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

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

March 2002

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Office of Water
Office of Ground Water and Drinking Water
Standards and Risk Management Division
Targeting and Analysis Branch
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This report is issued in support of the preliminary revise/not revise decisions for the Six-Year Review Notice of Intent. It is intended for public comment and does not represent final agency policy. EPA expects to issue a final version of this report with the publication of the final notice in 2002, reflecting corrections due to public comment on the preliminary notice and the supporting documents.

Acknowledgments

This document was prepared in support of the 1996-2002 Six-Year Review of Existing National Primary Drinking Water Regulations (NPDWRs) for EPA's Office of Ground Water and Drinking Water with James Taft as Targeting and Analysis Branch Chief. Judy Lebowich served as EPA co-team lead for the Six-Year Review and as the Work Assignment Manager for the development of this document. At different times throughout the process, Marc Parrotta and Wynne Miller have also served as co-team leads for the project. The Six-Year Review Work Group consists of representatives of the Office of Ground Water and Drinking Water, the Office of Science and Technology, the Office of General Counsel, the Office of Pesticide Programs, the Office of Research and Development, the Office of Policy, Economics and Innovation, the Office of Solid Waste and Emergency Response, and EPA Regions I, V, VII, IX, and X. Work Group members provided technical guidance throughout. The National Drinking Water Advisory Council (NDWAC) and many stakeholders provided valuable advice to improve the review process and this document. The Cadmus Group, Inc., served as the prime contractor for developing this document.

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ACRONYMS

ASTM	American Society for Testing and Materials
ATP	Alternate test procedure
ASDWA	Association of State Drinking Water Administrators
ATSDR	Agency for Toxic Substances and Disease Registry
AWWA	American Water Works Association
BAT	Best Available Technology
CFR	Code of Federal Register
CMR	Chemical Monitoring Reform
EPA	U.S. Environmental Protection Agency
FACA	Federal Advisory Committees Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	*Federal Register*
IRIS	Integrated Risk Information System
LOAEL	Lowest-Observed-Adverse-Effect Level
MCL	Maximum contaminant level
MCLG	Maximum contaminant level goal
MDL	Method detection limit
mL	milliliter
MOE	Margin of Exposure
NAS	National Academy of Sciences
NDWAC	National Drinking Water Advisory Council
NERL	National Exposure Research Laboratory
NIST	National Institute of Standards and Technology
NOAEL	No-Observed-Adverse-Effect Level

ACRONYMS

NPDWR	National Primary Drinking Water Regulation
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
OW	Office of Water
PAD	Population Adjusted Dose (aPAD – acute; cPAD – chronic)
PE	Performance evaluation
PQL	Practical quantitation level
PT	Proficiency Testing
PWS	Public water system
RfD	Reference dose (aRfD – acute RfD; cRfD -- chronic RfD)
RSC	Relative source contribution
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
SM	Standard Methods
TCR	Total Coliform Rule
TT	Treatment technique
USGS	United States Geological Survey
WS	Water Supply

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

EXECUTIVE SUMMARY

The Safe Drinking Water Act (SDWA), as amended in 1996, requires that the U.S. Environmental Protection Agency (EPA) review existing National Primary Drinking Water Regulations (NPDWRs) no less often than every six years and, if appropriate, revise them. This document describes the systematic approach that EPA used to review 68 chemical NPDWRs and the Total Coliform Rule (TCR) which were promulgated prior to the 1996 Amendments. This review is scheduled to be completed by August 2002. EPA developed this document based on recommendations of the National Drinking Water Advisory Council (NDWAC), through internal Agency deliberations, and discussions with the diverse stakeholders involved in drinking water and its protection.

As long as an NPDWR revision maintains or provides for the same or greater protection of public health, the SDWA 1996 Amendments give the Administrator discretion to determine if revision is appropriate. In order to determine that a revision is appropriate, EPA believes the revision must continue to meet the basic statutory requirements of the SDWA and present significant opportunities to improve the level of public health protection; and/or to achieve cost-savings while maintaining, or improving, the level of public health protection.

EPA applied the following basic principles to the review process:

- Health effects, analytical feasibility, treatment data, and analyses underlying existing regulations remain adequate and relevant, except in those instances where reliable, peer-reviewed, new data were available that indicated a need to re-evaluate an NPDWR (e.g., where a change in health risk assessment has occurred).

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

- EPA was unable to complete evaluation of certain new data within the time available for the review. For example, if a new health risk assessment for a contaminant was not completed during the review cycle, EPA generally made a "not revise" decision on the rationale that it was not appropriate to revise the regulation while the assessment was ongoing. When an updated assessment is completed, EPA will review the update and any new conclusions or additional information associated with the contaminant during the next review cycle. The Agency may make a determination to revise a particular NPDWR before August 2008 where justified by new public health risk information.

- During the review, EPA identified areas where information was inadequate or unavailable ("data gaps") and is needed before an NPDWR may be considered as a candidate for revision. Where EPA has been unable to fill such gaps during the review process, the Agency has provided information about the data gaps to the appropriate Agency group(s) for consideration and prioritization so that further research and data collection can be considered as part of a subsequent review.

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

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

To most efficiently utilize limited resources and assure continued public health protection, the Agency conducted the review in two phases: (1) an initial technical review of all 69 NPDWRs (see Appendix A for a list); and (2) an in-depth technical evaluation of those NPDWRs identified during the initial review as potential candidates for revision. The key elements of the review included: health effects, technology assessment (i.e., analytical measurement feasibility and treatment feasibility), and consideration of other regulatory requirements (e.g., monitoring). If the Agency identified a potential health or technological basis for a revision during the initial screening, EPA also conducted occurrence and exposure analyses and evaluated available economic information as a part of the in-depth review.

After completing these comprehensive analyses, EPA identified those NPDWRs that remain appropriate at this time, and those NPDWRs that may be appropriate for revision. The Agency will publish its preliminary determinations in the *Federal Register* and will seek public comment on them. After considering the public comments received and any new peer-reviewed data that may become available to the Agency, EPA will publish its final decision in the *Federal Register.*

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

SECTION I: INTRODUCTION

A. What Is the Purpose of the Six-Year Review?

Under the Safe Drinking Water Act (SDWA), the U.S. Environmental Protection Agency (EPA) must periodically review existing National Primary Drinking Water Regulations (NPDWRs) and, if appropriate, revise them. This requirement is contained in Section 1412(b)(9) of SDWA, as amended in 1996, which reads:

> *The Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this title. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.*

Prior to the 1996 Amendments, the SDWA required EPA to review NPDWRs at least every three years to determine whether any changes in technology, treatment techniques (TTs) or other means might provide better health protection. EPA was required to publish its findings in the *Federal Register* and provide an explanation, after opportunity for public comment, of any finding that such new technology, TT, or other means would not be feasible. Although the Agency did revise existing NPDWRs on occasion when new data became available, EPA did not have a systematic process for reviewing NPDWRs on a regular basis.

B. What Is the Purpose of This Protocol Document?

This protocol defines the systematic process EPA used to review most of the NPDWRs[1] promulgated prior to the 1996 Amendments during the 1996-2002 review cycle. Although this document is specific to the initial review under the 1996 SDWA Amendments, the Agency plans to adopt a similar approach, modified as appropriate and with stakeholder involvement, for subsequent review cycles.

EPA presented its initial ideas for the regulatory review protocol at a stakeholder meeting in November 1999. Based on the comments made at that meeting, EPA revised the draft

[1] Several NPDWRs promulgated prior to 1997 have been the subject of recent rulemaking or are the subject of ongoing rulemaking activity. The review of these NP DWRs has been incorporated into those rulemaking activities. Appendix A identifies each of the pre-1997 NP DWRs and indicates whether it is being reviewed in accordance with this protocol or whether it has been or will be reviewed as a part of a separate rulemaking activity.

protocol. Among other changes, the revised draft clarified the role of research in the process and expanded the discussion of the potential need to review/revise an NPDWR. The Agency provided its revised draft to a National Drinking Water Advisory Council (NDWAC) Working Group[2] that met during the Summer of 2000 to develop recommendations regarding the protocol process. The NDWAC Working Group submitted their recommendations to the full NDWAC in November 2000, which approved the recommended guidance and presented it to the Agency (NDWAC, 2000). EPA incorporated the majority of the NDWAC's recommendations into this document. In a few cases, however, EPA either decided not to incorporate a NDWAC recommendation, or to revise it, because of practical considerations and/or resource constraints. Appendix B contains a summary of those NDWAC recommendations that were not incorporated or that were substantially revised.

The systematic planning process used to develop this protocol satisfies the Agency's quality assurance requirements (USEPA, 2002c). The process described in this protocol addresses critical aspects of health protection and the setting of standards under the SDWA. In addition, this protocol allows for the fact that numerous types of regulatory changes may be considered and therefore, contains an element of flexibility to allow EPA the opportunity to consider a range of possible issues. The review process described in this protocol document culminates with decisions of whether or not to revise each of the reviewed NPDWRs.

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

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

C. What Information Will I Find In This Document?

This protocol is divided into three remaining sections as follows:

- **Section II: Overview of The Six-Year Review Process** provides a summary of the review process. It discusses how potential candidates for regulatory revision were identified; how this list was refined to develop a final list of NPDWRs nominated for revision; and the potential types of regulatory decisions that EPA considered.

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[2] The NDWAC Working Group and the full NDWAC operate in accordance with the provisions of the Federal Advisory Committees Act (FACA). All meetings are announced in the *Federal Register* and members of the public are welcome to attend as observers.

- **Section III: Detailed Discussion of the Review Process** provides an in-depth discussion of each of the analyses that were conducted (i.e., health effects, analytical and technology assessments, consideration of other regulatory revisions, occurrence and exposure, and evaluation of available economic information), and how these analyses interrelate.

- **Section IV: Stakeholder Involvement** discusses how EPA involved the public during the Six-Year Review process.

This protocol also contains five appendices as described below:

- **Appendix A: List of pre-1997 National Primary Drinking Water Regulations (NPDWRs)** identifies each of pre-1997 NPDWRs and indicates whether it is being reviewed in accordance with this protocol or whether it has been/will be reviewed as a part of a separate rulemaking activity.

- **Appendix B: Differences between the National Drinking Water Advisory Council's (NDWAC's) Recommendations and this Protocol** summarizes the NDWAC recommendations that EPA either modified or did not include in this protocol.

- **Appendix C: Overview of the IRIS Assessments** provides a discussion of how EPA conducts its Integrated Risk Information System (IRIS) health assessments.

- **Appendix D: Overview of the OPP Process for Toxicity Assessments** contains a discussion of the Office of Pesticide Programs (OPP) process for conducting toxicity assessments.

- **Appendix E: Overview of the Analytical Methods Review Process** describes EPA's process for approving new analytical methods for chemical drinking water contaminants and how the Agency has derived practical quantitation limits in the past.

SECTION II: OVERVIEW OF THE SIX-YEAR REVIEW PROCESS

This section provides an overview of the review process. It contains a discussion of the basic principles that EPA followed during the review, the types of analyses that EPA conducted, and the types of regulatory revisions that EPA considered. In addition, this section includes a figure that illustrates the review process. A more detailed discussion of each of the analyses, that were conducted under the review, is provided in Section III.

A. What Basic Principles Did EPA Follow During this Review?

EPA's primary goal was to identify and prioritize candidates for regulatory revision in order to target those revisions that are most likely to result in an increased level of public health protection and/or result in substantial cost-savings while maintaining the level of public health protection. In conducting the review, EPA applied the following basic principles:

- The Agency assumed that health effects, occurrence, analytical feasibility, treatment data, and analyses underlying existing regulations remain adequate and relevant, except in those instances where reliable, peer-reviewed[3], new data were available that indicated a need to re-evaluate an NPDWR (e.g., where a change in health risk assessment has occurred).

- If new data were available, EPA determined whether changes in existing standards were warranted. For example, in determining whether there was a change in analytical feasibility, the Agency applied the current policy and procedures for calculating the practical quantitation level for drinking water contaminants.[4]

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

[3] "Peer review" is a documented critical review of a sp ecific major scientific and/or technical work product. The peer review is conducted by qualified individuals (or organizations) who are independent of those who performed the work, but who are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to en sure that activities are technically adequate, competently performed, properly documented, and satisfy established qua lity requirements. The peer review is an in-depth assessment of the assumptions, calculation, extrapola tions, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific majo r scientific and/or technical work product and of the documentation that supports them.

[4] See: 50 FR 46880, November 13, 1985 (USEPA, 1985); 52 FR 25690, July 8, 1987 (USEPA, 1987); 54 FR 22062, May 22, 1989 (USEPA, 1989a).

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

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

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

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

B. What Types of Analyses Did EPA Conduct?

To most efficiently utilize limited resources and assure continued public health protection, the Agency conducted the review in two phases: (1) an initial technical review of all 69 NPDWRs included in this Six-Year Review (see Appendix A for a list); and (2) an in-depth technical evaluation of those NPDWRs identified during the initial review as potential candidates for revision. Figure 1, at the end of this section, illustrates the Six-Year Review process.

1. Initial Technical Review

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

- *Health effects review.* Identify NPDWRs for which the Agency has revised health risk assessments that indicate possible changes to the maximum contaminant level goal (MCLG) and perhaps to the maximum contaminant level (MCL);

- *Current technology review.* Identify NPDWRs where improvements in analytical measurement or treatment feasibility might allow the MCL to be established closer to the MCLG, or where adjustments in TT requirements might be appropriate; and/or

- *Other regulatory revisions review.* Identify NPDWRs where adjustments to system monitoring and reporting requirements might be appropriate and where such changes are not already being considered as a part of another activity.

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

2. In-Depth Technical Analysis

The Agency subjected the remaining NPDWRs to more in-depth technical analyses. If the initial review indicated a possible revision to the MCLG/MCL, EPA further considered health and technology factors that might affect the development of a revised MCLG/MCL or revised MCLG/TT requirements. The Agency also estimated potential occurrence and exposure at public water systems (PWSs) at concentrations of regulatory interest for the chemical NPDWRs and conducted a qualitative evaluation of available economic information. EPA based the qualitative economic evaluation primarily on available occurrence and exposure data, to determine whether the possible revision was likely to present an opportunity for significant gains in public health protection and/or significant cost-savings to PWSs and their customers that could be realized without lessening the level of public health protection.

If EPA identified data gaps that could not be filled during the current review cycle, the Agency did not conduct some or all of the remaining analyses. Although, Figure 1, on page 8 shows the identification of data gaps as the final step in the review; in some instances, data gaps were identified during earlier steps in the process. If the Agency identified data gaps, EPA determined that a revision to the NPDWR is not appropriate at this time.

After completing these comprehensive analyses, EPA identified those NPDWRs that remain appropriate at this time, and those NPDWRs that may be appropriate for revision. If the Agency decided that it was not appropriate to revise an NPDWR at this time, that decision was based on one of the following reasons.

- *Health risk assessment is in process*: The Agency is currently conducting, or has scheduled, a detailed review of current health effects information. Because the results of the assessment are not yet available, the Agency does not believe it is appropriate to make a "revise decision" at this time. EPA will consider the results of the updated health risk assessment during the 2002-2008 review cycle. However, if the results of the health risk assessment indicate a compelling need to reconsider the MCLG, EPA may decide to accelerate the review schedule for that contaminant's NPDWR.

- *NPDWR remains appropriate after data/information review*: The outcome of the review indicates that the current regulatory requirements remain appropriate and, therefore, no regulatory revisions are warranted. Any new information available to the Agency either supports the current regulatory requirements or does not justify a revision.

- *New information, but no revision recommended because*:

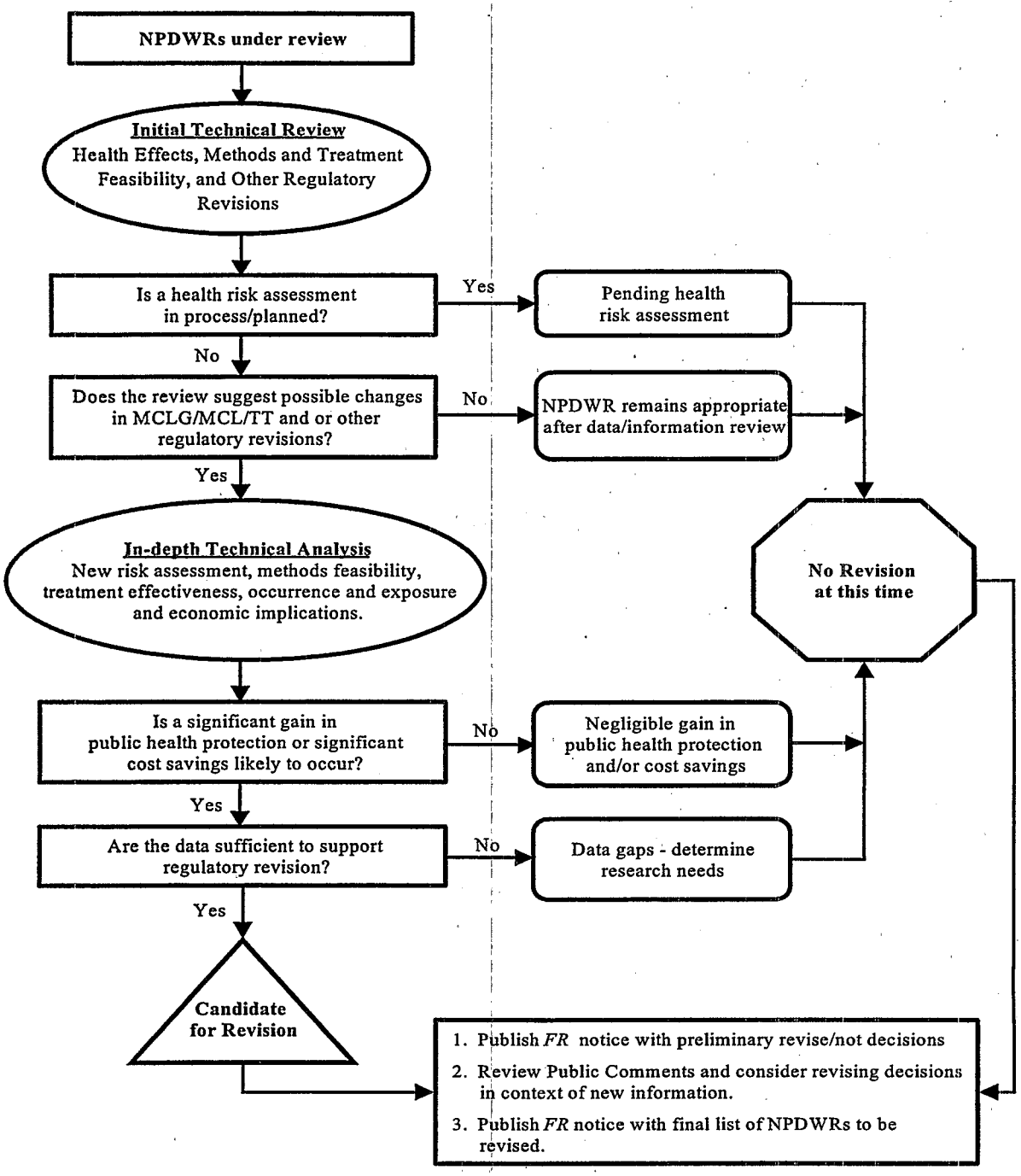
  - *Negligible gain in public health protection*: Any resulting changes to the NPDWR would not significantly improve the level of public health protection or result in a major cost-savings.

  - *Information Gaps*: Although results of the review support consideration of a possible revision, the available data are insufficient to support a definitive regulatory decision at this time.

EPA will publish preliminary review findings and seek public comment on them in the

Federal Register. After considering the public comments received and any new peer-reviewed data that may become available to the Agency, EPA will publish its final decisions in the *Federal Register*.

Figure 1: Overview of the Protocol and Making the Revise/Not Revise Decision



C. What Types of Regulatory Revisions Did EPA Consider?

As a part of the review, EPA considered regulatory revisions, with the primary goal of improving or maintaining public health protection. The types of revisions considered were based on the various components of each NPDWR. Some NPDWRs set enforceable MCLs for particular contaminants in drinking water. Others impose TTs to remove chemical contaminants or microbiological pathogens from drinking water. Most standards also include requirements for water systems to test for contaminants in the water to make sure standards are achieved. NPDWRs also specify recordkeeping and reporting requirements, define what constitutes compliance, and specify language and delivery requirements for public notification.

Some regulatory revisions that are not listed below (e.g., revisions to approved analytical methods) are already addressed through periodic rulemaking activities of SDWA, and thus, were not included in the Six-Year Review.

1. Changes to MCLGs

The SDWA requires EPA to establish non-enforceable health-based MCLGs. As a part of the Six-Year Review, EPA considered MCLG changes only in those instances where a new health risks assessment had been completed since the MCLG was promulgated or last revised, and where the most current assessment resulted in a revised reference dose (RfD) and/or cancer classification that significantly affected the calculation of the MCLG.

2. Changes to MCLs

An MCL is an enforceable standard for a contaminant. The SDWA generally requires the MCL to be set as close to the MCLG as is feasible. As a part of the Six-Year Review, EPA considered MCL revisions under the following circumstances[5]:

- The health effects review indicated a change to the MCLG that also indicated a change to the MCL was appropriate; and/or
- The current MCL was limited by analytical or treatment feasibility and the review of these capabilities indicated it might now be feasible to set the MCL closer to the MCLG.

3. Changes to Treatment Technique Requirements

When it is not economically or technically feasible to set an MCL, or when there is no reliable or economically feasible method to detect contaminants in the water, EPA sets a TT requirement in lieu of an MCL. A TT specifies a type of treatment (e.g., filtration, disinfection, other methods of control to limit contamination in drinking water, etc.) and means for ensuring

[5] Although the 1996 Amendments to SDWA allow EPA to set the MCL at higher than the feasible level if the benefits do not justify the costs, SDWA also pr ecludes the Agency from making an existing standard less stringent solely on economic considerations. Therefore, EPA does not believe it is appropriate to revise a pre-1997 MCL unless a health or technical basis exists for the revision.

adequate treatment performance (e.g., monitoring of water quality to ensure treatment performance, etc.).

Water TTs may improve to the point where more protective drinking water standards may be considered. Before EPA would consider a revision to TT requirements, the potential methods must be generally available and must have demonstrated consistent control of the subject contaminant in drinking water. As a part of the Six-Year Review, EPA reviewed available information on TTs for those chemical NPDWRs for which a TT is set in lieu of an MCL and no health risk assessment was in process to determine if changes to TT requirements might be warranted.

4. Changes to Other Treatment Technology

When EPA sets an MCL, the NPDWR also contains Best Available Technology (BAT) recommendations that address drinking water treatment processes. Although not required for compliance purposes, EPA sets BATs that have the capability to meet MCLs.

As part of the Six-Year Review, the Agency limited its review of BATs to those NPDWRs for which EPA was considering possible revisions to the MCL based on the health effects or analytical feasibility reviews. Before EPA would consider a revision to a BAT, the treatment technology must be generally available and must have demonstrated consistent removal of the subject contaminant under field conditions.

EPA has a separate program in place to periodically review specific treatment technology issues, such as compliance and variance technology for small systems (i.e., systems serving up to 10,000 people) for both the MCL-type and the TT-type rules (however, for microbiological contaminant regulations, no variances are allowed).[6] As a part of its periodic review of small system compliance and variance technology, the Agency also plans to include the identification of: (1) BATs for larger systems in future regulations, and (2) emerging technologies as potential compliance and variance technologies for all system sizes for existing and future regulations. EPA believes that this separate review of treatment technologies is appropriate because it maintains the focus of technology assessment within one program function (USEPA, 1998a).

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[6] The 1996 SDWA Amendments identify two classes of technologies for systems serving 10,000 and fewer persons: compliance technologies and variance t echnologies. A compliance technology is defined in §1412(b)(4)(E)(ii) as a technology or other means that is affordable and achieves compliance with an MCL or satisfies a TT requirement. EPA listed compliance technologies in the EPA publication entitled " *Small System Compliance Technology List for the Non-Mi crobial Contaminants Regulated Before 1996* " (USEPA, 1998a). Variance technologies, defined in §1412(b)(15)(A), are speci fied for those system size category/source water quality combinations for which there are no listed compliance technologies. Variance technologies, where they are permitted, may not achieve compliance with a particular MCL or TT requirement; however, they must achieve the maximum reduction or inactivation efficiency that is affo rdable, taking into consideration system size and source water quality. Variance technologies must also achieve a le vel of contaminant reduction that is protective of public health.

5. Changes to Other Regulatory Provisions

In addition to possible revisions to MCLGs, MCLs, and TTs, EPA considered other regulatory revisions, such as monitoring and system reporting requirements, as a part of the Six-Year Review process. EPA focused this review on issues that are not already being addressed, or have not been addressed, through alternative mechanisms (e.g., as part of a recent or ongoing rulemaking, in conjunction with possible Chemical Monitoring Reform, etc.). Where appropriate alternative mechanisms do not exist, EPA considered these implementation-related concerns if the potential revision met the following criteria:

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

SECTION III: DETAILED DISCUSSION OF THE SIX-YEAR REVIEW PROCESS

This section provides a detailed discussion of how EPA conducted its review of health risk assessments, technology assessments, other regulatory revisions, and, where appropriate, occurrence and exposure analyses, and economic considerations.

A. Health risk assessments

1. What Are the Objectives of the Health Effects Review?

The objectives for the examination of health effects under the Six-Year Review were to:

- To identify new health risk assessments for individual contaminants that could change the MCLG for the contaminant in question and affirm or change the MCL, thus, affording the same or greater protection of human health provided by the present MCLG;
- To use existing Agency health risk assessments in accomplishing the health effects data review;
- To ensure that the health effects data for each contaminant is the subject of a detailed review at least once in every two, Six-Year Review cycles (with the exception of pesticides that are still in active use, because they are subject to a detailed review that is conducted on a different schedule[7]); and
- To accomplish the review within the limitations imposed by Agency resources.

The procedure for review of health effects data differed depending on whether the substance to be controlled is a chemical contaminant or a microbiological pathogen/indicator, as discussed in detail below. The health risk assessment identified a list of NPDWRs that are possible candidates for regulatory revisions based on changes in health considerations. This list of NPDWRs was combined with those identified by other key elements of the review to develop a final list of NPDWRs that are candidates for additional evaluation.

[7] The health effects for these contaminants are reassessed no less frequently than every 15 years. Within EPA, health risk assessments for pesticides are conducted by the OPP under authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Food Quality Protection Act (FQPA) of 1996. A goal of FIFRA is that EPA reviews each pesticide's registration every 15 years. Under some circumstances, a pesticide's health effects may be reassessed more frequently.

2. *How Does EPA Review Health Effects Data for Chemical Contaminants?*

EPA uses a systematic approach in reviewing the health effects data for chemical contaminants. This approach considers the risk assessment policies that link the MCLG and MCL as well as the data that have become available since the time of regulation. The document, "Six-Year Review - Chemical Contaminants - Health Effects Technical Support Document" (USEPA, 2002d), describes how EPA reviewed the chemical contaminants and provides the results of the health effects technical review.

If there is evidence that a chemical may cause cancer, and if the cancer mode of action is linear, there is no dose below which the chemical is considered safe, and thus the MCLG is set at zero. In these instances, the MCL is based on feasible technology (analytical methods/treatment). If a chemical is carcinogenic and acts by a well-documented, nonlinear mode of action, the MCLG may be set at a level above zero. As the health risks of nonlinear carcinogens undergo reassessment, this may provide regulatory options for MCLGs for carcinogens that are greater than zero.

For non-carcinogenic chemicals, the MCLG is based on an oral RfD. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime. A change in an Agency RfD for a chemical could accordingly lead to a change in an MCLG and MCL. In deriving the MCLG for a non-carcinogen, the Agency applies a Relative Source Contribution (RSC) factor to allocate a portion of the total allowable exposure to drinking water. The RSC is one factor which will determine whether or not a change in RfD will lead to a change in the MCLG/MCL.

In the past, it was Agency policy to apply a risk management factor to the RfD for chemicals with equivocal data on carcinogenicity. This policy is a second factor that must be evaluated to determine the impact of a change in RfD on the MCLG/MCL for these chemicals.

For most of the 68 chemical NPDWRs included in the Six-Year Review, the MCLG is derived from the cancer classification and/or the RfD. Therefore, the health effects technical review focused on whether there has been a change to these values. The Agency reviewed the results of health risk assessments completed under the following programs to determine if there had been a change in critical effect or dose-response pattern that indicates the possible need for an MCLG revision.

- EPA's IRIS (see Appendix C)
- OPP (see Appendix D)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- National Academy of Sciences (NAS).

Where possible, an oral RfD or comparable value is derived and an assessment of carcinogenicity from oral exposure is conducted under each of these programs.

As a result of the health effects review, EPA placed each of the 68 chemical NPDWRs into one of the following categories:

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

- *New risk assessment since promulgation, but prior to 1997.* An IRIS, OPP, ATSDR, and/or NAS assessment has been completed since the NPDWR was promulgated but prior to 1997. None of these assessments reflected a change in RfD or cancer classification. However, since these assessments may not have specifically considered developmental and reproductive health effects, EPA conducted a full literature search, including developmental and reproductive toxicity, for those NPDWRs with non-zero MCLGs to identify any relevant studies that might affect the MCLGs of these contaminants.[8] In a few instances, the results of the literature search indicate that it might be appropriate to revise the RfD and/or cancer classification. EPA initiated updates to risk assessments for these chemicals, and established a schedule for their completion. EPA does not believe it is appropriate to revise the MCLG at this time.

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

- *Original NPDWR risk assessment.* No health risk assessment has been conducted since promulgation of the NPDWR. The Agency conducted a full toxicological literature search, including developmental and reproductive toxicity, for each of these contaminants with non-zero MCLGs to identify new toxicological studies that might have an impact on the MCLGs. In a few instances, the results of the literature search indicate that it might be appropriate to revise the RfD and/or cancer classification. EPA initiated updates to risk assessments for these chemicals, and established a

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

schedule for their completion. EPA does not believe it is appropriate to revise the MCLG at this time.

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

The document,"*Six-Year Review - Chemical Contaminants - Health Effects Technical Support Document*," (USEPA, 2002f) describes the process that EPA used to address the health effects aspect of the current review for the chemical contaminants.

3. How Does EPA Review Health Effects Data for Microbiological NPDWRs?

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

The 1989 TCR set an MCLG of zero for total coliforms because EPA was not aware of any data in the scientific literature supporting a particular value for the concentration of coliforms below which no known or anticipated adverse health effects occur, with an adequate margin of safety.

The memorandum, "Six-Year Review of the Total Coliform Rule - Comments Received" (USEPA, 2002e), describes the process EPA applied to the review of the TCR. Where appropriate, EPA applied the same approach to reviewing the TCR as it did to the review of the 68 chemical NPDWRs. However, because of the nature of the TCR, the pathogens it controls, the Agency focused its review on the implementation-related requirements.

B. Technology Assessments

1. What Are the Objectives of the Technology Assessment?

The SDWA generally requires that MCLs be set as close to the MCLG as is feasible. When determining feasibility, the Agency considers cost and capability of the analytical and treatment methods to respectively measure and remove/reduce drinking water contaminants, and the availability of these technologies. In some cases, particularly when the Agency sets a zero

MCLG, EPA establishes a higher MCL based on the limitations of analytical or treatment feasibility.

Where these constraints apply to the current MCL, the objectives of the technology assessment are to determine whether there have been improvements in analytical methods or treatment technologies that may allow EPA to lower the MCL.

2. How Does EPA Review Analytical Methods?

As described in Appendix E, EPA's OGWDW has a process in place to approve new and/or improved analytical methods for drinking water contaminants. The review and approval of new methods, updates to §§141.23, 141.24, or 141.25 and the approval of methods through §141.27 (alternate analytical techniques - also known as alternate test procedures or ATP) is generally performed through periodic method update rules. The review and approval of new methods and/or updates to the methods is also performed through the rulemaking process to regulate a contaminant or revise the standard for a contaminant, when appropriate (e.g. the January 22, 2001 final rule for arsenic, (66 *FR* 6975 (USEPA, 2001b)). More recent methods update rules include 62 *FR* 10167, March 5, 1997 (USEPA, 1997a), 64 *FR* 67449, December 1, 1999 (USEPA, 1999d) and 66 *FR* 3526, a proposed rule published January 16, 2001 (USEPA, 2001a).

The Six-Year Review will not duplicate those efforts per se but will use the information from these method updates in the review process. In those instances where the MCL has been established based on the limitations of analytical method capabilities and/or where the health effects analysis suggests that the MCLG/MCL should be lowered, EPA will review the existing approved methods in the context of potential changes in analytical feasibility. The goal of this part of the review is for EPA to determine whether the currently approved methods provide sufficient analytical capability to reliably measure the contaminant at levels lower than the current MCL. If it appears that the currently approved method capabilities (i.e., a method detection limit (MDL)) are the limiting factor for attaining a lower level of quantitation and therefore, revising an MCL, and if the occurrence/exposure analyses suggest a potentially significant gain in public health protection, EPA will include a request in the *Federal Register* for potential new and/or improved methods that are technologically and economically feasible. However, it should be noted that once a more sensitive method is approved for a contaminant, there may be a time lag between the time of promulgation and the ability of laboratories to begin using a new method and have an impact on the feasible level of quantitation.

The remainder of this section generally describes how EPA determines the feasible level of measurement for chemical and microbiological contaminants for SDWA purposes. It also discusses how EPA evaluated available, new data to determine if any changes in analytical feasibility for the chemical contaminants have occurred since promulgation of the NPDWR. The document,"Analytical Feasibility Support Document for the Six-Year Review of Existing National Primary Drinking Water Regulations: Reassessment of Feasibility for Chemical Contaminants," (USEPA, 2002g) describes the process that EPA used to address the analytical feasibility aspect of the current review for specific chemical contaminants.

Chemical Contaminants

OGWDW establishes a practical quantitation level (PQL) to estimate the level at which laboratories can routinely measure a chemical contaminant in drinking water. Historically, OGWDW has typically used two main approaches to determine a PQL for SDWA analytes. The preferred approach used data from Water Supply (WS) studies (which were predominantly used to certify drinking water laboratories[9]). In most cases, OGWDW used the WS method when sufficient WS data were available to calculate a PQL. In the absence of sufficient WS data, OGWDW used a multiplier method, in which the PQL was calculated by multiplying the EPA-derived MDL by a factor of 5 or 10.

Although there are several approaches that could be used for the reassessment or re-evaluation of the PQLs, to be consistent with the process that the Agency has used in the past, only the "WS data method" and the "MDL Multiplier method" were considered for this Six-Year Review process. Of these two approaches, the Agency preferred to use the WS data approach since it relies on actual data from a number of EPA Regional and State laboratories. In cases were the WS data were indicative of a change in the PQL, the MDL multiplier method was only used only to estimate what the potentially new PQL could be.

EPA reviewed analytical capabilities for contaminants under two circumstances: (1) for those NPDWRs where the current MCL is set at the PQL and there is no indication that the MCLG would change; and (2) for those NPDWRs that have undergone a health effects review and there is a potential change in an MCLG and it may be less than the current MCL. For each of these chemical NPDWRs, the following steps were taken to evaluate whether changes in analytical feasibility have occurred:

(1) a *methods comparison* step was used to identify whether the ability to detect (and therefore quantify) these contaminants at lower levels has increased;

(2) a *methods usage over time* step was used to identify the analytical methods that appear to be the most widely-used for the analysis of particular contaminants.

(3) a *Water Supply data analysis* step was used to determine if a PQL can be recalculated (if sufficient WS information is available) or if there is an indication that a PQL may be lower using the available information.

The results of these three steps aided in assessing whether a PQL might change for a specific contaminant and, if so, estimating what the new PQL might be. Ultimately, the purpose of this analysis was to determine whether the analytical method capabilities would support a lower MCL.

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[9] Because the Water Supply (WS) program has been ex ternalized, the Agency is currently deciding how it should assess the multiple laboratory data that are used to determine the PQL for chemical contaminants. Appendix E briefly discusses the externalization of the Performance Evaluation program.

Microbiological Contaminants

For microbes, EPA does not have, or currently envision, a routine pathogen monitoring requirement, but rather employs indicators of water quality (e.g., total coliforms, *E. coli*). PQLs have not been used for microbial indicators because, for approval, the method must be able to detect a single cell (i.e., MDL and PQL must both be one cell) in a 100 milliliter (mL) water sample (40 CFR 141.21(f)). In addition, the false-positive and false-negative (i.e., recovery) rates must be reasonable. EPA is considering whether to define "reasonable" in numerical terms.

In some cases, EPA may require systems to determine the density of a particular pathogen or indicator in either their source waters or drinking waters. For example, under the future Long Term 2-Enhanced Surface Water Treatment Rule (LT2-ESWTR), EPA may require surface water systems to determine the density of *Cryptosporidium* in the source water to determine the level of water treatment the system would need. In this case, the accuracy and precision of the method at low levels of pathogen density would have to be determined using interlaboratory studies. The method would have to be sufficiently sensitive to detect a single oocyst. Therefore the PQLs and MDLs are not meaningful. In addition, it may be appropriate to determine an MDL and PQL for some required non-microbial measurements associated with microbial water quality such as turbidity, disinfectant residual, and algal microcystins. Currently, accurate measurement of microbiological density is problematic. Moreover, regulation of microbiological contaminants are currently treatment-technique based. Therefore, this protocol primarily focused on the review of treatment technology related to the regulation of microbiological contaminants.

3. How Does EPA Review Treatment Technologies?

As discussed previously, an NPDWR either identifies the BAT for meeting the MCL (even though BAT is not required for compliance purposes), or establishes enforceable TT requirements. Currently, for all the pre-1997 chemical NRDWRs reviewed in accordance with this protocol that include an MCL, the MCL is set equal to the MCLG or the PQL. None of these MCLs are currently limited by treatment feasibility. Thus, although EPA generally reviews treatment technologies through alternative mechanisms, there are a few scenarios for which EPA reviewed treatment feasibility as a part of the Six-Year Review process:

- The health effects technical review identified a potential change to the MCLG/MCL; or
- A health risk assessment is not in process for the contaminant and one of the following two conditions applied:
  (1) the analytical feasibility review identified a possible change to the MCLG/MCL; or
  (2) the NPDWR is a TT-type rule.

EPA also considered revisions that clarify or modify BAT or TT requirements where existing requirements were not clear or were incorrectly specified. In addition, and where appropriate, EPA evaluated the likelihood that systems would discontinue existing treatment if EPA were to raise the MCL.

Treatment capabilities of existing BATs and TTs are well documented by EPA and other organizations. Likewise, small system compliance and variance technologies are well documented and periodically reviewed by the Agency. During the development of NPDWRs, EPA provides state-of-the-science and feasibility of treatment information primarily through its technical support documents (e.g., EPA technologies and costs reports, and guidance materials published to assist in regulatory implementation). As part of the Six-Year Review process, EPA used these same resources, in addition to newer treatment and cost reports, peer-reviewed data, and other available treatment technology information including that received by EPA from stakeholders.

The evaluation of treatment technologies will support the regulatory review process by identifying any known water treatment limitations that might affect a revision of an MCL. In the case of TT-type rules, this effort supports consideration of whether changes to TT requirements are warranted. For example, consideration will be given to any new treatment processes that may now be available and appropriate. If the Agency identifies treatment technology-related research needs as a part of the Six-Year Review process, those research needs will be forwarded to the appropriate Agency group(s) for consideration and prioritization as a part of the overall drinking water research strategy.

The document,"*Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In Support of EPA Six-Year Review of National Primary Drinking Water Regulations*," (USEPA, 2002h) describes the process that EPA used to address the treatment feasibility aspect of the current review for specific chemical contaminants.

C. Other Regulatory Revisions

1. What Are the Objectives of Reviewing Other Regulatory Revision Options?

In addition to possible revisions to MCLGs, MCLs, and TTs, EPA considered other regulatory revisions, such as monitoring and system reporting requirements, as a part of the Six-Year Review process. EPA focused this review on issues that are not already being addressed, or have not been addressed, through alternative mechanisms (e.g., as part of a recent or ongoing rulemaking, in conjunction with possible Chemical Monitoring Reform). Where appropriate alternative mechanisms do not exist, EPA considered these implementation-related concerns if the potential revision met the following criteria:

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

The document, "Consideration of Other Regulatory Revisions for Chemical Contaminants in Support of the Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2002b) summarizes the specific issues identified during the review

process. Some of these issues (e.g., the need to specifically define new system/new source monitoring requirements for chemical contaminants) have already been addressed in the recently published arsenic and radionuclides NPDWRs (66 *FR* 6975, January 22, 2001 (USEPA, 2001b); 65 *FR* 76707, December 7, 2000 (USEPA, 2000d)).

D. Occurrence and Exposure Analysis

1. What Are the Objectives of the Occurrence and Exposure Analysis?

The objectives of the occurrence and exposure analysis components of the review process are to estimate the numbers of PWSs at which contaminants occur at levels of regulatory interest in drinking water, and to evaluate the number of people exposed to these levels. This analysis is not necessary for the TCR, since national data are not available and are not needed. If an organism is known to be transmitted by the fecal-oral route, and has caused at least one waterborne disease outbreak in this country, that is sufficient reason to control the organism nationally. The number of systems affected by an organism depends on the characteristics of the waterborne organism and the type of water source. Therefore, the remaining discussion of the occurrence and exposure analysis pertains only to the chemical NPDWRs under review.

Combined with results of the other technical analyses described in Section III (e.g., health effects), the results of the occurrence and exposure analysis were used to help determine which revisions are most likely to provide the greatest public benefit. In some cases, these results may also be used as a factor when recalculating RSCs.[10] EPA plans to perform further, in-depth, occurrence and exposure analysis prior to any proposed revision to an NPDWR.

2. How Did EPA Conduct the Occurrence and Exposure Analysis?

During the current review cycle, EPA used data voluntarily provided by eight States as a part of the Agency's occurrence analyses for its Chemical Monitoring Reform (CMR) evaluation (USEPA, 1999b). EPA augmented this information with other data that were voluntarily submitted by an additional eight States, based on the same geographic diversity and agricultural and industrial pollution potential analyses utilized in the CMR analyses.

The Agency does not believe it is appropriate to revise a pre-1997 NPDWR solely on the basis that a contaminant is low-occurring or high-occurring at PWSs. However, the estimated occurrence and exposure to a contaminant at PWSs at concentrations between the current MCL and any possible MCL is a factor in determining whether there is likely to be a significant gain in public health protection, if EPA were to revise the MCL. Occurrence and exposure estimates also may be a factor in determining the likely change in public health protection and/or cost-savings if EPA were to make changes to other regulatory provisions. Therefore, EPA focused the detailed occurrence and exposure analysis on those chemical contaminants that have been

[10] While occurrence and exposure estimates factor into the derivation of an RSC, a much more important factor is exposure information for other media (air, food, etc.) relative to that for water. Exposure information for other media will be assessed as a part of the health risk assessment described in Section III.A. of this document, and not as a part of the occurrence and exposure assessment described in this section.

identified as potential candidates for revision by the health effects, technology, and/or other regulatory revisions reviews.

As a part of the Stage 1 analysis, EPA estimated the percent of PWSs (and the total population served by those PWSs) with at least one analytical result exceeding the following thresholds: the lowest level of detection reported by the States; one-half the current MCL, and the current MCL. Of the chemicals review under this first regulatory review cycle, all were analyzed in this way, except for: contaminants for which not enough data were available; contaminants for which the NPDWR specifies a TT-type requirement instead of an MCL; and contaminants for which EPA did not request data, since the Agency determined there was no health or technological basis for revising, and because these data would have required extra burden for States to transmit.

Based on the outcome of the health effects, technology, and other regulatory revision reviews, EPA performed a more detailed, "Stage 2" statistical analysis of occurrence to estimate the numbers of systems (and the corresponding affected populations) with mean contaminant concentrations above the levels of regulatory interest. In general, EPA utilized the results of the other technical reviews to determine the level(s) of regulatory interest for each contaminant for which the Agency performed Stage 2 analysis.

The document,"*Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Regulatory Review*," (USEPA, 2002i) describes the process that EPA used to address the occurrence and exposure aspect of the current review for specific chemical contaminants.

E. Consideration of Economic Factors

1. What Were the Objectives of EPA's Evaluation of Economic Impacts?

While SDWA provides the Agency broad discretion to consider economic impacts in the context of the Six-Year Review, the statute precludes EPA from using economic impacts as the sole basis for a revision that would provide less health protection than the current standard (anti-backsliding). However, if new peer-reviewed scientific health effects research indicates that an MCLG could be raised while maintaining public health protection, then such a change is permitted. For NPDWRs published prior to the 1996 SDWA Amendments, consideration of economic factors is of limited use when determining whether revisions are appropriate, except in those situations where a health or technical basis exists for a potential regulatory revision. Therefore, EPA qualitatively evaluated available economic information for those NPDWRs identified as potential candidates for revision by the health and technology reviews. The purpose of this analysis was to determine whether a potential revision is likely to provide an opportunity for significant gains in public health protection and/or the potential for significant cost-savings that at least maintain the current level of public health protection.

2. *How Did EPA Consider Economic Impacts?*

EPA did not quantify likely costs and benefits as a part of the review, since many of the factors that are needed for such calculations depend on specific regulatory options that will not be defined until EPA begins the actual rulemaking process. EPA therefore qualitatively assessed likely costs and benefits based on the other technical analyses performed as a part of the review. For example, in those instances where the health effects and/or technology reviews indicated that a more stringent MCL may be appropriate, EPA considered the difference between the levels of occurrence and exposure at the current MCL and the occurrence and exposure at the lower concentration(s) indicated by those reviews. On the other hand, if the health effects review indicated it might be appropriate to raise the MCLG/MCL, EPA considered whether such a revision would be likely to offer an opportunity for significant cost-savings to PWSs and their customers. In making this assessment, EPA considered the number of PWSs with concentrations above the current MCL that are likely to avoid the need to install treatment.

For any NPDWR for which the Agency makes a revise decision, the Agency will conduct detailed cost and benefit analyses, as required, prior to proposing specific regulatory revisions.

SECTION IV: STAKEHOLDER INVOLVEMENT

Section IV discusses how the Agency involved the public during the Six-Year Review process. More specifically, it lists those organizations with which EPA coordinated during the Six-Year Review process (i.e., key stakeholders), describes the mechanisms EPA used to keep these stakeholders involved, and discusses the Agency's plans for involving the Science Advisory Board (SAB) in the review process.

A. Who Are the Key Stakeholders in the Six-Year Review Process?

The key stakeholders include members of the following:

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

B. How Have Stakeholders Been Involved in the Six-Year Review Process?

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

EPA invited representatives from State and Tribal communities, PWSs, public health organizations, academia, environmental and public interest groups, engineering firms, and other stakeholders to a stakeholder meeting in Washington, DC, in November 1999 (64 *FR* 55711, October 14, 1999 (USEPA, 1999a)). Approximately 50 participants attended, including representatives from the invited groups. EPA discussed its preliminary strategy for the Six-Year Review and invited stakeholder comment. Stakeholders generally agreed that EPA had identified the appropriate key elements for the review; however, in some cases, stakeholders suggested that EPA needed to be more proactive in seeking out new information that might affect the regulatory decision (USEPA, 1999c). The executive meeting summary is available on EPA's drinking water web page, http://www.epa.gov/safewater/ccl/novmtg.html.

In the Spring of 2000, the NDWAC formed a working group to develop recommendations regarding the process the Agency should apply to conducting a periodic and systematic review of existing NPDWRs. The Working Group held two meetings and a conference call during June through September 2000 (USEPA, 2000a-2000c). The NDWAC approved the Working Group's recommendations in November 2000 and formally provided them

to EPA in December 2000 (NDWAC, 2000). The NDWAC recommended that EPA's review include consideration of five key elements, as appropriate: health effects, analytical and treatment feasibility, implementation-related issues, occurrence and exposure, and economic impacts. The NDWAC suggested that the Agency conduct a preliminary screening review of each NPDWR to identify potential candidates for an in-depth analysis. Except where noted in Appendix B, EPA has followed the protocol recommended by the NDWAC.

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

C. How Does EPA Plan to Involve the Science Advisory Board?

EPA plans to consult with the SAB Drinking Water Committee prior to publishing the final its final revise/not revise decisions in the August 2002 time frame. The Agency will request their review and comment on whether the protocol EPA developed based on the NDWAC recommendations was consistently applied and appropriately documented.

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APPENDICES

Appendix A: **Pre-1997 National Primary Drinking Water Regulations (NPDWRs)**

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Appendix A: List of Pre-1997 National Primary Drinking Water Regulations (NPDWRs)

Table A-1 identifies the NPDWRs promulgated prior to the 1996 SDWA Amendments (pre-1997 NPDWRs) and the rulemaking by which they were originally promulgated. EPA plans to review these NPDWRs by 2002 in accordance with the review protocol described in this document. Table A-2 identifies the remaining pre-1997 NPDWRs which are being or have already been reviewed in separate actions and the NPDWRs promulgated after the 1996 SDWA Amendments. The NPDWRs listed in Table A-2 will be reviewed as a part of the 2002-2008 review cycle.

Table A-1: Pre-1997 NPDWRs Reviewed in Accordance with this Protocol

Contaminant	Corresponding NPDWR	Contaminant	Corresponding NPDWR
Chemical Contaminants		**Chemical Contaminants (continued)**	
Acrylamide	Phase II Rule	cis-1,2-Dichloroethylene	Phase II Rule
Alachlor	Phase II Rule	trans-1,2-Dichloroethylene	Phase II Rule
Antimony	Phase V Rule	Dichloromethane (Methylene chloride)	Phase V Rule
Asbestos	Phase II Rule	1,2-Dichloropropane	Phase II Rule
Atrazine	Phase II Rule	Di(2-ethylhexyl)adipate (DEHA)	Phase V Rule
Barium	Phase IIB Rule	Di(2-ethylhexyl) phthalate (DEHP)	Phase V Rule
Benzene	Phase I Rule	Dinoseb	Phase V Rule
Benzo[a]pyrene	Phase V Rule	Diquat	Phase V Rule
Beryllium	Phase V Rule	Endothall	Phase V Rule
Cadmium	Phase II Rule	Endrin	Phase V Rule
Carbofuran	Phase II Rule	Epichlorohydrin	Phase II Rule
Carbon tetrachloride	Phase I Rule	Ethylbenzene	Phase II Rule
Chlordane	Phase II Rule	Ethylene dibromide (EDB)	Phase II Rule
Chromium (total)	Phase II Rule	Fluoride	Fluoride Rule; Phase II Rule revised monitoring requirements
Copper	Lead and Copper Rule (LCR)	Glyphosate	Phase V Rule
Cyanide	Phase V Rule	Heptachlor	Phase II Rule
2,4-D	Phase II Rule	Heptachlor epoxide	Phase II Rule
Dalapon	Phase V Rule	Hexachlorobenzene	Phase V Rule
1,2-Dibromo-3-chloropropane (DBCP)	Phase II Rule	Hexachlorocyclopenta-diene	Phase V Rule
1,2-Dichlorobenzene (*o*-Dichlorobenzene)	Phase II Rule	Lead	LCR
1,4-Dichlorobenzene (*p*-Dichlorobenzene)	Phase I Rule	Lindane	Phase II Rule
1,2-Dichloroethane (Ethylene dichloride)	Phase I Rule	Mercury (Inorganic)	Phase II Rule
1,1-Dichloroethylene	Phase I Rule	Methoxychlor	Phase II Rule

Table A-1: Pre-1997 NPDWRs Reviewed in Accordance with this Protocol

Contaminant	Corresponding NPDWR
Monochlorobenzene (Chlorobenzene)	Phase II Rule
Nitrate (as N)	Phase II Rule
Nitrite (as N)	Phase II Rule
Oxamyl (Vydate)	Phase V Rule
Pentachlorophenol	Phase IIB Rule
Picloram	Phase V Rule
Polychlorinated biphenyls (PCBs)	Phase II Rule
Selenium	Phase II Rule
Simazine	Phase V Rule
Styrene	Phase II Rule
2,3,7,8-TCDD (Dioxin)	Phase V Rule
Tetrachloroethylene	Phase II Rule
Thallium	Phase V Rule
Toluene	Phase II Rule
Toxaphene	Phase II Rule
2,4,5-TP (Silvex)	Phase II Rule
1,2,4-Trichlorobenzene	Phase V Rule
1,1,1-Trichloroethane	Phase I Rule
1,1,2-Trichloroethane	Phase V Rule
Trichloroethylene	Phase I Rule
Vinyl chloride	Phase I Rule
Xylenes (total)	Phase II Rule
Microorganisms	
Total coliforms (including fecal coliform and *E. coli*)	Total Coliform Rule (TCR)

Dates of original promulgation are as follows:

- Phase II Rule: 56 *FR* 3526, January 30, 1991 (USEPA, 1991a)
- Phase V Rule: 57 *FR* 31776, July 17, 1992 (USEPA, 1992)
- Phase IIB Rule: 56 *FR* 30266, July 1, 1991 (USEPA, 1991c)
- Phase I Rule: 52 *FR* 25690, July 8, 1987 (USEPA, 1987)
- LCR: 56 *FR* 26460, June 7, 1991 (USEPA, 1991b)
- Fluoride Rule: 51 *FR* 11396, April 2, 1986 (USEPA, 1986)
- TCR: 54 *FR* 27544, June 29, 1989 (USEPA, 1989b)

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

Table A-2: NPDWRs Not Covered by this Protocol
[1] Dates of original promulgation are as follows: – Arsenic Rule: 40 *FR* 59566, December 24, 1975 (USEPA, 1975) – Radionuclides Rule: 41 *FR* 28402, July 9, 1976 (USEPA, 1976) – IESWTR: 63 *FR* 69478, December 16, 1998 (USEPA, 1998c) – LT1ESWTR: 67 *FR* 1811, January 14, 2002 (USEPA, 2002a) – SWTR: 54 *FR* 27486, June 29, 1989 (USEPA, 1989b) – Stage 1 DBPR Rule: 63 *FR* 69389, December 16, 1998 (USEPA, 1998b) – TTHM Rule: 44 *FR* 68624, November 29, 1979 (USEPA, 1979) [2] Indicates date of rule revision. – Arsenic Rule: 66 *FR* 6976, January 22, 2001 (USEPA, 2001b) – Radionuclides Rule: 65 *FR* 76707, December 7, 2000 (USEPA, 2000c) [3] After promulgation of the revised arsenic NPDWR on January 22, 2001, EPA initiated a review of the new maximum contaminant level (MCL), and postponed the effective date of the rule until February 22, 2002. EPA requested independent expert panel reviews of the science, cost and benefits analyses for the January 2001 rule, and in July 2001, sought additional public comment on a range of MCLs. Following receipt of the final expert panel reports in the Fall of 2001, EPA requested comment on the reports. EPA will continue to evaluate the expert panel reports, the voluminous comments received during these comment periods, and other relevant information and comments as they become available as part of the next six-year review; EPA expects to make a final decision on whether to revise the January 2001 rule as part of that six-year review, which is due in August 2008. In the meantime, as announced by the Administrator on October 31, 2001, EPA will not further postpone the January 2001 rule, and EPA also does not expect to take any other additional action relative to the July 2001 proposal in the interim. The revised arsenic MCL became effective on February 22, 2002. The date for compliance with the MCL remains January 23, 2006. [4] Indicates anticipated date of promulgation.

Appendix B: Differences between the National Drinking Water Advisory Committee's (NDWAC's) Recommendations and this Protocol

This table indicates those NDWAC recommendations that EPA either did not incorporate or that EPA changed substantially in this protocol document. Overall, EPA incorporated the majority of the NDWAC's recommendations.

NDWAC Recommendation	EPA Response
EPA should review the basis of all existing National Primary Drinking Water Regulations (NPDWRs) during the first review round (i.e., the review round ending August 2002)	EPA does not believe that such a review is practical in light of resource constraints and has not incorporated it into the protocol. EPA will review the basis of existing regulations only if new data suggest the need for regulatory revision(s).
Effective with review rounds starting after August 2002, EPA should complete both the review and the revision within the six-year window.	This recommendation does not apply to the 1996-2002 review round.
EPA should fully consider "other regulatory revisions" (e.g., monitoring requirements system data reporting requirements, etc.) as a part of the Six-Year Review process.	EPA believes that many of these issues are best addressed through mechanisms other than the Six-Year Review process. Where appropriate alternative mechanisms to consider these issues are not available, EPA may consider them as a part of the Six-Year Review if they meet the following criteria: • they indicated a potential change in 40 CFR 141 requirements; • they are "ready" for rulemaking – that is, the problem to be resolved has been clearly identified and specific option(s) have been formulated to address the problem; and • they clearly improve the level of public health protection and/or represent significant cost-saving while maintaining or improving public health protection.
EPA should consider non-regulatory options, in addition to regulatory changes, if the costs of other regulatory compliance are considered to be too high or interim measures are needed pending promulgation of a rule.	EPA agrees that this suggestion has merit but believes it is outside the scope of the Six-Year Review effort and should be addressed through alternative mechanisms. The recommendation has not been incorporated into the protocol document.

NDWAC Recommendation	EPA Response
EPA should consider changes in State data-reporting requirements, as well as changes to system data-reporting requirements, as a part of the Six-Year Review process.	EPA believes that revisions to State data-reporting requirements are best considered through other mechanisms outside the scope of the Six-Year Review effort. The recommendation has not been incorporated into the protocol document.
EPA should consider multi-media mitigation options as a part of the Six-Year Review process.	Efforts to pursue multi-media mitigation for contaminants are outside the scope of the six-year process, except in those instances where the SDWA specifically authorizes EPA to consider a multi-media approach as a part of the NPDWR. Therefore, consideration of multi-media mitigation is outside the scope of the 1996-2002 Six-Year Review.
EPA should quantify, to the maximum extent practicable, costs and benefits associated with possible regulatory revisions.	EPA does not believe it is practicable to quantify costs and benefits during the review phase. This is best done as a part of the rulemaking phase before EPA proposes actual revisions. Instead, EPA will conduct a qualitative assessment of economic considerations for those NPDWRs where a health or technical basis exists for a possible regulatory revision.

Appendix C: Overview of the IRIS Assessments

The Integrated Risk Information System (IRIS) is an EPA database containing Agency consensus scientific positions on potential adverse human health effects that may result from chronic exposure to chemical substances found in the environment.[11] Assessments by IRIS undergo internal and external peer reviews by health scientists.

The main reasons for including a chemical in the IRIS program are (1) Agency statutory, regulatory, or program implementation needs; and (2) availability of new scientific information or new methodology that might significantly change current IRIS assessment.

IRIS assessments are based solely on scientifically valid studies. Evaluations of original toxicological and epidemiological studies conducted by the National Toxicology Program, National Cancer Institute, National Institute of Environmental Health Sciences, EPA's National Center for Environmental Assessment, industry, universities, etc., are all used in risk assessment. These studies are individually evaluated for their soundness, methodological strength and weaknesses, and whether or not they have been conducted according to current quality standards.

IRIS reviews are not based on secondary sources such as reviews conducted by other national or international organizations (e.g., State of California, World Health Organization or the International Agency for Research on Cancer), although such assessments are often examined as part of the IRIS review.

A full list of chemicals assessed in IRIS and those for which assessments are planned can be found on IRIS web site (http://www.epa.gov/iris). A large number of these IRIS assessments are of direct relevance to the regulatory function of Office of Water (OW) and more specifically to the six-year review. Some of the reviews are being conducted by OW. Others were nominated for review by OW.

[11] IRIS contains chemical specific health effects inform ation. Information on synergistic effects of chemical mixtures is scarce and is seldom available for inclusion in IRIS.

Appendix D: Overview of the OPP Process for Toxicity Assessments

Under the requirements of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a registrant (manufacturer) is required to submit animal toxicity data on the potential human health effects that may be posed by pesticide chemicals. Toxicity data are provided during the initial registration of a pesticide as well as during the periodic re-registration review of the pesticide as required by FIFRA. The schedule, priority, for when an existing pesticide enters a re-review is set in part by regulatory requirements which include provisions to give priority to certain active ingredients. The Office of Pesticides Programs (OPP) will establish the review schedule taking into account the procedures outlined in the Act. A more complete discussion of the re-registration process can be found in Section 4(a)-(f) of FIFRA.

In 1998, The Office of Water's (OW's) Office of Ground Water and Drinking Water (OGWDW) and the OPP established major areas of coordination on cross-cutting scientific issues. Included in the major efforts was the harmonization of the human health hazard assessments and dose-response relationships for pesticides. The two offices have agreed to share health effects data and coordinate activities on the issues such as endpoint selection, dose-response information, and quantifying risks. Therefore, the OW and OPP are working closely on establishing consistency in health effects endpoints through resource and information sharing.

The OPP receives health effects data that are generated under specific scientific guidelines established by the Agency and conducted under the requirements of Good Laboratory Practices. These guidelines are available on the EPA's Internet site at the following location: http://www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/indexx.html.

In addition to the required guideline studies, the OPP will obtain and review open literature data on adverse effects to test species. Although these studies are not used in establishing health end-points (reference doses (RfDs) and cancer potency or threshold values), they are used in establishing the "weight of evidence" for an adverse effect. Data sources include, but are not limited to, published, peer-reviewed journal articles in the open literature and toxicity data submitted to other U.S. federal or international agencies that do not conform to the OPP's test guidelines.

Below is a brief overview of end-point selection.

Toxicity Assessment

Non-Cancer Effects:

Reference Dose. For non-cancer effects, toxicity is represented by an RfD; it may be calculated for acute effects (acute RfD (aRfD)) and chronic effects (chronic RfD (cRfD)). RfDs are calculated by determining the No-Observed-Adverse-Effect Level (NOAEL) or bench-mark dose point of departure from either acute or chronic toxicity studies (the choice of study depends on which type of RfD is being calculated - aRfD or cRfD) and dividing it by the appropriate uncertainty factors. Typically, an uncertainty factor is applied to account for: variation within the human population (i.e., intraspecies); the differences between humans and animals as the

animal data are extrapolated to humans (interspecies); the duration of the study; the end point used in the calculation (NOAEL or Lowest-Observed-Adverse-Effect Level (LOAEL)); and the completeness of the database.

If the RfD will be used in dietary risk assessment, then it is adjusted to take into account the Food Quality Protection Act (FQPA) Safety Factor for infants and children. Such an adjusted RfD is called a Population Adjusted Dose (PAD). Like the RfD, it may be acute (aPAD) or chronic (cPAD). In making the decision regarding the FQPA Safety Factor, the Agency takes into account both information on the toxicity of the pesticide and the completeness of the toxicity and exposure databases. For more information on how the Agency applies the FQPA Factor, see the document "Standard Operating Procedures for use of FQPA Safety Factor," April 26, 1999 at http://www.epa.gov/pesticides/trac/science/. However, these standard operating procedures are currently under revision; and notification of the release of these revisions is posted at: http://www.epa.gov/oppfead1/trac/science.

Cancer Effects:

Linear Effect - *Cancer Potency Factor* (*q1**). The cancer potency factor, which is commonly known as a q1*, is the relative strength of a carcinogen. The bigger the q1*, the more potent the carcinogen. It is calculated using a computer model that assumes linearity at doses below which the effect occurred in the studies.

Non-Linear Effect - *Margin of Exposure*. For some carcinogenic pesticides, it is not considered appropriate to calculate a potency factor. In these cases, the cancer effect is assumed to have a threshold, as for non-cancer effects, and as such, a Margin of Exposure (MOE) is derived. The MOE is a ratio calculated by dividing the toxicity Point of Departure (such as a NOAEL or benchmark dose) by the estimated or calculated exposure level. EPA has not yet established a policy on the level of risk that is of no concern for non-linear cancer risk assessment.

During the review of the toxicity data and the dose-response assessment, the pesticide being evaluated undergoes review by several in-house peer review committees.

Appendix E: Overview of the Analytical Methods Review Process

A. What Section of SDWA Requires the Agency to Specify Analytical Methods?

The Safe Drinking Water Act (SDWA) directs EPA to promulgate National Primary Drinking Water Regulations (NPDWRs) which specify either maximum contaminant levels (MCLs) or treatment techniques (TTs) for drinking water contaminants (SDWA section 1412; 42 U.S.C. § 300g-1). According to SDWA (Section 1401(1)(D)), NPDWRs include "criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including accepted methods for quality control and testing procedures to insure compliance with such levels." (42 U.S.C. § 300f(1)(D)) Moreover, EPA is to set an MCL for such NPDWRs "if, in the judgement of the Administrator, it is economically and technologically feasible to ascertain the level of a contaminant in water in public water systems." (SDWA section 1401(1)(C)(i); 42 U.S.C. § 300f(1)(C)(i)). Alternatively, if it is not economically or technologically feasible to so ascertain the level of a contaminant, the Administrator may identify known TTs, which sufficiently reduce the contaminant in drinking water, in lieu of an MCL (SDWA section 1401(1)(C)(ii)).

B. What is the Typical Process for Approving Methods for SDWA Analytes?

Methods are initially approved as a part of an MCL or monitoring requirement rulemaking. Thereafter, as revisions to the approved methods are published or as new technologies are developed, the Agency, from time-to-time, will group a set of methods for proposal in a methods update rule. It generally takes 18 to 24 months to promulgate a methods update rule. This can increase significantly if there is adverse public comment on a proposed method.

The revised or new methods included in a methods update rule may be from EPA, other Federal or State agencies, or standards organizations (e.g. American Society for Testing and Materials (ASTM) or Standard Methods (SM)). These non-EPA entities have independent review and/or collaborative testing requirements. In addition, under 40 CFR 141.27 (alternate analytical techniques, also known as alternate test procedures or ATP) methods may also be developed by private laboratories, vendors or groups. Independent review and collaborative testing of these privately developed methods is accomplished by requiring submission of the method to the Agency under the alternate test procedure (ATP) program. An alternate technique is accepted "only if it is substantially equivalent to the prescribed test in both precision and accuracy as it relates to the determination of compliance with the MCL." (40 CFR 141.27(a)) Initially, many ATP applications are missing data. Once a completed ATP application is recorded by the Agency, the ATP pass/fail decision generally takes three to four months. For successful ATPs, this period is followed by the formal rulemaking process, which was described above as taking 18-24 months.

C. What Factors Does the Agency Consider in Approving Analytical Methods and in Determining Feasible Limits?

In deciding whether an analytical method is economically and technologically feasible to determine the level of a contaminant in drinking water, the Agency generally considers the following (50 *FR* 46880, November 13, 1985 (USEPA, 1985); 52 *FR* 25690, July 8, 1987 (USEPA, 1987); 54 *FR* 22062, May 22, 1989a):

- Is the method sensitive enough to address the level of concern (i.e., is quantitation sufficient to meet the MCL)?
- Does the method give reliable analytical results at the MCL? What is the precision (or reproducibility) and the bias (accuracy or recovery)?
- Is the method specific? Does the method identify the contaminant of concern in the presence of potential interferences?
- Is the availability of certified laboratories, equipment and trained personnel sufficient to conduct compliance monitoring?
- Is the method rapid enough to permit routine use in compliance monitoring?
- What is the cost of the analysis to Water Supply systems?

Regarding the first criteria (i.e., sensitivity), the method detection limit (MDL) and the practical quantitation level (PQL) are two performance measures used by EPA to estimate the limits of performance of analytic chemistry methods for measuring contaminants in drinking water. For SDWA analytes, EPA defines the MDL as "the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero"(40 CFR Part 136 Appendix B). MDLs can be operator, method, laboratory, and matrix specific. MDLs are not necessarily reproducible within a laboratory or between laboratories on a daily basis due to the day-to-day analytical variability that can occur and the difficulty of measuring an analyte at very low concentrations. In an effort to integrate this analytical chemistry data into regulation development, the Agency uses the PQL to estimate or evaluate the minimum, reliable quantitation level that most laboratories can be expected to meet during day-to-day operations. EPA's Drinking Water program generally defines the PQL as "the lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions" (50 *FR* 46906, November 13, 1985 (USEPA, 1985)) For several SDWA analytes, EPA has set the MCL at the PQL.

D. How Are PQLs Typically Determined for SDWA Contaminants?

Historically, EPA's OGWDW has used two main approaches to determine a PQL for SDWA analytes. The preferred approach, the WS method, uses data from WS studies to calculate the lower limit of quantitation. The WS method was used in most cases when sufficient WS data are available to calculate a PQL. In the absence of WS data, the second approach that EPA used was the MDL multiplier method. In this approach, the PQL was calculated by multiplying the EPA-derived MDL by a factor of 5 or 10. The 5 or 10 multiplier was used to account for the variability and uncertainty that can occur at the MDL.

1. How Were Water Supply Studies Conducted?

Water supply laboratory performance evaluation (PE) studies have been an integral part of EPA's certification program for drinking water laboratories for over 20 years. Historically, EPA's National Exposure Research Laboratory (NERL) in Cincinnati, Ohio conducted WS studies for all current and proposed drinking water contaminants. Although EPA conducted the WS studies semi-annually, for certification purposes, laboratories were only required to demonstrate acceptable performance once a year (141.23(k)(3) and 141.24(f)(17)).

Each WS study included WS samples (or sample concentrates) that were analyzed for both SDWA analytes and analytes being considered for regulation under the SDWA. During these WS studies, EPA-NERL sent participating laboratories a set of the stable WS sample concentrates in sealed glass ampules, a data reporting form, and appropriate instructions. EPA-NERL sent WS samples to all laboratories that conducted drinking water analyses, including utility laboratories, commercial laboratories, and State and EPA Regional laboratories. With appropriate dilution, the laboratory then analyzed the WS samples using the specified procedures. Afterwards, the laboratory sent the completed reporting form to EPA for evaluation. After evaluation, EPA returned a fully detailed report to each participating laboratory.

At this point in time, WS PE studies are no longer performed by EPA. On July 18, 1996 (61 *FR* 37464 (USEPA, 1996)), EPA proposed options for the externalization of the PE studies program (now referred to as the Proficiency Testing or PT program). After evaluating public comment, in the June 12, 1997 final notice EPA stated that the Agency has decided (62 *FR* 32113 (USEPA, 1997b)):

> *...on a program where EPA would issue standards for the operation of the program, the National Institute of Standards and Technology (NIST) would develop standards for private sector PE (PT) suppliers and would evaluate and accredit PE suppliers, and the private sector would develop and manufacture PE (PT) materials and conduct PE (PT) studies. In addition, as part of the program, the PE (PT) providers would report the results of the studies to the study participants and to those organizations that have responsibility for administering programs supported by the studies.*

2. PQL Determinations - How Are WS Studies Evaluated and What Criteria Are Used?

The derivation of the PQL involves determining the concentration of an analyte at which a set percentage of the laboratories achieve results within a specified range of the spiked value. Historically, the percentage of laboratories was set at 75 percent, while a range of acceptance limits around the spiked value were used. In many cases, EPA derived PQLs only from the data submitted by the EPA Regional and State laboratories that participate in the WS studies.

A PQL derived from WS data in such a manner is considered a stringent target for routine laboratory performance because:

- WS samples are prepared in reagent water and therefore do not contain the matrix interferences that may occur in field samples.

- Laboratories analyze only a small number of samples for the study and are aware that the samples are for the purposes of PE (i.e., they are not "blind" samples).

In deriving a PQL from WS study data, the Agency typically sets a fixed percentage or 2 sigma (2 standard deviation) acceptance window around the known concentration (or spike value) of the WS samples. Then percentage of laboratories achieving results within the specified acceptance window (y-axis) is plotted against the known spike concentration of the Water Supply study samples (x-axis). While the acceptance limits for inorganics typically range from 15 to 30 percent, the acceptance limits for organics generally range from 40 to 50 percent. Several SDWA analytes have acceptance limits of 2 sigma (2 standard deviation). Linear regression or graphical analysis is performed on the WS data to determine the concentration at which 75 percent of EPA Regional and State laboratories achieve acceptable results.