

Review of National Primary Drinking Water Regulations: Overall Development Process

*(This Issue Paper Is for Stakeholder Discussion and
May Not Reflect Official EPA Policy)*

BACKGROUND

The U.S. Environmental Protection Agency (EPA) is in the process of implementing provisions related to the review and setting of the nation's drinking water standards. The mandate upon which the EPA is acting is contained within the Safe Drinking Water Act (SDWA), as amended. Section 1412(b)(9) of SDWA reads:

"The Administrator shall, not less than every 6 years, review and revise, as appropriate, each national primary drinking water regulation (NPDWR) 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."

This paper relates to the process and strategy EPA proposes to use, subject to comments and other input of the diverse stakeholders involved in drinking water and its protection. First, it is important to outline how EPA proposes to approach the 6-year review mandate:

- As a part of the review process, EPA proposes to subject regulated contaminants to an evaluation, based on available data, to determine whether the Agency could justify possible rule revisions. For example, new health effects findings and/or new laboratory methods for analyzing the subject contaminants may be available that suggest the need to revise a maximum contaminant level goal (MCLG) and/or a maximum contaminant level (MCL). In order to initiate a sound review process, EPA is developing a protocol that would be used henceforward. It is possible that some degree of prioritizing will be required throughout the review process.
- Based upon the review, EPA may decide to revise drinking water standards. Regulation of a contaminant could conceivably be revised in any of the following ways: change the MCLG; change the maximum contaminant level MCL; modify monitoring and/or treatment requirements; or drop a contaminant from regulations if it is no longer a public health concern. Any revision to a regulation must result in an equal or greater level of health protection and present a meaningful opportunity for reduction of public health risks.

In the above process, EPA assumes that, unless information to the contrary exists, the existing regulations are adequate, i.e., that an in-depth review would only be pursued where reliable data are available that indicate a need to re-evaluate a NPDWR. The Agency will require defensible, scientific methods to carry out a review leading to a revision: per Section 1412 of SDWA, as amended, EPA must use defensible methods

including quality assurance measures to ensure that scientifically sound results are used in final decisions for regulatory revisions.

The following sections describe in greater detail "what," "how" and "when" EPA expects to go forward in this regard to meet the 2002, first 6-year deadline.

Overall Goals for August 2002

As mentioned, the first six-year period ends in August 2002, six years following enactment of the 1996 SDWA Amendments. While SDWA states that EPA is to review and revise the regulations every six years, EPA does not believe it is practicable to complete the rule changes by 2002. EPA's intention is that by August 2002 the Agency will complete the review process, and then proceed to revise regulation as appropriate. By August 2002 the Agency will identify which NPDWRs are to be revised, and produce a schedule for completing the necessary rule changes. EPA is soliciting comment on this, and on several other concerns.

The following are the major milestones for meeting the schedule.

- August 2000 - Publish a protocol for selection of NPDWRs to undergo full review process
- August 2001 - Publish a draft notice identifying which NPDWRs EPA will plans to revise, and why, along with draft supporting materials
- August 2002 - Publish a final notice with EPA determinations and a schedule for revising selected NPDWRs

ISSUES/METHODS

NPDWRs to be Considered

For the first 6-year review period, EPA plans to review all NPDWRs promulgated prior to August 1996 (see listing attached), with the exception of those contaminants for which rulemaking is scheduled to occur between now and August 2002 or for which reviews already are planned on their own schedule. The Agency believes that it has already made progress in reviewing and revising existing NPDWRs through current regulation development for the following: arsenic, radionuclides (gross alpha, beta emitters, and radium-226/228), microbial contaminants under the surface water treatment rule, the ground water rule, and disinfection byproducts. Also, EPA notes that atrazine and copper are being reviewed on a separate schedule, and that the Total Coliform Rule (TCR) may fall within the subject review. It should be noted that the processes described within this and other attached issue papers were developed for addressing chemical contaminants and not specifically for addressing microbial contaminants, which may require additional considerations.

NPDWRs not included in the 2002 round may be reviewed on 6-year cycles based on the date of their promulgation, or possibly on an alternative 6-year cycle. The Agency may

decide to: (i) cluster these contaminants for review and revision on one separate cycle, or (ii) consolidate them in the 2008 cycle with NPDWRs included in the current round in order to minimize the number of review efforts. EPA is seeking stakeholder input as to whether the review, as mentioned above, will be a reasonable approach.

The Protocol

During the first year of this project, EPA will develop an overall protocol to use during this and subsequent review rounds.

As part of protocol development, EPA is developing initial screens to apply to each NPDWR being reviewed. These initial screens will include subjecting the contaminants to reviews of health effects and technology-related information. These screens and other factors such as occurrence and monitoring are discussed in separate issue papers which are attached.

The initial analyses will likely identify a number of contaminants for which no further review is needed, for example due to a lack of new health data: these contaminants would therefore be dropped from further consideration as possible candidates for revision during the current round. Subsequent analysis would be required on contaminants that were "caught" in the screening process. During this phase of the review, EPA would determine whether sufficient data are available on which to base a rulemaking. For example, even though the initial screening suggests a lower MCLG/MCL, no methods may be available to detect at lower levels. Data gaps identified during this process would be considered, and may be utilized in prioritizing research needs. For the contaminants that remain as potential candidates for revision, EPA will determine priorities for rulemaking. During this process the status of analytical and/or treatment technologies, occurrence/exposure assessments, monitoring requirements, and rough estimates of benefits and costs will be considered.

[Attached is a diagram](#) depicting the proposed strategy for the 6-year review to help the reader visualize key components of the process-- all of which are to be further developed. It is again noted that the attached diagram does not specifically address microbiological contaminants, which are to given further consideration. EPA seeks stakeholder input in regard to the protocol and it's components.

Later Stages of the Review

Once the protocol has been applied to the regulated contaminants, the Agency will publish draft and final listings of NPDWRs to be revised, i.e., in 2001 and 2002, respectively. The types and levels of analyses have yet to be determined but would be fully disclosed in the notices.

The final FR notice in 2002 is expected to announce (1) the NPDWRs which EPA proposes to revise, and (2) discussion of processes and schedules by which EPA will propose and promulgate revisions.

KEY QUESTIONS FOR STAKEHOLDERS

- Will meeting the August 2002 goal described above be sufficient to satisfy the statutory requirement?
- Should EPA review NPDWRs that were promulgated/reviewed since 1996 on their own separate 6-year cycles; or, consolidate into one distinct cycle or, alternatively, into the second 6-year cycle ending in 2008?
- Are there circumstances under which it might be appropriate for EPA to deregulate a contaminant (e.g., very low occurrence/exposure)?
- Are there factors EPA should be considering initially within the protocol other than those discussed? At what point in the analysis should costs and benefits be considered? Other comments on the draft protocol?
- Please address written comments on the discussion questions to the Office of Ground Water and Drinking Water
 - **Mailing Address:**
Office of Ground Water and Drinking Water (4601)
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0003
 - **Phone and Fax:**
Phone: 202-564-3750
Fax: 202-564-3753 (Director's office)