing regulatory revision
- EPA is performing a formal health effects assessment of the regulated contaminant, the results are due after the cutoff data for the review, or EPA completed a health effects assessment, but then identified new information with potential to affect the MCLG and the MCL is set equal to the MCLG.

Excluding such contaminants from subsequent steps in the NPDWR review decision tree improves the efficiency and effectiveness of the review process. It prevents duplicative Agency data collection and analysis efforts for recent or ongoing actions to review and revise NPDWRs. It also avoids recommendations based on inadequate information for contaminants with ongoing or pending health effects assessments that already have MCLs set equal to their respective MCLGs. For a contaminant that has an ongoing health effects assessment and an MCL above its MCLG, EPA's review continues to branches that evaluate whether there is potential to lower the MCL. The Agency's review of new information that may affect the MCL for these contaminants is one of several refinements of the protocol. During Six-Year Review 1, EPA took no further action on any contaminants with ongoing health effects assessments. The refinement addresses the SDWA requirement that EPA set each MCL as close to the MCLG as feasible; a common limitation is the analytical capability at the time the NPDWR is promulgated, especially for a contaminant with an MCLG equal to zero.

#### 3.1.1 Inputs to the Initial Review

The questions in the Initial Review Branch are screening-level questions. For Six-Year Review 2, EPA answered these questions for each contaminant covered by a NPDWR. The first two questions in the branch require information regarding whether a contaminant is the subject of recent or ongoing rules. For Six-Year Review 2, the regulatory schedule for the Office of Ground Water and Drinking Water (OGWDW) provided the inputs to these two decisions. Exhibit 1-2 lists the contaminants that are subject to recent or ongoing rules.

**Exhibit 3-1. Initial Review Branch**

The third question requires information regarding whether a formal Agency health effects assessment is in progress, and if results will be available by the cutoff date for the review (March 1, 2009). 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 “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. EPA’s Office of Science and Technology (OST) tracks the status of health effects assessments and provides summaries to OGWDW that identify the contaminants with ongoing health effects assessments and their expected completion dates.

For Six-Year Review 2, OST collected health effects information for contaminants that were not part of an ongoing or recent rule. These contaminants were in one of two lists for the purpose of tracking health effects information:

- Contaminants with ongoing formal EPA health effects assessments
- All other regulated drinking water contaminants that reached this decision tree point.

OGWDW established a cutoff date (March 1, 2009) after which it would not be feasible to fully review and evaluate the potential to revise a contaminant's MCLG during Six-Year Review 2.

### **3.1.2 Output of Initial Review**

The outputs of the initial review branch are: (1) a list of regulated contaminants excluded from further review branches during the current cycle<sup>3</sup>, (2) a list of contaminants that proceed to the Health Effects and MCLG branch for questions about the potential to revise the MCLG, and (3) a list of contaminants that proceed to the MCL Branch 2 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:

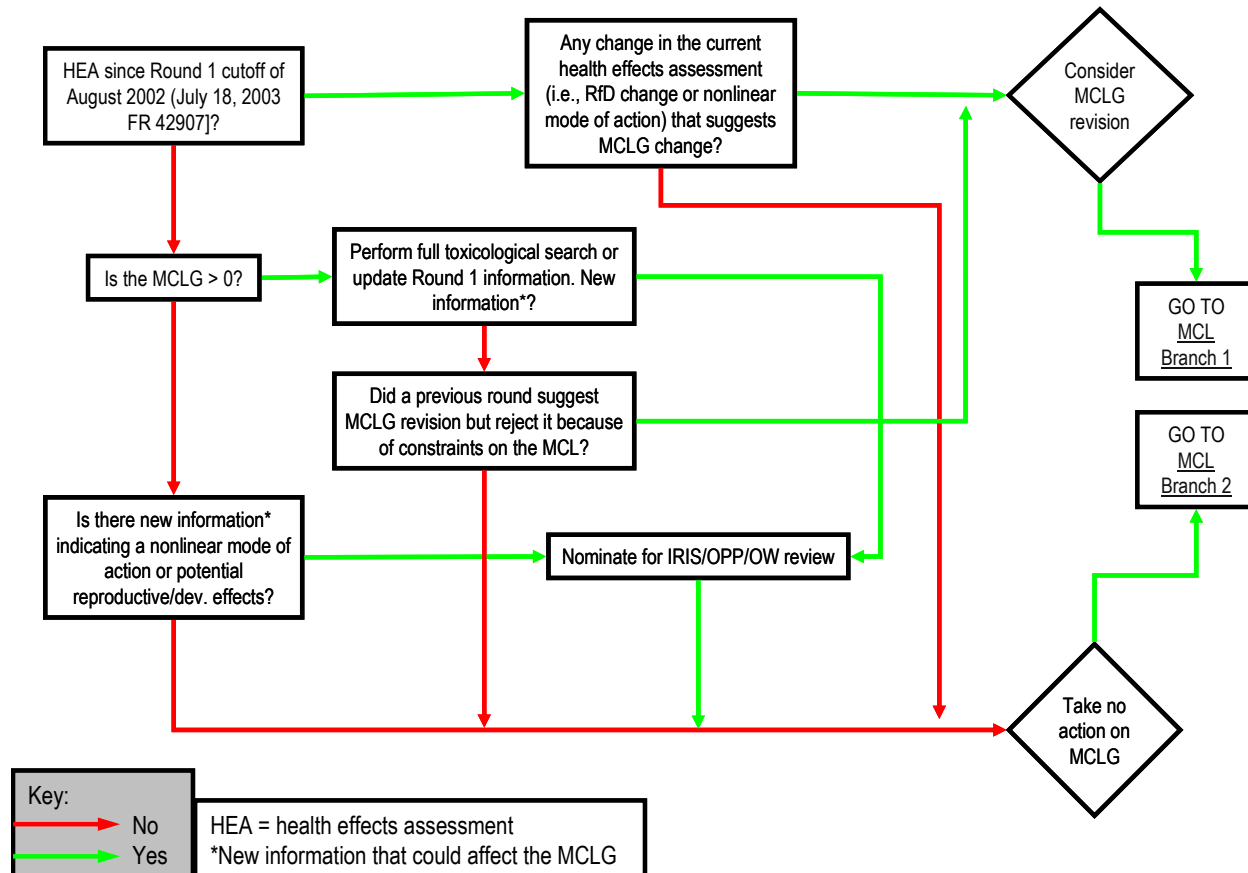
- A revised or new health effects assessment be completed during the current cycle before March 1, 2009
- The assessment results in a change to the RfD or cancer risk.

Another refinement to the protocol for the second cycle 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.

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<sup>3</sup> Contaminants that have a "Take no action" result on the Initial Review may still be affected by a cross-cutting issue affecting multiple contaminants 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 contaminants having a formal health effects and toxicological assessment completed during the current review cycle and by the cutoff date (March 1, 2009). For Six-Year Review 2, OGWDW used the status summaries provided by OST to answer this question.

For contaminants that have a new health effects assessment, this branch asks whether there was a change in toxicological parameters that affect the MCLG. For Six-Year Review 2, OST provided this information in a summary report that indicated:

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

OST obtained RfD and cancer classification information from the formal health effects assessment documents developed by sources such as IRIS, OPP, and OW. OST took the following steps to derive a possible MCLG:

- Classified the contaminant in one of three OW Categories based on cancer risk classifications

- Derived a possible MCLG value (or range of values) using the method associated with each OW Category.

The document, “Six-Year Review 2 – Health Effects Assessment – Summary Report” (USEPA, 2009e) describes how OST assigned the OW Categories to contaminants and derived MCLG values.

The next question in this branch divides contaminants that did not have a recent health effects assessment into two categories for the purpose of a literature search: (1) those with nonzero MCLGs, and (2) those with MCLGs of zero. Subsequent questions address whether literature searches indicate a need for a new formal health effects assessment. For Six-Year Review 2, OST 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) to search for new health effects information that indicates potential that the current RfD values or cancer risk categories are not adequately representing health risks.

OST’s review for each chemical began with the authoritative reviews or assessments by IRIS, OPP, the National Academy of Sciences (NAS), the Agency for Toxic Substances and Disease Registry (ATSDR), the National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), California EPA (CalEPA), World Health Organization (WHO), European Commission Concise International Chemical Assessment Documents (CICADS), International Programme on Chemical Safety/Environmental Health Criteria (IPCS/EHC), International Agency for Research on Cancer (IARC), Health Canada, Joint Expert Committee on Food Additives (JECFA), and Joint FAO/WHO Meeting on Pesticide Residues (JMPR). OST obtained each organization’s most recent assessment available. OST 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 (DART®), Chemical Carcinogenesis Research Information System (CCRIS), and Hazardous Substances Data Bank (HSDB).

For contaminants for which health effects assessments were completed during Six-Year Review 2, OST also conducted supplemental literature searches covering the period from either the two years preceding the publication date of a final IRIS, OPP, or NAS assessment or the three years prior to the publication of an ATSDR Toxicological Profile.

The purpose of the literature search was to identify:

- Whether there was 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
- Whether there was 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.

OST provided OGWDW with summary information from the literature review, including a recommendation about whether new information might lead OW to nominate the contaminant for a formal health effects assessment.

The final 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 Six-Year Review 1, 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
- 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.

During the Six-Year Review 2, EPA revisited these decisions to consider whether new information (e.g., changes in analytical feasibility or new occurrence and exposure analyses) may affect that decision.

### **3.2.2 Outputs from Health Effects and MCLG Review**

The Health Effects and MCLG Branch sorts the contaminants into the following categories based on health effects information:

- Contaminants for which there is potential to revise the MCLG based on the availability of new Agency health effects information, or contaminants for which there was a potential to revise the MCLG during the first Six-Year Review, but for which EPA took no action
- Contaminants 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 OW, IRIS, or OPP
- Contaminants for which there is no potential to revise the MCLG during Six-Year Review 2.

The decision tree directs the first category of contaminants to the MCL branch that reflects potential for MCLG revision (MCL Branch 1). 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).

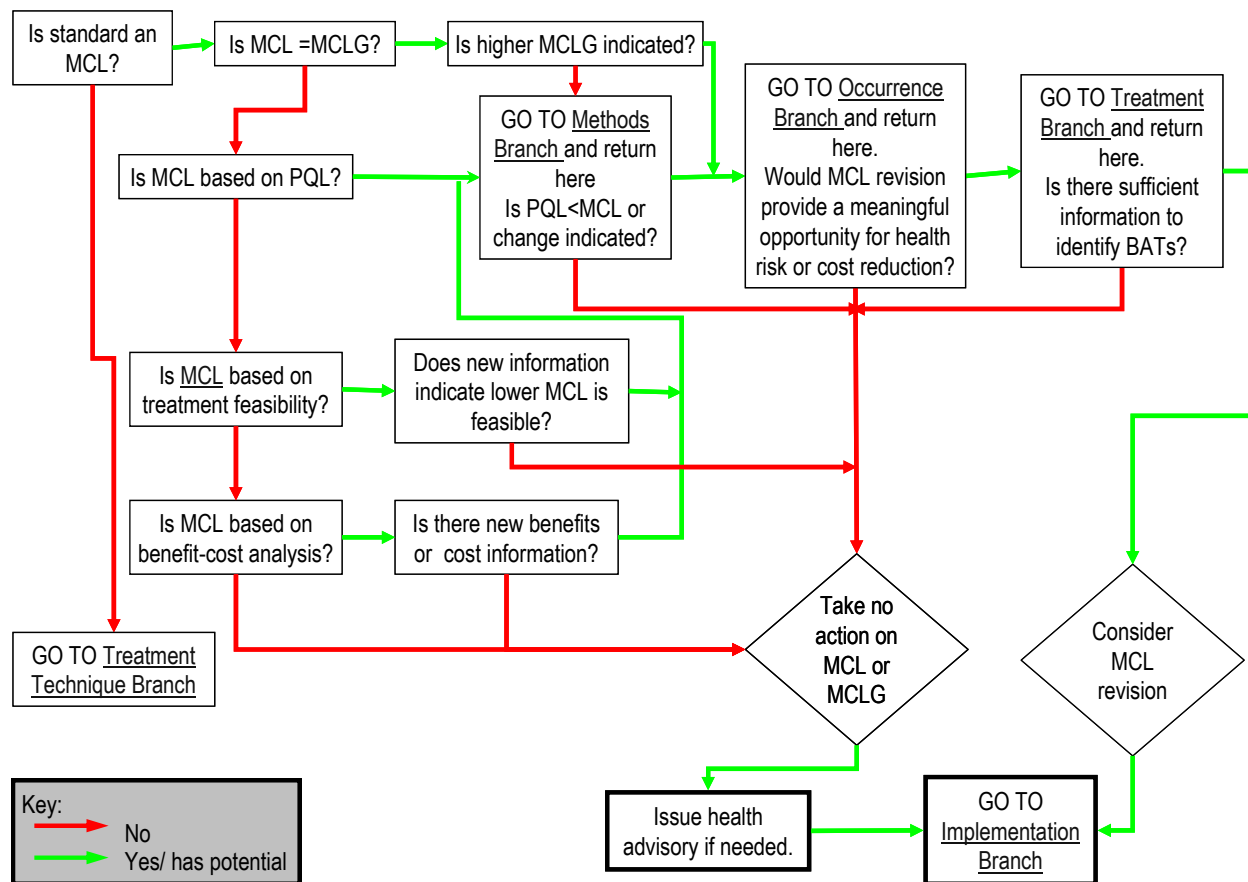
### **3.3 Maximum Contaminant Level (MCL) Branches**

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, as well as 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

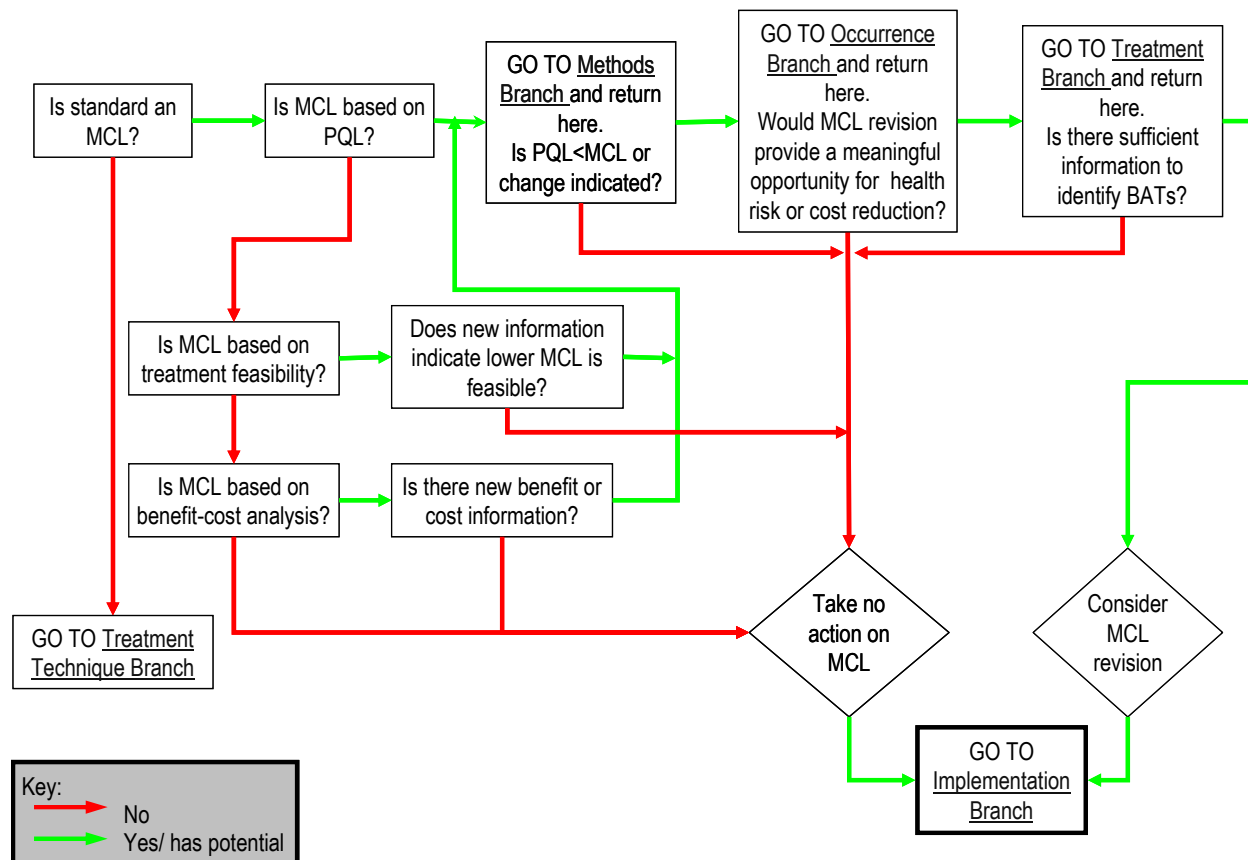
quantitation limit (PQL), which is based on the detection capability that most laboratories can reliably and consistently achieve using approved analytical methods within specified limits of precision and accuracy. Thus, the PQL is the most common limiting factor with respect to feasibility. Consequently, the MCL branches address analytical feasibility before treatment feasibility.

The decision tree includes two MCL Branches: one for contaminants with a possible MCLG revision (MCL Branch 1; **Exhibit 3-3**), and the other for contaminants with no action regarding the MCLG (MCL Branch 2; **Exhibit 3-4**).

**Exhibit 3-3. Maximum Contaminant Level Branch 1 (Potential for MCLG Revision)**



### Exhibit 3-4. Maximum Contaminant Level Branch 2 (No Potential for MCLG Revision)



#### 3.3.1 Inputs to Maximum Contaminant Level (MCL) 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 following:

- Whether the standard is an MCL or a TT
- Whether a higher or lower MCLG is indicated, if applicable
- The basis for the current MCL.

For Six-Year Review 2, OGWDW used the NPDWRs and supporting rule documents to answer the first and third questions. OGWDW used health effects information provided by OST to determine whether there is potential for a higher or lower MCLG.



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 OGWDW'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.

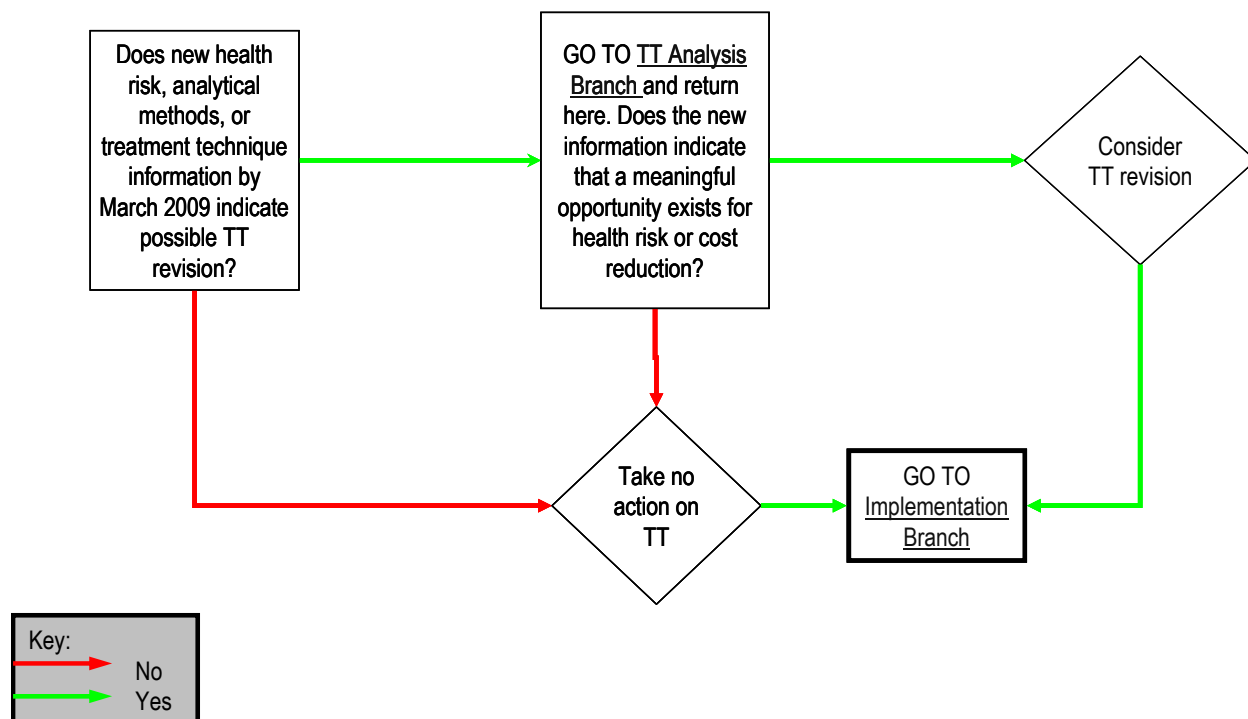
### 3.3.2 Outputs from Maximum Contaminant Level (MCL) Review

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. After completing an MCL branch, the decision tree directs the review to the Implementation Branch.

## 3.4 Treatment Technique Branch

When a contaminant has a TT standard instead of an MCL, the protocol uses the Treatment Technique Branch of the decision tree (**Exhibit 3-5**), instead of either of the MCL Branches. The purpose of the Treatment Technique Branch is to identify whether there is potential to revise a TT standard.

**Exhibit 3-5. 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 contaminants have a TT in lieu of an MCL: acrylamide, copper, *Cryptosporidium*, epichlorohydrin, *Giardia lamblia*, lead, *Legionella*, and viruses. Of these contaminants, all except acrylamide and epichlorohydrin were affected by recent or ongoing rule revisions during Six-Year Review 2. USEPA (2009f) describes the information that the Agency obtained during its review of the TT for acrylamide and epichlorohydrin.

### 3.4.2 Outputs from Treatment Technique Review

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

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

The decision tree then directs the review to the Implementation branch.

## 3.5 Treatment Technique Analysis Branch

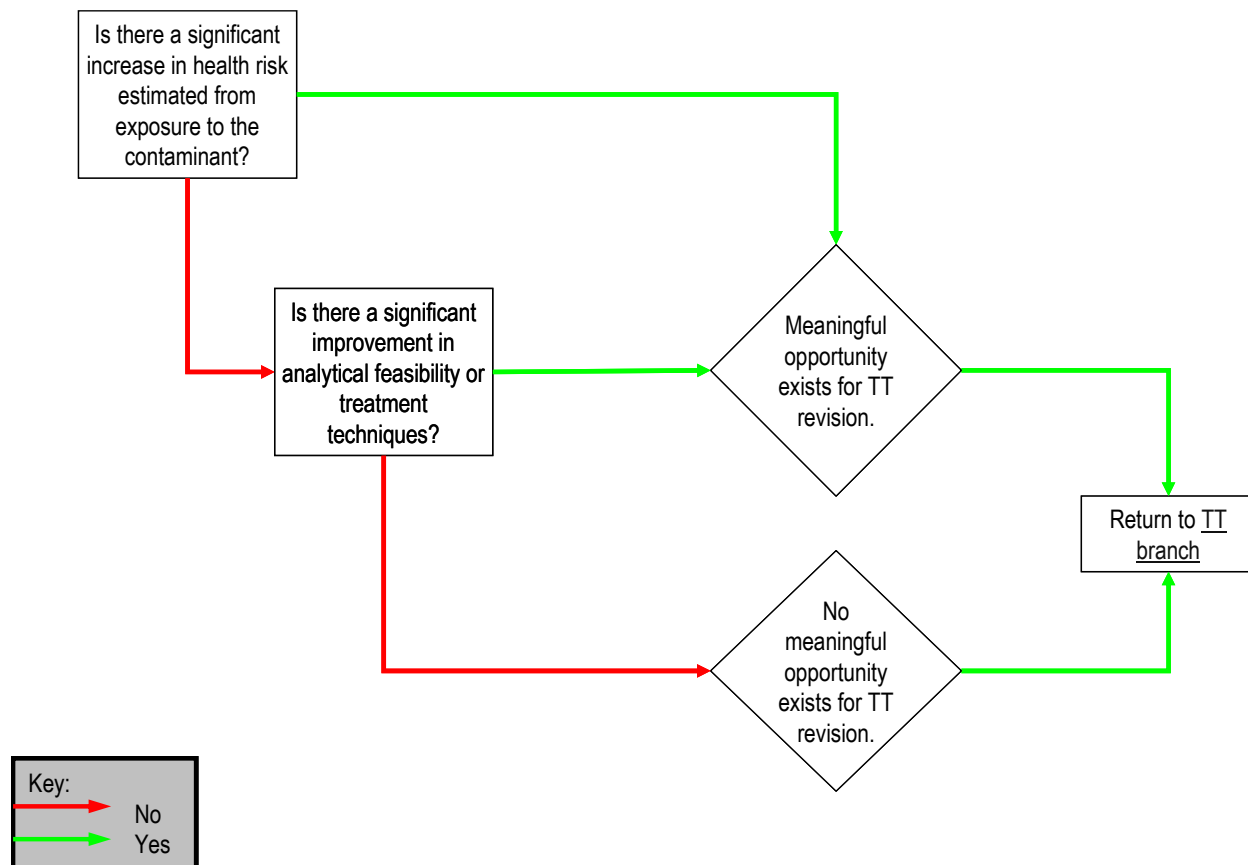
The purpose of the Treatment Technique Analysis Branch (**Exhibit 3-6**) is to determine whether the new information that could affect the TT standard has the potential to constitute a meaningful opportunity to revise the TT standard.

### 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?
- Is there a significant improvement in analytical feasibility or treatment technique?

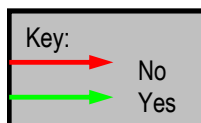
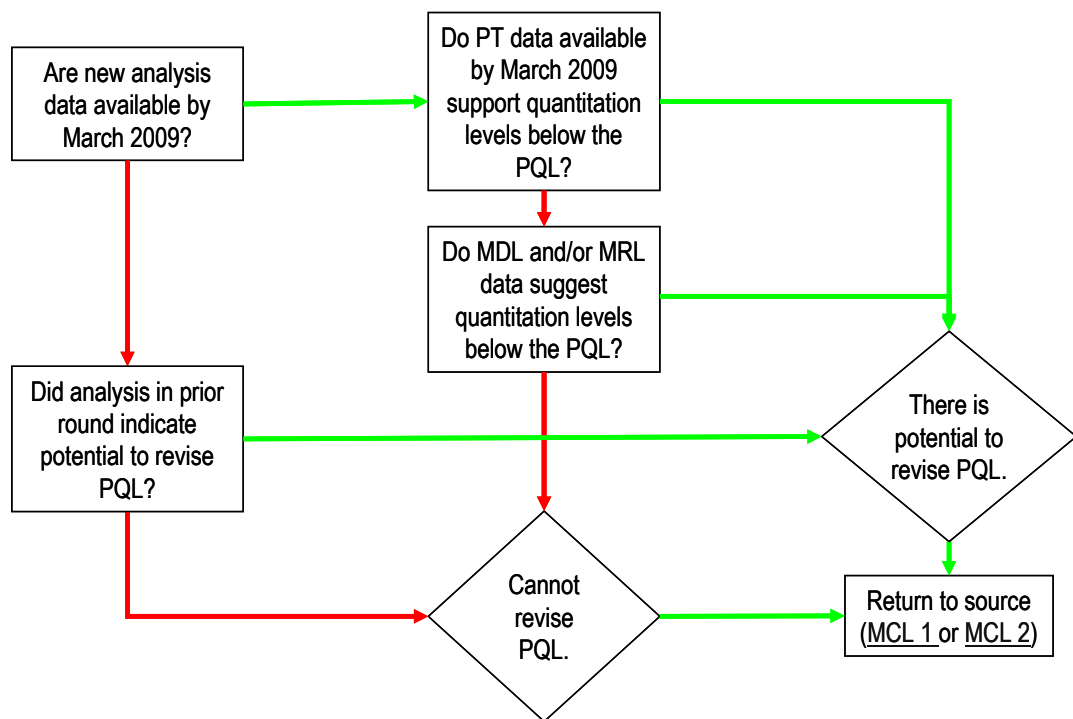
The first question identifies whether new health effects information indicates health risks that are significantly different from those considered at the time EPA promulgated the NPDWR. The second question addresses whether there are significant changes in analytical feasibility constraints that might 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 3-6. Treatment Technique Analysis Branch****3.5.2 Outputs from Treatment Technique Analysis Review**

The Treatment Technique Analysis Branch identifies contaminants for which new information has the potential to constitute 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 3-7**) 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% of laboratories can measure concentration within the promulgated acceptance criteria.

**Exhibit 3-7. Analytical Methods Branch**

The branch considers two categories of contaminants:

- Contaminants for which the MCL is limited by analytical feasibility (i.e., the MCL is set at the PQL), and the MCLG is still appropriate.
- 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, Six-Year Review 2 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 SDWA analytes: (1) Performance Evaluation (PE) data from Water Supply (WS) 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 [50 *FR* 46880 (November 13, 1985); 52 *FR* 25690 (July 8, 1987); 54 *FR* 22062 (May 22, 1989)]. Using PE data to derive the PQL for chemical NPDWRs involves determining the concentration of an analyte at which 75% of EPA Regional and State laboratories achieve results within a specified acceptance window [see 54 *FR* 22062 (May 22, 1989)].

### 3.6.1 Inputs to Methods Review

The Methods Branch includes the following questions:

- Are new data available by the cutoff date (March 1, 2009) that EPA selected for Six-Year Review 2?
- Do the new analytical methods data indicate potential to revise the PQL?
- Do other new data such as method detection limit (MDL) and/or minimum reporting level (MRL) information indicate potential to revise the PQL?
- Do previous data or analyses (i.e., Six-Year Review 1) indicate potential to revise the PQL?

The document, “Analytical Feasibility Support Document for the Second Six-Year Review of Existing National Primary Drinking Water Regulations” (USEPA, 2009b), describes the process EPA used to evaluate the potential to revise PQL values and provides the results for each contaminant. The protocol developed for Six-Year Review 1 primarily utilized PE data from WS studies. These were laboratory accreditation studies conducted under EPA oversight until 1999, when the program was privatized. Now, the National Environmental Laboratory Accreditation Conference (NELAC) conducts the accreditation program via Proficiency Testing (PT) studies. EPA could not obtain actual PT study data from NELAC or any PT providers. One PT provider, however, made pass/fail rates from its PT studies available to EPA. This provider accounts for approximately 50% of the PT results nationwide (USEPA, 2009b). Because current PE data or comparable PT data were not available for this review, EPA modified the review process.

The PQL reassessments for Six-Year Review 2 use a variety of data. The primary data sources are:

- PE data available through late 1999, for which EPA derived passing rates during Six-Year Review 1
- Laboratory passing rates based PT data (i.e., the percent of laboratories passing a proficiency test for a given study) from late 1999 through 2004 for a single PT provider.

EPA relied primarily on the PT passing rate results at and below the current PQL to indicate potential for PQL revision. Passing rates for the older PE data provided supplemental information, especially when there were no PT studies with true values below the current PQL. 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% for PT studies with true values below the PQL in the “PQL reassessment supports reduction of the current PQL” category. USEPA (2009b) provides a complete summary of the data and results by contaminant.

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 minimum reporting levels in the Information Collection Request (ICR) database (USEPA, 2009c). 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, 2009c). EPA received voluntary submissions of compliance monitoring data for public water systems from 51 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). EPA evaluated the distribution of MRL values for each contaminant 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 potential to change 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 Six-Year Review 1 (USEPA, 2003a). USEPA (2009b) provides the MDLs reviewed during Six-Year Review 2. 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 is a meaningful opportunity for health risk reduction. The report “Development of Estimated Quantitation Levels for the Second Six-Year Review of National Primary Drinking Water Regulations”(USEPA, 2009c) describes the method that EPA used to develop EQLs. 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 Six-Year Review 2.

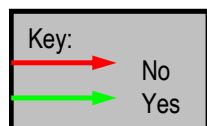
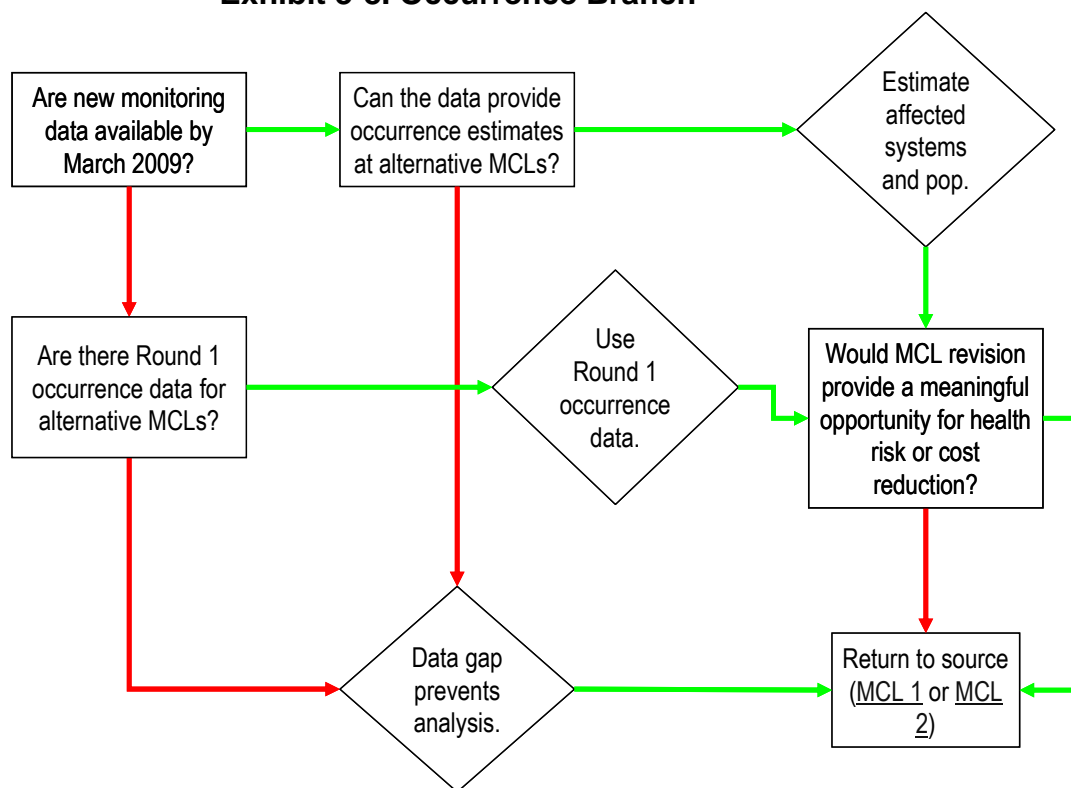
### **3.6.2 Output from Methods Review**

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 3-8**) is to determine whether the potential to revise an MCL presents a meaningful opportunity to:

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

**Exhibit 3-8. Occurrence Branch**

EPA's goal in evaluating contaminant occurrence is to:

- Estimate the number of public water systems (PWSs) in which contaminants occur at levels of interest based on health effects or analytical methods information
- Evaluate 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.

### 3.7.1 Inputs to Occurrence Review

The initial questions elicit information regarding the availability of monitoring data for estimating occurrence at alternate thresholds (e.g., MCLs and EQLs). For Six-Year Review 2, the responses to these questions reflected new data that OGWDW received. EPA issued an ICR as a one-time request for States to submit historical monitoring data (covering the years 1998 through 2005) for regulated contaminants voluntarily to EPA. A total of 51 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. USEPA (2009a) provides a detailed description of the extensive data

management efforts, quality assurance evaluations, and communications with State data management staff.

The ICR contaminant occurrence dataset comprises more than 17 million analytical records from approximately 136,000 PWSs in 45 States. Approximately 265 million people are served by these PWSs nationally. The number of States and PWSs represented in the dataset varies across contaminants because of variability in voluntary State data submissions and contaminant monitoring schedules. This is the largest, most comprehensive set of drinking water compliance monitoring data ever compiled and analyzed by EPA.

EPA used a two-stage analytical approach to analyze these data and characterize the national occurrence of contaminants. The “stage 1” analysis is a simple, non-parametric count of occurrence or regulated contaminants in public water systems. A typical stage 1 analysis generates a count of the number (or percentage) of systems with at least one analytical detection of a specific contaminant, or with at least one analytical detection with a concentration greater than a concentration threshold of interest, i.e., a possible MCLG or EQL. This approach provides information on peak occurrence levels, which are relevant for contaminants with acute health effects. It generates conservative (i.e., potentially upwardly biased) occurrence estimates, however, for contaminants with chronic health effects.

For the contaminants with chronic health effects, EPA developed “stage 2” analysis estimates by generating estimated long-term mean concentrations at each system in the ICR dataset. A complete description of the two-stage analytical approach and a detailed presentation of occurrence estimates are in USEPA (2009a). EPA calculated the system means for the stage 2 analysis using a simple arithmetic average of all detection and non-detection data for each public water system. Because the contaminant concentrations associated with the non-detection data are unknown, EPA assigned three different values to the non-detect results to estimate a range of system-level means, which then allowed EPA to estimate the number and percent of systems with estimated means exceeding selected threshold values. Two of the three values are based on the MRL values that accompany the non-detect results in the ICR dataset. The MRL is the lowest level that can be reliably achieved within specified limits of precision and accuracy under routine laboratory operating conditions using a given method. The three values that EPA substituted for non-detect results were MRL, one-half of the MRL, and zero.

The most conservative approach was to assume that all non-detect results were equal to the MRL. This approach yields an upper-bound estimate of each system’s level of exposure. EPA also explored the less conservative assumption that concentrations for the non-detected results were uniformly distributed between the MRL and zero, thereby substituting one-half of the MRL for all non-detected results. Finally, EPA considered the assumption that the actual concentration for each non-detected result was typically much smaller than the MRL, supporting the use of zero to represent each non-detect. This method yielded a lower-bound estimate of the system’s mean and also reflects the approach that may be used to calculate annual averages for compliance. This simplified review method differs from the stage 2 approach in the Six-Year Review 1, which used more sophisticated modeling methods to address the non-detected results. That analysis, however, was based on a substantially smaller dataset (i.e., data from 16 States instead of 45 States). EPA used the three non-detection replacement assumptions in the stage 2



analyses to obtain reasonable bounds on the actual system mean concentrations. After EPA calculated system means for each of the three substitution methods, it compared the results to the various thresholds of interest to estimate the number and percent of systems with a mean concentration above a health threshold of concern and corresponding populations.

Another refinement for Six-Year Review 2 was to include 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 stage 1 and stage 2 occurrence analysis results are not adequate to evaluate the cost savings potential for contaminants with the potential for higher MCLG values. Therefore, for Six-Year Review 2, OGWDW also evaluated source water quality information for these contaminants. This information came from two national data sources: the National Water Quality Assessment (NAWQA) program conducted by the U.S. Geological Survey (USGS), and EPA's STORET (short for STOrage and RETrieval) data system, which are part of OGWDW's National Contaminant Occurrence Database (NCOD). The document, "Occurrence Analysis for Data in Potential Source Waters for the Second Six-Year Review of NPDWRs" (USEPA 2009d), provides additional details on this review.

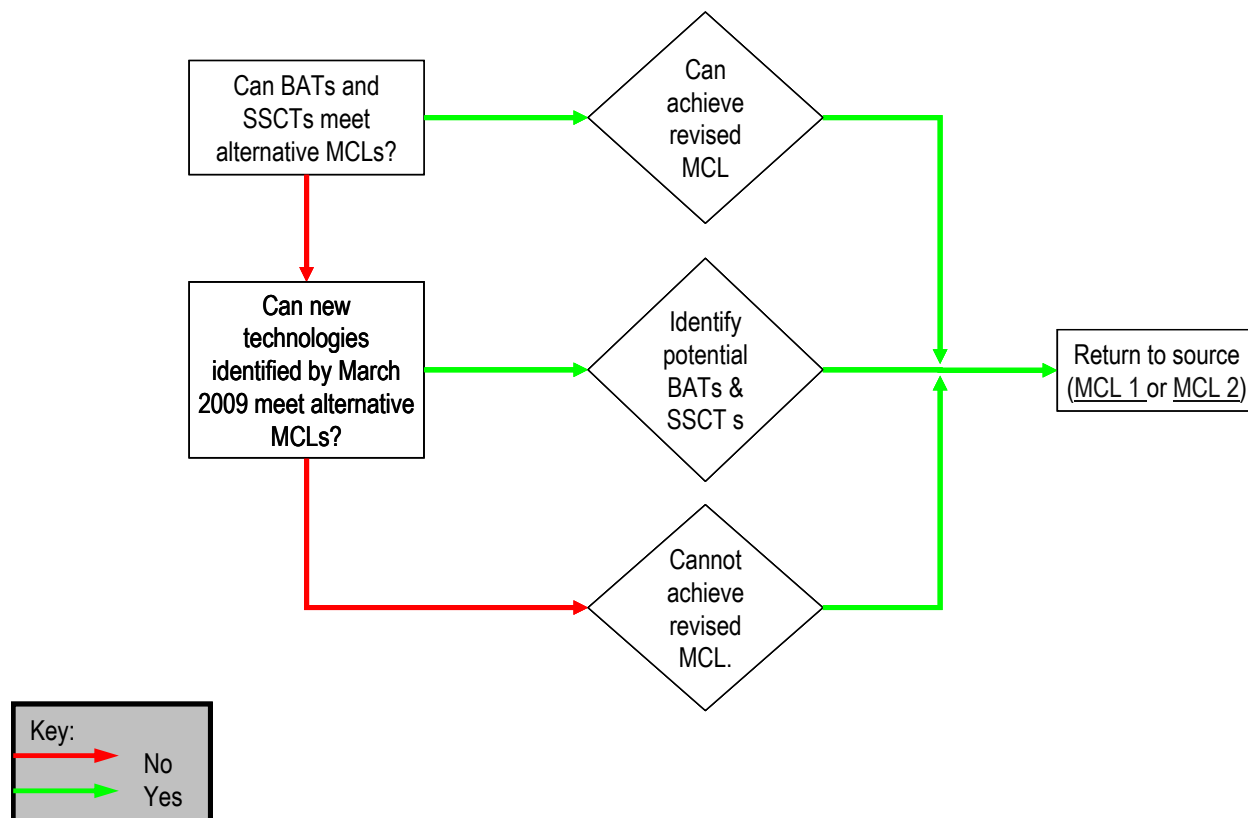
Regardless of the occurrence data source and analysis method, EPA must determine whether the extent of occurrence represents a meaningful opportunity to reduce health risks or costs. There is no single quantitative threshold that applies to all contaminants. The EPA Administrator has the discretion to determine which revisions are appropriate, and may consider a variety of factors including but not limited to the type of health effects for the general population and sensitive populations and lifestages 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 Review 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 Review Branch (**Exhibit 3-9**) 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 3-9. Treatment Branch****3.8.1 Inputs to Treatment Technology Review**

The Treatment Technology 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 (March 1, 2009) meet alternative MCLs?

For Six-Year Review 2, 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, OGWDW conducted a review of treatment performance studies for all technologies that are applicable for the contaminant in question. OGWDW 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. OGWDW 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. The document, “Water Treatment Technology Feasibility Support Document for Chemical Contaminants for the Second Six-Year Review of National Primary Drinking Water Regulations” (USEPA, 2009f), provides additional data and analysis details.

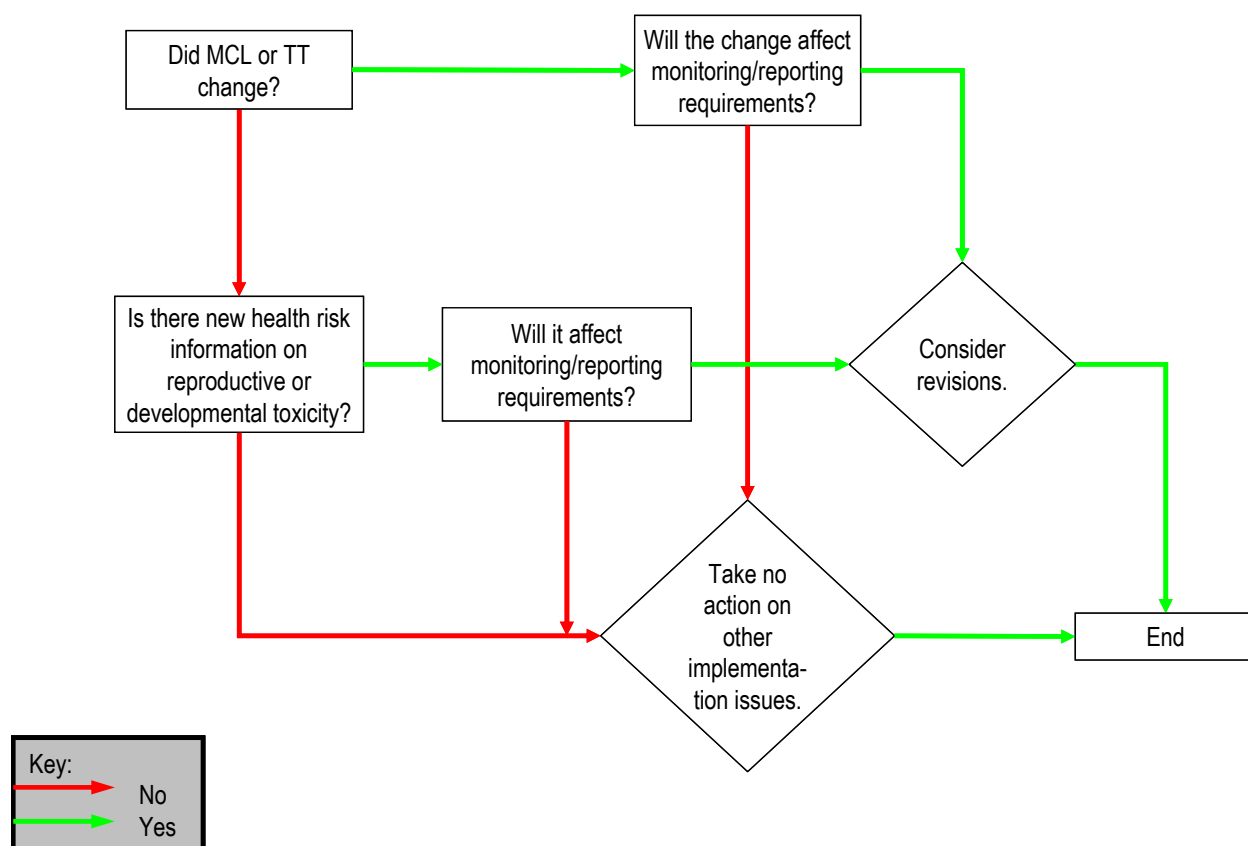
### 3.8.2 Output of Treatment Technology Review

The output of the Treatment Technology 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 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 requirements for a contaminant and new health risk information may also warrant revisions.

**Exhibit 3-10. Implementation Branch**



#### 3.9.1 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 requirements for a particular contaminant. For Six-Year Review 2, EPA focused this review on issues that were not already being addressed through alternative mechanisms, such as a part of 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. The report “Consideration of Other Regulatory Revisions in Support of the Second Six-Year Review of the National Primary Drinking Water Regulations” (USEPA, 2009g) provides a description of the stakeholder process that EPA used to identify inputs for the implementation review.

### **3.9.2 Outputs from Implementation Review**

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

## 4 References

- USEPA. 2000. Science Policy Council Handbook: Peer Review, 2nd Edition. EPA Report 100-B-00-001. Washington, DC: Office of Science Policy, Office of Research and Development. December 2000. Available on the Internet at: <http://www.epa.gov/OSA/spc/pdfs/prhandbk.pdf>.
- USEPA. 2003a. Analytical Feasibility Support Document for the Six-Year Review of Existing National Primary Drinking Water Regulations (Reassessment of Feasibility for Chemical Contaminants). EPA 815-R-03-003. March 2003.
- USEPA. 2003b. Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Review of Existing National Primary Drinking Water Regulations. EPA 815-R-03-006. June 2003.
- USEPA. 2003c. EPA Protocol for Review of Existing National Primary Drinking Water Regulations. EPA Report 815-R-03-002. Washington, DC: Office of Ground Water and Drinking Water. June 2003. Available on the Internet at: [http://www.epa.gov/safewater/standard/review/pdfs/support\\_6yr\\_protocal\\_final.pdf](http://www.epa.gov/safewater/standard/review/pdfs/support_6yr_protocal_final.pdf).
- USEPA. 2009a. Analysis of Occurrence Data from the Second Six-Year Review of Existing National Primary Drinking Water Regulations. EPA 815-B-09-006.
- USEPA. 2009b. Analytical Feasibility Support Document for the Second Six-Year Review of Existing National Primary Drinking Water Regulations. EPA 815-B-09-003.
- USEPA. 2009c. Development of Estimated Quantitation Levels for the Second Six-Year Review of National Primary Drinking Water Regulations. EPA 815-B-09-005.
- USEPA. 2009d. Occurrence Analysis for Potential Source Waters for the Second Six-Year Review of National Primary Drinking Water Regulations. EPA 815-B-09-004.
- USEPA. 2009e. Six-Year Review 2 – Health Effects Assessment – Summary Report. EPA 822-R-09-006.
- USEPA. 2009f. Water Treatment Technology Feasibility Support Document for Chemical Contaminants for the Second Six-Year Review of National Primary Drinking Water Regulations. EPA 815-B-09-007.
- USEPA. 2009g. Consideration of Other Regulatory Revisions in Support of the Second Six-Year Review of the National Primary Drinking Water Regulations. EPA 815-B-09-008.