

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 141 and 142**

[WH-FRL-7015-4]

RIN 2040-AB75

National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of proposed rulemaking.

SUMMARY: Today's action proposes and requests comment on a range of MCL options for the drinking water standard for arsenic. In particular, EPA is requesting comment on whether the data and technical analyses associated with the arsenic rule published in the January 22, 2001, **Federal Register** (66 FR 6976) as well as any new information that may be available would support setting the enforceable arsenic standard, or Maximum Contaminant Level (MCL), at 3 micrograms per liter ($\mu\text{g/L}$) (the feasible level), 5 $\mu\text{g/L}$ (the level proposed in June 2000), 10 $\mu\text{g/L}$ (the level published in the January 2001 rule), or 20 $\mu\text{g/L}$.

To assist commenters, today's document provides a brief summary of the principal data and technical analyses that accompanied the January 2001 arsenic rule and solicits comment on key issues associated with this information and analyses. In providing comment on these issues, commenters should focus on the preamble, technical support documents, and record associated with the January 2001 rule (not the June 2000 proposal (65 FR 38888)) because EPA made many changes to the analyses supporting the January decisions in response to public comment on the June 2000 proposal. In developing comments, commenters may also wish to consider information EPA plans to have in a notice in the fall of 2001, which will request comment on the results of the additional analyses of key scientific, technical and economic elements of the rule. The comment period for today's notice ends October 31, 2001, because the Agency expects this comment period to overlap with the fall 2001 notice's comment period on the scientific, cost, and benefits reviews.

On May 22, 2001, EPA published in the **Federal Register** (66 FR 6976) a final rule delaying the effective date of the arsenic rule until February 22, 2002, in order to conduct reviews of the science and costing analyses. Additional information about these reviews as well

as a review of the benefits analysis for the January 22, 2001, rule are provided in today's document. EPA expects the results of these reviews to be available within the comment period for today's proposal.

This proposal does not affect the clarifications to compliance and new source contaminants monitoring regulations also issued on January 22, 2001, (66 FR 6976), for inorganic, volatile organic, and synthetic organic contaminants. Those regulations go into effect on January 22, 2004, as provided in the January 22, 2001, final rule.

DATES: Your comments on a range of arsenic MCLs from 3 $\mu\text{g/L}$ to 20 $\mu\text{g/L}$ must be in writing and either postmarked or received by EPA's Water Docket by October 31, 2001.

ADDRESSES: You may mail your written comments to the W-99-16-VI Arsenic Comments Clerk, Water Docket (MC-4101); U.S. EPA; 1200 Pennsylvania Avenue, NW.; Washington, DC 20460. Comments may be hand delivered (e.g., courier or overnight delivery service) to EPA's Water Docket, located at 401 M Street, SW.; East Tower Basement Room 57; in Washington, DC; between 9 a.m. and 3:30 p.m. Eastern Time, Monday through Friday. Comments may be submitted electronically to *owdocket@epa.gov*. See **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing and docket review.

FOR FURTHER INFORMATION CONTACT: The Safe Drinking Water Hotline, phone: (800) 426-4791 or (703) 285-1093, e-mail: *hotline-sdwa@epa.gov* for general information, meeting information, and copies of arsenic regulations and support documents. For inquiries about the on-going cost of compliance review, contact: Mr. Amit Kapadia, (202) 260-1688, e-mail: *kapadia.amit@epa.gov*. For all other questions about this document, contact Irene Dooley, (202) 260-9531, e-mail: *dooley.irene@epa.gov*.

SUPPLEMENTARY INFORMATION:**Regulated Entities**

A public water system (PWS), as defined in 40 CFR 141.2, provides water to the public for human consumption through pipes or other constructed conveyances, if such system has "at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year." A public water system is either a community water system (CWS) or a non-community water system (NCWS). A community water system, as defined in § 141.2, is "a public water system which serves at least fifteen service connections used by

year-round residents or regularly serves at least twenty-five year-round residents." The definition in § 141.2 for a non-transient non-community water system (NTNCWS) is "a public water system that is not a [CWS] and that regularly serves at least 25 of the same persons over 6 months per year." EPA has an inventory totaling over 54,000 CWSs and approximately 20,000 NTNCWSs nationwide. Entities potentially regulated by this action are CWSs and NTNCWSs. The following table provides examples of the regulated entities under this rule.

TABLE OF REGULATED ENTITIES

| Category | Examples of potentially regulated entities |
|---|--|
| Industry | Privately owned/operated community water supply systems using ground water, surface water, or mixed ground water and surface water. |
| State, State, Tribal, and Local Government. | State, Tribal, or local government-owned/operated water supply systems using ground water, surface water, or mixed ground water and surface water. |
| Federal Government. | Federally owned/operated community water supply systems using ground water, surface water, or mixed ground water and surface water. |

The table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in §§ 141.11 and 141.62 as revised by the January 22, 2001 (66 FR 6976) arsenic rule.

Additional Information for Commenters

No facsimiles (faxes), compressed or zipped files will be accepted, and comments must be submitted in writing. In providing comment on these issues, commenters should focus on the preamble, technical support documents, and record associated with the January 2001 arsenic in drinking water regulation (not the June 2000 proposal (65 FR 38888)). EPA addressed comments prepared for the June 2000 proposed rule in the response-to-comments document in the docket for W-99-16-III and summarized responses

to the major comments in the preamble of the January 2001 regulation. Please submit an original and three copies of your comments and enclosures (including references) and identify your submission by the docket number W-99-16-VI. To ensure that EPA can read, understand, and therefore properly respond to comments, the Agency would prefer that comments cite, where possible, the question(s) or sections and page numbers in the document or supporting documents to which each comment refers. Commenters should use a separate paragraph for each issue discussed. Commenters who want EPA to acknowledge receipt of their comments should include a self-addressed, stamped envelope.

EPA uses WordPerfect as its standard software, so electronic submissions (including 3.5 inch floppy disks) must be submitted in WordPerfect 8 (or older version) or ASCII file format (unless four hard copies are also submitted). Comments submitted in other electronic formats (e.g., Word, pdf, Excel, and compressed or zipped files) must also be submitted as hard copies. For purposes of dating dual hard copy/electronic copy submissions, the date of the electronic copy will be recorded as the date submitted. Please indicate that you are sending hard copies so the Docket can link your two submissions rather than log in two sets of your comments. Electronic comments on this document may be filed online at many Federal Depository Libraries.

The Agency's response-to-comments document for W-99-16-VI will address the comments received for this proposal, and this document will be made available in the docket. Since the comment period ends October 31, 2001, the response-to-comment document will not be completed until sometime later in the fall of 2001. To facilitate development of a response-to-comments document, EPA appreciates receiving an electronic version in addition to the original and three copies for large submissions (e.g., over 10 pages). The Agency does not send out individual replies to respond to those who submit comments.

Availability of Docket

For an appointment to review the docket for this rulemaking, call (202) 260-3027 between 9 a.m. and 3:30 p.m. Eastern Time, Monday through Friday and refer to Docket W-99-16-VI. Every user is entitled to 100 free pages, and after that the Docket charges 15 cents a page. Users are invoiced after they copy \$25, which is 267 photocopied pages. The Safe Drinking Water Hotline can provide some hard copies of some of the

supporting documentation and some electronically, phone: (800) 426-4791 or (703) 285-1093, e-mail: hotline-sdwa@epa.gov. EPA's arsenic-in-drinking-water web page contains links to the arsenic **Federal Register** notices and other supporting material at www.epa.gov/safewater/arsenic.html.

Abbreviations Used in This Proposed Rule

>—greater than
 <—less than
 §—section
 µg—micrograms, one millionth of a gram (3.5 × 10⁻⁸ ounce, 0.000000035 oz.)
 µg/L—micrograms per liter, same as parts per billion (ppb)
 AES—Atomic emission spectroscopy
 ARBRP—Arsenic Rule Benefits Review Panel of SAB
 AWWARF—American Water Works Association Research Foundation
 BAT—Best available technology
 CCR—Consumer Confidence Report
 CFR—Code of Federal Regulations
 CWS—Community water system
 DWSRF—Drinking Water State Revolving Fund
 EA—Economic analysis
 EO—Executive Order
 EPA—U.S. Environmental Protection Agency
 ERDDAA—Environmental Research, Development, and Demonstration Authorization Act, SAB
 FACA—Federal Advisory Committee Act
 FR—**Federal Register**
 FRFA—Final regulatory flexibility analysis
 FSIS—Federalism summary impact statement
 GW—Ground water
 ICP—Inductively coupled plasma
 ICR—Information Collection Request
 ISCV—Intra-system coefficient of variation
 IRFA—Initial regulatory flexibility analysis
 ISCV—Intra-system coefficients of variation
 L—Liter, also referred to as lower case "l" in older citations
 MCL—Maximum contaminant level
 MCLG—Maximum contaminant level goal
 mg—milligrams, one thousandth of a gram, 1 mg = 1,000 µg
 mg/L—milligrams per liter
 NAS—National Academy of Sciences
 NCWS—Non-community water system
 NDWAC—National Drinking Water Advisory Council, EPA FACA group
 NODA—Notice of Data Availability
 NPDWR—National primary drinking water regulation
 NRC—National Research Council, the operating arm of NAS
 NTNCWS—Non-transient non-community water system
 NTTAA—National Technology Transfer and Advancement Act
 OMB—Office of Management and Budget
 P.L.—Public Law
 PNR—Public Notification Rule
 POTW—Publicly owned treatment works, wastewater treatment
 POU—Point-of-use treatment devices
 PRA—Paperwork Reduction Act
 PWS—Public water systems
 REF—Relative exposure factors
 RFA—Regulatory Flexibility Act
 RUS—Rural Utilities Service

SAB—Science Advisory Board
 SBA—Small Business Administration
 SBAR—Small Business Advocacy Review
 SBREFA—Small Business Regulatory Enforcement Fairness Act
 SDWA—Safe Drinking Water Act
 SW—Surface water
 UMRA—Unfunded Mandates Reform Act
 U.S.—United States
 USGS—U.S. Geological Survey
 VSL—Value of statistical life
 WTP—Willingness to pay

Table of Contents

- I. Background and History Preceding This Document
 - A. What is in the arsenic rule published on January 22, 2001?
 1. Summary of arsenic regulation
 2. Changes to the Consumer Confidence Report (CCR) for arsenic
 3. Changes to public notification for arsenic
 4. Arsenic rule's effect on State/Tribal primacy programs
 - B. What did EPA's Administrator announce on March 20, 2001?
 - C. How has the effective date of the arsenic rule changed?
 1. March 23, 2001 **Federal Register** 60-day delay notice
 2. April 23, 2001 **Federal Register** 9-month extension proposal
 3. May 22, 2001 **Federal Register** February 22, 2002 effective date
 4. Effect on CCR for calendar year 2001
 - D. With what regulatory standard for arsenic must systems comply now?
- II. EPA's Plans to Review Parts of the Arsenic Rule
 - A. What is the purpose of today's action and what happens now?
 - B. What approach will EPA use to review the science, costs, and benefits of the rule?
 1. Overview
 2. Approach to review of health science
 3. Approach to review of cost of compliance estimates
 4. Approach to review of benefits estimates
 - C. How did EPA assess the occurrence of arsenic?
 1. Summary of arsenic occurrence analysis
 2. Request for occurrence comments
 - D. How did EPA evaluate the health risks of arsenic in drinking water?
 1. Summary of health risk elements
 2. Request for comment on health issues
 - E. How did EPA calculate the national costs of compliance with the arsenic in drinking water rule?
 1. Summary of cost elements of January 22, 2001 rule and record
 2. List of cost issues and request for comments
 - F. How did EPA calculate the benefits of the arsenic rule?
 1. Summary of the January 22, 2001, benefits assessment
 2. List of key benefit analysis issues
 - a. Discounting benefits over a cancer latency period
 - b. Consideration of non-quantifiable benefits in the regulatory decision-making process
 3. Request for comments on benefits

- G. What process is EPA planning for review of financial, technical, and planning tools for small systems?
1. Small system review process
 2. List of small system issues
 - a. Affordability, availability of financial assistance, and treatment technology
 - b. SDWA Capacity Development Framework
 3. Request for small systems comment
- III. Process to be Employed after Technical Reviews and Public Comment
- A. How will EPA notify the public of results of the technical reviews and the nature of the public comments?
 - B. What process will EPA use to make final decisions on the rule?
- IV. Administrative Requirements
- A. Executive Order 12866, Regulatory Planning and Review
 - B. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.
 - C. Unfunded Mandates Reform Act (UMRA) of 1995
 - D. Paperwork Reduction Act (PRA)
 - E. National Technology Transfer and Advancement Act
 - F. Executive Order 12898: Environmental Justice
 - G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
 - H. Executive Order 13132, Federalism
 - I. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments
 - J. Consultations with the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services
 - K. Likely Effect of Compliance With the Arsenic Rule on the Technical, Financial, and Managerial Capacity of Public Water Systems
 - L. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- V. References

I. Background and History Preceding This Document

A. What Is in the Arsenic Rule Published on January 22, 2001?

1. Summary of Arsenic Regulation

In the Monday, January 22, 2001, **Federal Register** (EPA 2001a), EPA issued regulations revising the arsenic drinking water standard and clarifying compliance and new-source contaminants monitoring provisions (66 FR 6976). The Agency established a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero milligrams per liter (mg/L) in § 141.15(b) and an enforceable Maximum Contaminant Level (MCL) for arsenic of 0.01 mg/L (*i.e.*, 10 micrograms per liter (µg/L)) for both community water systems (CWSs)

and non-transient non-community water systems (NTNCWSs) in § 141.62(b)(16). (Although EPA lists drinking water standards in Title 40 of the Code of Federal Regulations (40 CFR) in units of mg/L, except where noted, the Agency will refer to arsenic concentrations in µg/L in this preamble.) As part of the arsenic regulation, EPA also listed the approved analytical methods to measure compliance (§ 141.23(k)(1)), as well as the best available technologies (BAT) (§ 141.62(b)), small system technologies that could achieve compliance with the MCL (§ 141.62(d)), consumer confidence report requirements for CWSs, and public notification requirements for PWSs for the new MCL. Because the Agency identified affordable technologies for small systems, the rule did not list any small system variance technologies under § 1412(b)(15)(A) of the Safe Drinking Water Act (SDWA).

All but one of the five existing arsenic analytical technologies can be used for compliance determinations. As noted in the June 2000 proposal (65 FR 38888 at 38913) and January 2001 rule (66 FR 6976 at 6988), inductively coupled plasma (ICP)—atomic emission spectroscopy (AES) methods in EPA Method 200.7 and Standard Methods 3120 B have unacceptably high detection limits (see footnote 15 to table in § 141.23(k)(1); 66 FR 6976 at 7062).

EPA established an effective date of March 23, 2001, and a compliance date (§ 141.6(j)) for the arsenic regulation of January 23, 2006, five years after issuance for all systems. However, the consumer confidence reporting requirements for arsenic listed in § 141.6(j) had a March 23, 2001 compliance date.

EPA intended to issue a small entity implementation or compliance guide shortly after issuing the rule (66 FR 6976 at 7033). However, because of the on-going reviews, the Agency believes that it is premature to distribute small entity guidance at this time.

2. Changes to the Consumer Confidence Report (CCR) for Arsenic

On August 19, 1998, EPA issued part 141 subpart O, the final rule requiring community water systems to provide annual water quality report to their customers (63 FR 44512; EPA, 1998a). Reports are now due by July 1 for the preceding calendar year (§ 141.152(a)). Any time arsenic is detected, the report must list the MCL (50 µg/L), the MCLG (none), and the highest level used to determine compliance and the range of detected levels, according to §§ 141.153(d)(4)(i), (ii), and (iv), respectively. Section 141.153(d)(6) requires the CCR to identify MCL

violations, steps taken to address violations, and potential health effects using the language in appendix A of subpart O. In addition, using the authority of section 1414(c)(4)(B)(vi) of SDWA (63 FR 44512 at 44514), systems that detect arsenic between 25 µg/L and 50 µg/L are also required to provide an informational statement (§ 141.154(b)).

As published, the arsenic rule would make two reporting changes for systems detecting arsenic below 50 µg/L that would affect the CCR due by July 1, 2002, for calendar year 2001 (66 FR 6976 at 6991). First, CWSs would be required to include a revised informational statement (§ 141.154(b)) about arsenic when detected from 5 µg/L to 10 µg/L. In the arsenic rule, the Agency retained § 141.154(b) reporting requirements because the MCL is higher than the technologically feasible MCL (66 FR 6976 at 6991). Second, as proposed in § 141.154(b) and finalized in § 141.154(f), systems detecting from 10 µg/L to 50 µg/L would also provide the arsenic health language in appendix A to subpart O (§ 141.154(f)), even though systems are in compliance with the 50 µg/L MCL through January 22, 2006. (January 23, 2006, is the effective date for the MCL of 10 µg/L (§ 141.60(b)(4)).) As explained in section I.C.4, the current 9-month extension of the effective date until February 22, 2002, affects the CCR requirements of the January 2001 rule for calendar year 2001 reports.

3. Changes to Public Notification for Arsenic

On May 4, 2000, EPA issued the final Public Notification Rule (PNR) to revise the minimum requirements that public water systems must meet for public notification of violations of EPA's drinking water standards (65 FR 25982; EPA, 2000b). Systems must begin to comply with the revised PNR regulations on October 31, 2000 (if they are in jurisdictions where the program is directly implemented by EPA, such as Wyoming and many Tribes), or on the date that a primacy State/Tribe adopts the new requirements (no later than May 6, 2002).

The January 2001 arsenic rule would require CWSs and NTNCWSs to provide a Tier 2 public notice for arsenic MCL violations (> 10 µg/L) and to provide a Tier 3 public notice for violations of the monitoring and testing procedure requirements. In addition, public water systems must give notice for all violations when operating under a variance or exemption and for violating conditions of the variance or exemption. The arsenic regulation (66 FR 6976) amended the PNR, subpart Q of part

141, for purposes of compliance starting January 23, 2006 (§ 141.6(j); 66 FR 6976 at 7061).

4. Arsenic Rule's Effect on State/Tribal Primacy Programs

States must submit applications for revised primacy no later than 2 years after promulgation of a new standard unless the State requests and is granted an additional 2-year extension. Interim primacy enforcement authority (§ 142.12(e)) allows States to implement and enforce drinking water regulations once State regulations are effective and the State has submitted a complete and final primacy revision application.

In the arsenic rule, EPA reduced requirements for submitting revisions for existing regulated contaminants (§§ 142.16(e) and (j)), so that information required in § 142.16(e) is not required for States revising the MCL for arsenic. In addition, revisions to § 142.16(j) clarified that States may inform the Agency in their applications of any changes to their existing monitoring plans and waiver procedures. These regulations are effective for purpose of compliance on January 22, 2004 (§ 141.6(k); 66 FR 6976 at 7061).

Currently, the Navajo Nation is the only federally recognized Indian Tribe with primacy to enforce drinking water regulations. EPA Regions implement the rules for all other Tribes under section 1451(a)(1) of SDWA. Tribes must submit a primacy application (§ 142.76) to have oversight for the inorganic contaminants (*i.e.*, the Phase II/V rule) to obtain the authority for the revised arsenic MCL. Tribes with primacy for drinking water programs are eligible for grants and contract assistance (section 1451(a)(3) of SDWA). Tribes are also eligible for grants under the Drinking Water State Revolving Fund Tribal set-aside grant program authorized by section 1452(i) of SDWA for public water system expenditures.

EPA is aware of the practical implications of the ongoing reviews and delayed effective date on States and Tribes in terms of primacy and other requirements. EPA will consult with States and interested Tribes before addressing the effects on State primacy in future **Federal Register** notices.

B. What Did EPA's Administrator Announce on March 20, 2001?

On March 20, 2001, the Administrator announced in a press release that EPA would delay the effective date for the arsenic rule 60 days. That extension was in accordance with the White House (WH) memorandum of January 20, 2001, entitled "Regulatory Review Plan,"

which was published in the **Federal Register** (WH 2001) on January 24, 2001 (66 FR 7702). The January 20, 2001, memorandum from Andrew Card, Assistant to the President and Chief of Staff, communicated the President's plan to ensure that his appointees had the opportunity to review new regulations "at the outset of his Administration" in order to avoid "costly, burdensome, or unnecessary regulation * * *." For regulations that had been published in the **Federal Register**, but were not yet in effect, the memorandum requested departments and agencies to postpone their effective dates for 60 days. In order to provide safe and affordable drinking water, the Administrator announced plans to seek independent reviews of the science behind the arsenic standard and the cost estimates used to develop the rule.

C. How Has the Effective Date of the Arsenic Rule Changed?

1. March 23, 2001 **Federal Register** 60-Day Delay Notice

On March 23, 2001 (EPA 2001b), the **Federal Register** published EPA's 60-day delay of the effective date for the arsenic regulation (66 FR 16134), in accordance with the White House memorandum, "Regulatory Review Plan" (66 FR 7702). The delay changed the effective date for the arsenic regulation from March 23, 2001, to May 22, 2001, including the dates for compliance with the consumer confidence reporting requirements for § 141.154(b) and (f) that were specifically linked to the new arsenic regulation.

2. April 23, 2001 **Federal Register** 9-Month Extension Proposal

On April 23, 2001 (EPA 2001c), EPA proposed (66 FR 20580) to extend the effective date for the arsenic rule from May 22, 2001, to February 22, 2002, in order to obtain independent reviews of the science, cost, and benefit analyses used to support the arsenic in drinking water regulation. The notice outlined the process for the science and cost reviews.

3. May 22, 2001 **Federal Register** February 22, 2002 Effective Date

After reviewing the comments received on the 9-month proposed delay of the effective date, the Agency issued a final rule (EPA 2001f) on May 22, 2001 (66 FR 28342), delaying the final effective date until February 22, 2001, so the Agency could proceed as planned with the proposed reviews and opportunities for additional public comment. EPA identified mechanisms

for reviewing the science and cost estimates in the notice and provided responses to comments in the preamble (66 FR 28342 at 28345) that are in the response-to-comment document for docket W-99-16-IV (EPA 2001).

4. Effect on CCR for Calendar Year 2001

The final rule for the 9-month delay (66 FR 28342 at 28350) also changed the § 141.6(j) compliance date to February 22, 2002, for the new arsenic consumer confidence reporting requirements in §§ 141.165(b) and (f). The delay will affect some systems that send out calendar year 2001 reports. CWSs that send out calendar year 2001 reports prior to February 22, 2002 must comply with the old arsenic CCR requirements (those in effect prior to the January 2001 rule). CWSs that send their reports after February 22, 2002, will have to comply with the new arsenic CCR requirements. In light of the current analyses being conducted on aspects of the arsenic rule, the Agency plans to address CCR reporting issues and options in the fall 2001 notice.

D. With What Regulatory Standard for Arsenic Must Systems Comply Now?

In the process of extending the effective date for the arsenic rule, EPA has not changed the compliance date for the MCL issued in the January 2001 rule. Until January 23, 2006, the MCL for arsenic is 50 µg/L, which only applies to CWSs (§§ 141.11(a) and (b)), and there is no MCLG for arsenic (§ 141.51(b)).

II. EPA's Plans to Review Parts of the Arsenic Rule

A. What Is the Purpose of Today's Action and What Happens Now?

The January 22, 2001, rule established an MCLG of 0 µg/L and an MCL of 10 µg/L for arsenic and explained in detail the rationale for this decision. However, because of concerns raised by some stakeholders concerning the arsenic in drinking water regulation, especially small community systems that may bear a high cost burden to comply with the new standard, EPA has decided to request further comment on the arsenic standard set in the January 22, 2001, drinking water rule.

As a result, today EPA proposes and requests stakeholder input on a range of MCL options for arsenic from 3 µg/L to 20 µg/L. In developing comments, commenters should refer to the information provided in the January 22, 2001, arsenic rule, the background documents supporting that rule, the notice and request for comment on the scientific, technical, and benefits

reviews that EPA plans to publish in the fall of 2001, and any new (post-January 2001) information commenters wish to provide. EPA is accepting comments until October 31, 2001, on today's notice to facilitate commenters' ability to examine the most current information. The Agency also anticipates that the comment period for the notice summarizing the fall 2001 reviews will overlap with today's comment period, thereby allowing commenters to provide a single set of comments covering both today's notice and the expected fall 2001 notice, if they wish.

EPA is also undertaking additional analyses on science, cost, and benefits issues, as explained in section II.B., and expects these analyses to be completed in August 2001. Once the analyses are completed, EPA will consider this new information and provide for an additional opportunity for public comment on the new analyses along with EPA's preliminary conclusion about whether the January 2001 arsenic rule should be revised, and if so, what the revised standard should be. EPA will consider the public comments, as well as the record for the arsenic rule for this reconsideration, and issue a final decision on whether to revise the January 2001 rule. In particular, EPA is considering whether to retain the revised MCL of 10 µg/L or replace it with another standard—specifically, 3 µg/L (the feasible level), 5 µg/L (the level proposed in June 2000) or 20 µg/L (another alternative considered in the June 2000 proposal). If EPA does decide to revise the January 2001 rule, EPA will issue a new revised rule.

B. What Approach Will EPA Use To Review the Science, Costs, and Benefits of the Rule?

1. Overview

EPA understands and appreciates that the question of setting a final arsenic in drinking water standard is a controversial one for several reasons. From an economic standpoint, the new regulation can be expected to have significant impacts on a number of drinking water utilities, especially those serving less than 10,000 people in areas of high naturally occurring arsenic. Stakeholders have an understandable desire to ensure that any new regulation be based on accurate and reliable compliance cost estimates. Stakeholders also want to be confident that the health risks associated with a new standard have been appropriately evaluated and are based on the best available science.

The Agency is committed to safe and affordable drinking water for all Americans. At the same time, we want

to be sure that the conclusions about arsenic in the rule are supported by the best available science and policy decisions based on thorough cost-benefit considerations. The Agency is therefore moving rapidly to review arsenic research and national cost and benefit estimates related to the arsenic standard so that communities that need to reduce arsenic in drinking water can proceed with confidence that the new standard is based on sound science and accurate cost-benefit estimates. Independent review of the science, cost, and benefits analysis behind the arsenic in drinking water standard will help resolve questions that have arisen about the health basis and costs and benefits of reducing arsenic in drinking water.

EPA's criteria for conducting the reviews will be to ensure that reviewers are recognized experts in their fields and are as impartial and objective as possible; that the reviews can be completed in August 2001; and that the results of the reviews are made available for public comment. EPA plans to utilize the mechanisms for the reviews described in the following section.

EPA does not plan to seek outside, expert review of its approaches for estimating occurrence or determining the availability of analytical methods and their capabilities but is requesting further public comment on these aspects of the January 2001 rule.

2. Approach to Review of Health Science

Under a cooperative agreement with EPA, on May 21 the National Academy of Sciences (NAS) convened a subcommittee of the National Research Council's (NRC) Committee on Toxicology to prepare a report updating the scientific analyses, uncertainties, findings and recommendations of the report "Arsenic in Drinking Water (NRC 1999)." NAS posts information about the arsenic study, including project scope, the subcommittee membership and biographies, meetings, and meeting summaries of the closed sessions (NRC 2001a and NRC 2001b) in the website www.nationalacademies.org under Current Projects (the short cut to the direct NRC arsenic project address, www4.nas.edu/cp.nsf/af89ea56d4264b948525639b0043e7c7/7ae42f9d0397214b85256a3100711f15?OpenDocument, is available from www.epa.gov/safewater/arsenic.html). Information on NRC's committee process is also available on the NAS website under Frequently Asked Questions at www.nationalacademies.org/about/faq4.html. Specifically, the subcommittee is reviewing relevant

toxicological and health-effects studies published and data developed since the 1999 NRC report, including the toxicological risk-related analyses performed by EPA in support of its regulatory decision-making for arsenic in drinking water and the health effects discussion in EPA's SAB December 2000 report entitled, "Arsenic Proposed Drinking Water Regulation: A Science Advisory Board Review of Certain Elements of the Proposal (EPA 2000f)." The subcommittee is addressing only scientific topics relevant to toxicological risk and health effects of arsenic.

The subcommittee will meet approximately three times to discuss and evaluate issues and will produce a consensus report in August 2001. On May 21, the NRC subcommittee heard presentations from EPA, the Small Business Administration, a consultant for Albuquerque, researchers, industry, environmental and other interested or affected parties. At the open session meeting on June 20, the committee heard from EPA's Administrator. The draft consensus report will undergo the established NRC peer review process before NRC issues the final report that is available to the public. In addition, EPA will make the NRC's report available to the general public and request comment on its recommendations as part of a notice this fall.

3. Approach To Review of Cost of Compliance Estimates

The National Drinking Water Advisory Council (NDWAC) is chartered under the Federal Advisory Committee Act (FACA) to advise, consult with, and make recommendations to EPA. The Agency asked the NDWAC, and the Council agreed to convene a panel of nationally recognized technical experts to review the cost of compliance estimates associated with the regulatory options that were considered in the proposed rule and discussed in the January 2001 rule. On May 4, 2001 (EPA 2001d), EPA requested nominations for the working group (66 FR 22551). In particular, the working group is reviewing the costing methodologies, assumptions, and information underlying the system-size as well as the aggregated national estimate of system costs underlying the January 2001 arsenic in drinking water rule. As a part of this review, the group is evaluating significant alternative costing approaches or critiques where there is adequate information upon which to evaluate the basis for such alternate estimates or approaches.

The working group first met May 29–30, 2001, as announced in the May 22,

2001, **Federal Register** (EPA 2001f). Working group members have been asked to attend a series of meetings (June 28–29 in Denver, Colorado; July 9–10 in Phoenix, Arizona; and July 19–20 in Washington, DC) over the summer of 2001 (June 15, 2001 **Federal Register**, EPA 2001h), participate in discussion of key issues and assumptions at these meetings, and review work products of the working group. The working group will make a recommendation to the full NDWAC based on its review of the national cost estimates. The NDWAC, will in turn, make a recommendation to EPA. All NDWAC working group meetings and full NDWAC meetings are open to the public, and meeting information is posted on the calendar accessible from www.epa.gov/safewater. EPA posts the working group member list and meeting summaries at <http://www.epa.gov/safewater/ndwac/council.html>. The report of the working group and the final recommendations of the NDWAC will be made available for public review and comment.

4. Approach To Review of Benefits Estimates

The EPA Science Advisory Board (SAB), which also is chartered under the FACA, was established in 1978 by the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA) (42 U.S.C. 4365), to provide such scientific advice as may be requested by the Administrator. At the request of the Agency the SAB has convened a panel, the Arsenic Rule Benefits Review Panel (ARBRP), to review the Agency's analysis of quantified and unquantified benefits associated with the arsenic drinking water rule. The Agency has asked this panel of nationally recognized technical experts to review the Agency's analysis of quantified and unquantified arsenic benefits analysis as required by SDWA, and evaluate whether the components, methodology, criteria and estimates reflected in EPA's benefits analysis are reasonable and appropriate in light of: (1) The SAB's benefits transfer report (EPA 2000d; available on the SAB Website at www.epa.gov/sab/eeacf013.pdf); (2) EPA's Guidelines for Preparing Economic Analyses (EPA 20001; www.epa.gov/economics); (3) relevant requirements of the Safe Drinking Water Act (SDWA; www.epa.gov/safewater/sdwa/sdwa.html); (4) NDWAC recommendations to EPA on benefits (unpublished October 29, 1998, Benefits Working Group Report to the National Drinking Water Advisory Council; EPA 1998b); and (5) recent literature.

Panel members have been asked to attend one or more meetings over the summer of 2001, participate in discussion of key issues and assumptions at these meetings, and review the previously described documents and literature. The first meeting of the ARBRP will be on July 19–20, in Washington, D.C. (EPA 2001i). To ensure that the SAB's recommendations are fully considered in decision making, the Agency has asked for a report to be made available to the Administrator in August 2001 to coincide with the findings and recommendations from independent reviews of the health effects by NRC and costs by NDWAC. All ARBRP meetings are open to the public and time will be allotted for presentations by the public. Meeting information is posted on the calendar accessible from www.epa.gov/safewater. The report of the ARBRP and the final recommendations of the SAB will be made available for public review and comment.

C. How Did EPA Assess the Occurrence of Arsenic?

1. Summary of Arsenic Occurrence Analysis

EPA's occurrence estimates were a fundamental building block in cost of compliance estimates as well as its benefits estimates. To develop this occurrence estimate, EPA used arsenic compliance monitoring data consisting of almost 77,000 observations from 25 States to estimate the distribution of arsenic in finished drinking water in public water systems (PWS) in the U.S. These States voluntarily submitted the data from public water systems. Figure V–1 in the June 2000 proposed rule (65 FR 38888 at 38906) is a map of the 25 States from which EPA used data to estimate occurrence. These States are distributed throughout the U.S., with at least one located in each of the seven geographic regions that the Agency used in its analysis (EPA 2000h). Ten other States (Florida, Idaho, Iowa, Louisiana, Pennsylvania, South Dakota, Maryland, Nebraska, Vermont, and West Virginia) submitted compliance monitoring data, but those data were not complete enough to estimate State occurrence (66 FR 6976 at 7029). EPA lists the database parameters used to derive its national occurrence estimate in Appendix D–2 of the occurrence document (EPA 2000h).

In order to estimate a national occurrence distribution of arsenic, EPA began with individual water systems and built up estimates for States, regions, and the nation. For each PWS in its database, the Agency estimated the mean arsenic concentration over

time in finished water. (Although MCL compliance is determined by computing a running annual average of quarterly samples, EPA elected to characterize arsenic occurrence in each system in terms of the mean arsenic concentration over time, rather than by a set of running averages; for the benefits estimates, the long-term mean is preferable, because health risks are determined by mean exposure to arsenic over time; for the cost estimates, the approach used may not accurately predict costs in all cases, since some systems with a long-term average below the standard might still exceed it during some compliance cycles.) Next, the Agency collected the system mean estimates into State distributions, then merged the State distributions into regional and finally, national distributions. The regions used in the analysis are shown in Figure V–1 in the June 2000 proposed rule (65 FR 38888 at 38906). In combining the regional distributions into a national distribution, the Agency weighted each region by the total number of systems in the region, not just the number of systems in the States in its database. This procedure has the same effect as assigning the regional distributions to the 25 States for which there are no observations in the database.

EPA estimated separate arsenic occurrence distributions for community water systems (CWS) and non-transient, non-community water systems (NTNCWS), and for systems with ground water (GW) and surface water (SW) sources. Systems identified as having ground water under the influence of surface water were treated as surface water systems. Table III.C–1 (66 FR 6976 at 6996) shows the Agency had data from 17 States for ground water NTNCWS, compared to 25 States for CWS, so there are, on average, fewer States with NTNCWS data in each region. Moreover there is no data about NTNCWS from any States in the Southeast region (Alabama, Florida, Georgia, Mississippi, and Tennessee). EPA therefore used the occurrence distribution for ground water CWS as a surrogate for ground water NTNCWS in the Southeast. For surface water NTNCWS, EPA used the occurrence estimates from surface water CWS, because the characteristics of source water for NTNCWS are expected to be similar to source water for CWS, and there is a larger CWS data set to draw from.

Table III.C–5 of the January 2001 rule (66 FR 6976 at 6998) shows EPA's estimated arsenic occurrence distributions for the U.S. The results are comparable to those of two other arsenic

occurrence studies: the National Arsenic Occurrence Survey (Frey and Edwards, 1997) and USGS (2000).

In addition to the distributions of system means, EPA estimated nationwide intra-system coefficients of variation (ISCV). For a given water system, the ISCV quantifies the variation of mean arsenic levels at the system's entry points to the distribution system (i.e., sampling points of individual wells and treatment points) around the overall system mean. EPA estimated separate ISCVs for ground water CWS, surface water CWS, and ground water NTNCWS. Each of these ISCVs was assumed to be constant throughout the U.S. EPA used the estimated ISCVs as part of its cost simulation model summarized today in section II.E.

Since the completion of its occurrence analysis for the arsenic rule (EPA 2000h), EPA has received additional occurrence data from one State, North Carolina. More occurrence data from other States may become available in the future.

2. Request for Occurrence Comments

Some stakeholders expressed concern that EPA estimated nationwide occurrence using data from only 25 States, and that the national occurrence estimate was therefore not as reliable as it should have been. Many commenters provided occurrence data about their individual system, which could not be used in the statistical approach. Some commenters suggested that EPA should either request data from all States, or else augment its data set with data from other sources. As noted in EPA's Response-to-Comments document for the January 2001 rule, EPA's occurrence estimates are based on finished water data from States for which data of adequate quality in the range of interest (3–20 µg/L) were available. EPA requests comment on the assumptions, data, methodologies, and results of its occurrence analysis, as well as any new occurrence data that commenters believe EPA should consider in its occurrence assessment. EPA also requests comment on whether it is appropriate to use long-term averages as a proxy for compliance in computing costs for various levels of the standard.

D. How did EPA Evaluate the Health Risks of Arsenic in Drinking Water?

1. Summary of Health Risk Elements

Arsenic ingestion at various levels has been linked to a variety of health effects, both cancerous and non-cancerous. These health effects include cancer of the bladder, lungs, skin, kidney, nasal

passages, liver, and prostate. Arsenic ingestion has also been associated with cardiovascular, pulmonary, immunological, neurological, endocrine, and reproductive and developmental effects. In almost all cases, the drinking water levels at which these associations have been found are higher than the current 50 µg/L standard and the levels typically found in U.S. drinking water. Extrapolating these associations down to levels of regulatory interest (i.e., less than 50 µg/L) entails uncertainty and there has been debate among stakeholders over the appropriate methodology for doing so. Of all the studies noted in the report issued by the National Research Council (NRC 1999) and literature reviewed by EPA, the Agency believes that those studies focusing on bladder and lung cancer provide the best basis to quantify dose response relationships and extrapolate these relationships down to the levels of regulatory interest. Therefore, the Agency based its assessment of the quantifiable health risk reduction benefits on the risks of arsenic-induced bladder and lung cancers.

The Agency's approach for the health risk quantitative analysis includes five components. First, EPA developed relative exposure factor (REF) distributions, where the life-long REFs indicate the sensitivity of exposure of an individual relative to the sensitivity of exposure of an "average" person weighing 70 kilograms and consuming approximately 2 liters of water per day. These REFs incorporate data from the recent EPA water consumption study (EPA 2000a) with age, sex, and weight data. Second, EPA calculated arsenic occurrence distributions for the population exposed to arsenic levels above 3 µg/L. Third, EPA chose risk distributions for bladder and lung cancer for the analysis from Morales et al. (2000), a peer-reviewed article published in July 2000, which presented additional analyses of bladder cancer risks as well as estimates of lung and liver cancer risks for the same Taiwanese population analyzed in the NRC report. EPA summarized and analyzed the new information from the Morales et al. (2000) article in a Notice of Data Availability (NODA) (EPA 2000e) published on October 20, 2000 (65 FR 63027). Although the data used were the same as used by the NRC to analyze bladder cancer risk in their 1999 publication, Morales et al. (2000) considered more dose-response models and evaluated how well they fit the Taiwanese data, for both bladder cancer risk and lung cancer risk. Fourth, EPA developed estimates of the projected

bladder and lung cancer risks faced by exposed populations using Monte-Carlo simulations, bringing together the relative exposure factor, occurrence, and risk distributions. These simulations resulted in upper-bound estimates of the actual risks faced by U.S. populations exposed to arsenic concentrations at or above 3 µg/L in their drinking water. Finally, EPA identified three significant sources of uncertainty and made adjustments to address one of these to derive alternate, lower risk estimates that reflect exposure to arsenic in cooking water and in food in Taiwan. EPA also recognized and considered qualitatively two other sources of uncertainty (e.g., the shape of the dose response curve at low exposure levels and the different health and nutritional status of the Taiwanese study population relative to the typical U.S. population) that it was not able to quantify (see page 7021 of the January 22, 2001 rule) that might also lead to lower risk estimates if it were possible to account for them quantitatively. EPA also indicated, in the preamble to the January 2001 rule, that it believed that its health risk analysis comprised a plausible range of likely risk associated with various concentrations of arsenic in drinking water. This analysis is described in more detail at pages 7001–7009 and 7020–7021 of the January 22, 2001, rule. Finally, EPA considered the non-monetizable benefits associated with avoiding certain adverse health impacts known to be caused by arsenic at higher concentrations, which also may be associated with low level concentrations, which included other nonquantified cancer endpoints and adverse cardiovascular, pulmonary, immunological, neurological, endocrine, reproductive, and developmental effects. EPA listed reductions in these health effects as unquantified benefits in Tables III.E–3 and III.E–7 that listed the monetizable benefits. In moving off the feasible MCL of 3 µg/L, EPA considered the costs and benefits, including the unquantified benefits (66 FR 6976 at 7022 and 7023).

2. Request for Comment on Health Issues

EPA has asked the National Academy of Sciences (NAS) to update the findings and recommendations of the NRC report, Arsenic in Drinking Water (NRC 1999), based on new studies and analyses, including EPA's risk analyses. EPA recognizes that there are a number of uncertainties inherent in its risk analysis that reflect the state of existing science, available research, and the difficulties associated with applying epidemiological data from one

population to another. The NAS, in its 1999 NRC report, and the Science Advisory Board, in its 2000 report (EPA 2000f), highlighted a number of key issues, as have stakeholders who have participated in the arsenic rule development process. EPA requests comment and any additional data that may be available in the following areas:

(1) Are the data from the southwestern Taiwanese studies presented in the NRC report still the most appropriate data set for the dose-response assessment and risk estimation? What are the uncertainties in the data on which the risk estimates are based, and what is the likely effect of these uncertainties on the quantitative risk estimates?

(2) Did EPA's analyses of U.S. risk provide appropriate adjustments for population differences, including factors such as diet, health status, life style (e.g., smoking, cooking water use), when extrapolating from the Taiwanese study population to the U.S. population? Is it possible and appropriate for EPA to make additional quantitative adjustments to account for such differences using existing data?

(3) Part of EPA's analysis requires the determination of an arsenic level that is projected to cause an adverse effect in one per cent of the population (ED₀₁). Is the dose-response analysis conducted by EPA, as well as any available more recent data, adequate for estimating an ED₀₁?

(4) Did EPA's analysis appropriately consider and characterize the available data on mode of action of arsenic, the dose-response information, and the information on uncertainties, when assessing the public health impacts?

(5) Are EPA's risk estimates at 3, 5, 10, and 20 µg/L consistent with available scientific information, including information from new studies?

(6) What is known or can be inferred about the latency period between exposure to arsenic in drinking water and increased incidence of cancer based on existing research?

E. How Did EPA Calculate the National Costs of Compliance With the Arsenic in Drinking Water Rule?

1. Summary of Cost Elements of January 22, 2001 Rule and Record

EPA listed the national cost estimate for the January 22, 2001, rule in Table III.E.1 (66 FR 6976 at 7010). (This information is discussed at greater length in the Technology and Cost document (EPA 2000i) in the record for the January 22, 2001, rule.) The table presented national cost estimates for the

MCL of 10 µg/L and the other three options considered in the proposed rule published on June 22, 2000. Treatment costs represent the vast majority of the total national costs for all four MCL options. For the MCL of 10 µg/L, the treatment costs are estimated to be \$169.6 million per year using a 3% discount rate and \$193 million per year using a 7% discount rate.

In summary, EPA developed the cost of compliance estimate for the arsenic in drinking water rule as follows. The treatment costs were derived using occurrence data, treatment train unit costs, and decision trees. The occurrence data provide the number of systems that would need to install treatment in each size category. The treatment train unit cost estimates provide a measure of how much a technology will cost to install. Decision trees vary by system size and are used as a prediction of the treatment technology trains that facilities would likely install to comply with the options considered for the revised arsenic standard. An analysis of the available treatment trains for arsenic removal and the unit costs for the 13 treatment trains (listed in Exhibits A-7 through A-22 in EPA 2000g) used in the national cost estimate are described in the December 2000 document entitled "Technologies and Cost for the Removal of Arsenic in Drinking Water" (EPA 2000i). The decision tree and a description of the model used to calculate the national cost estimate are described in the December 2000 document entitled "Arsenic in Drinking Water Rule Economic Analysis (EPA 2000g).

Many of the comments EPA received on the June 2000 proposed rule were on the national cost estimate and the available treatment technologies. EPA reviewed these comments and comments from the Drinking Water Committee of EPA's Science Advisory Board. The January 2001 rule incorporates a number of changes based on these comments, which are discussed in detail in sections V.F and V.G of the preamble (66 FR 6976 at 7034) and are discussed more extensively, in the Technology and Cost document (EPA 2000i). The major changes are summarized in today's document.

EPA received many comments on the proposed rule stating that the Agency did not adequately consider problems with waste generation and disposal when evaluating which technologies would be most appropriately used for achieving compliance. Prior to issuing the arsenic rule, EPA re-examined the 25 treatment trains considered for the proposed rule. The Agency eliminated

five treatment trains due to concerns about hazardous waste. The ability to discharge brine streams to publicly owned treatment works (POTWs) was another issue related to waste generation and disposal. Comments indicated that potential increases in total dissolved solids and technically based local limits at the POTW would limit the discharge of brines to POTWs. EPA eliminated brine discharge to POTWs from activated alumina processes as a Best Available Technology due to the arsenic concentration in the brine. EPA also significantly reduced the use of anion exchange with POTW discharge in the decision tree for the January 2001 rule. These issues are discussed in greater detail on pages 7036-7038 of the January 2001 preamble.

The national cost estimate generated a large number of stakeholder comments. Many of these comments stated that EPA underestimated the costs for implementing the proposed rule. Many of these comments referred to the report "Cost Implications of a Lower Arsenic MCL" as the basis for their comments. This report (Frey et al. 2000a) was published by the American Water Works Association Research Foundation (AWWARF) in May 2000. The national cost estimates in the AWWARF report were updated in October 2000 (Frey et al. 2000b). For the MCL of 10 µg/L, the October 2000 Update lists a national compliance cost estimate of \$345 million per year with no sensitivity considerations (lower bound) and \$585 million per year with sensitivity considerations (upper bound). (These upper and lower bound estimates result from different assumptions about cost model input variables.) EPA reviewed the May 2000 AWWARF report and the October 2000 update and summarized factors in the report in detail on pages 7040-7041 of the January 2001 preamble that EPA identified as being key reasons for the differences in cost estimates. These factors include differences in flow rate assumptions, unit costs, and national estimates for arsenic occurrence. The Arsenic Response-to-Comments Document (EPA 2000j) also includes more detail on EPA's review of the national cost estimates in "Cost Implications of a Lower Arsenic MCL."

In commenting on the proposed rule, the SAB also expressed concern that the Agency's cost estimates appeared low. The SAB identified two concerns in particular: (1) The assumptions regarding disposal options for brine and other residuals (see discussion in section II. E. 1. of the revision EPA made to address these concerns); and (2)

whether the technologies identified as BAT have been implemented or optimized for arsenic removal at the treatment plant scale, and whether doing so would reduce their effectiveness for the other purpose for which they have been designed, in which case compliance costs could be underestimated.

A Working Group of the National Drinking Water Advisory Council (NDWAC) is reviewing the costing methodologies, assumptions, and information underlying the system-size as well as the aggregated national estimate of system costs of the arsenic rule. As a part of this review, the Working Group is also evaluating significant alternative costing approaches where there is adequate information upon which to evaluate the basis for the alternate estimates or approaches, including the AWWARF cost reports. The group may identify and comment on additional factors affecting these cost estimates (e.g., number of entry points to the distribution system) in addition to those discussed in the January 2001 rule. The NDWAC Working Group will make a recommendation to the full NDWAC based on their review of the national cost estimates.

2. List of Cost Issues and Request for Comments

Specific questions related to the cost of compliance analysis for the arsenic rule on which EPA is interested in receiving public comment include the following:

(1) Did EPA use appropriate "baseline" assumptions (e.g., occurrence, co-occurring contaminants, affected systems, entry points, design and average flows, availability of land, in-place treatment)? If not, how could these assumptions be improved and what data would support such revised assumptions?

(2) Did EPA identify an appropriate set of treatment "trains" and make appropriate assumptions about the costs of technologies included in those treatment trains as a part of the process of developing national cost estimates? Has EPA identified restrictions that may limit or eliminate treatment technology and residuals management combinations, including the application of treatment technologies to arsenic on a large scale, and integration of arsenic removal with other treatment plant objectives? If not, how could these assumptions and inputs be improved?

(3) Did EPA use an appropriate "decision tree" for the final rule? If not, how can that decision tree be improved?

F. How Did EPA Calculate the Benefits of the Arsenic Rule?

1. Summary of the January 22, 2001, Benefits Assessment

Of the various health effects linked to arsenic ingestion, in the January 2001 rule EPA prepared a quantitative assessment of lung and bladder cancer. Other health effects and possible non-health benefits that EPA was unable to quantify were considered qualitatively as required by SDWA, and as discussed in the January 2001 rule.

The process by which EPA analyzed the benefits of reduced bladder and lung cancer cases for the arsenic rule involved several steps. These steps included the calculation of risk reductions, calculation of the number of cancer cases avoided, monetization of avoided bladder and lung cancer cases, qualitative analysis of non-quantifiable benefits, and a sensitivity analysis of benefits estimates to examine the impacts of discounting over a latency period and accounting for other adjustments such as voluntariness and controllability.

Using the risk estimate calculations described in section II.C. of today's notice, EPA calculated the number of bladder and lung cancer cases avoided for CWSs and NTNCWSs (see Table III.D-3, 66 FR 6976 at 7009). Note that EPA derived separate cancer risks for NTNCWSs, as summarized in the preamble to the June 2000 proposal (pages 38952-38956) and described in section 5.3.3 of the Economic Analysis (EPA 2000g). The lower- and upper-bound risk estimates were applied to the exposed population to generate cases avoided for Community Water Systems (CWS) serving fewer than 1 million customers. Since the Agency had arsenic occurrence information for very large systems (those serving greater than one million customers), their system-specific arsenic distributions could be directly computed and cases avoided calculated from these distributions (appendix b.2 in EPA 2000g). In the proposal and January 2001 rule, EPA adjusted the number of bladder cancer cases avoided to reflect a possible lower mortality rate in Taiwan (a lower death rate would increase the number of estimated Taiwanese cases to include more non-fatal cancers) than was assumed in the risk assessment process, which is described in section 5.4.1 of the Arsenic Economic Analysis (EPA 2000g). The Agency adjusted the upper-bound U.S. cancer cases avoided to assume an 80% mortality rate for bladder cancer and 100% fatality for lung cancer in Taiwan. The Agency then divided the U.S. cases avoided into

morbidity (non-fatal) and premature fatality cases based on U.S. mortality rates of 26% for bladder cancer and 88% for lung cancer.

In order to monetize the benefits from bladder and lung cancer cases avoided, the Agency used two different values. First, a Value of Statistical Life (VSL) estimate was applied to those cancer cases that result in a mortality. As noted, EPA assumed a 26% mortality rate for bladder cancer and an 88% mortality rate for lung cancer. The current VSL value used by the Agency is \$6.1 million, in 1999 dollars (66 FR 6976 at 7012). VSL does not refer to the value of an identifiable life, but rather to the value of small reductions in mortality risks in a population. A "statistical" life is thus the sum of small individual risk reductions across an entire exposed population and is not the value for saving a particular individual's life.

Second, EPA used a Willingness to Pay (WTP) value (66 FR 6976 at 7012) to monetize the cancer cases that do not result in a mortality. A WTP value for avoiding a non-fatal cancer is currently not available; therefore the Agency used a WTP estimate to reduce a case of chronic bronchitis as a proxy. The mean value of this WTP estimate is \$607,000 in 1999 dollars. A complete discussion of the VSL and WTP values and how they are calculated can be found in Chapter 5 of the Arsenic Economic Analysis (EPA 2000g).

There are also a number of non-quantifiable benefits that EPA considered in its analysis of the benefits for the arsenic rule. Chief among these are certain health impacts identified in various studies involving arsenic levels greater than 50 µg/L. To date, the extent to which these impacts occur at levels below 50 µg/L has not been determined. These additional health effects include other cancers such as skin, kidney, nasal passage, liver, and prostate cancers and non-cancer endpoints such as cardiovascular, pulmonary, immunological, neurological, and endocrine impacts. These health effects and the relevant studies linking these health effects to arsenic in drinking water are discussed in section III.D of the preamble to the rule (66 FR 6976 at 7000). Table III.E-3 in the preamble to the rule (66 FR 6976 at 7012) shows the estimated benefits from reducing arsenic in drinking water for arsenic levels of 3, 5, 10, and 20 µg/L. This table also includes a listing of the potential non-quantifiable benefits associated with reducing arsenic in drinking water.

The Agency also provided a sensitivity analysis on benefits estimates in the rule to examine the impacts of

discounting over a latency period and adjustments for income growth and the nature of the risk (the extent to which the risk is voluntary and controllable). In a July 2000 letter, the EEAC of the SAB recommended that benefits estimates for environmental regulations include adjustments for latency and for income growth in the primary analysis, while adjustments for other factors, such as the extent to which risk is voluntary or controllable, be addressed in a sensitivity analysis. For the arsenic rule, the Agency chose to address all of these factors in a sensitivity analysis because it lacked quantitative data on cancer latency periods associated with arsenic exposure in drinking water. The sensitivity analysis used a range of latencies from 5 to 20 years and discount rates of 3 and 7%. It also adjusted for income growth and included a 7% increase in valuation to account for the lack of voluntariness and controllability of risk. The sensitivity analysis showed that the adjustments to monetized benefits could range from a 10% increase (accounting for income growth only) to a 70% decrease (accounting for income growth, latency, and voluntariness/controllability). The sensitivity analysis did not provide estimates accounting only for latency and income growth. Tables III.E-5 and III.E-6 in the January 2001 preamble illustrate the sensitivity of monetized benefits estimates to different assumptions for latency period duration, discount rate, rate of income growth, and inclusion of a voluntariness and controllability factor. A more detailed description of this analysis is shown in section III.E.2.b of the preamble to the rule (66 FR 6976 at 7012) and Chapter 5 of the Arsenic Economic Analysis (EPA 2000g).

2. List of Key Benefit Analysis Issues

Significant issues associated with the benefits analysis for the arsenic in drinking water rule addressed topics such as the timing of health benefits accrual (latency) and the Agency's consideration of non-quantifiable benefits in its regulatory decision-making process. The Agency requests comments on these and related issues in the following summary.

Specific issues related to the benefits analysis for the arsenic rule include:

a. Discounting benefits over a cancer latency period. The SAB has recommended that EPA should discount its monetized benefits over a cancer latency period (EPA 2000d). A latency period is generally defined as the time between exposure to an environmental carcinogen and the resulting cancer fatality. Precise information on the

latency period for most cancers is generally unavailable, but latency periods can be significant. The latency period may also be defined in several different ways. This period can be defined as the time between exposure and the resulting fatality or the time between exposure and onset or diagnosis of the cancer. This definition does not consider the time between exposure and early adverse changes at the cellular level in the body (*i.e.*, before clinical expression of cancer). Definition of the latency period can have a significant impact on the length of time over which benefits are discounted, especially for cancer illnesses where the period of morbidity (*e.g.*, non-fatal illness) is lengthy. EPA has specifically requested the National Academy of Sciences, in their review of the health risks of arsenic in drinking water, to examine this issue in more detail and discuss what is known or can be inferred about the latency period between exposure to arsenic in drinking water and increased incidence of cancer based on existing research.

b. Consideration of non-quantifiable benefits in the regulatory decision-making process. Some stakeholders have argued that EPA did not fully consider the non-quantifiable benefits in its decision-making process for the arsenic rule and that EPA should have performed sensitivity analyses to characterize the potential magnitude of these benefits. Other stakeholders have argued that EPA placed too much emphasis on non-quantifiable benefits in the choice of the arsenic MCL. EPA requests comment on how to handle non-quantifiable benefits in its selection of a final arsenic MCL.

3. Request for Comments on Benefits

(1) How should total benefits and costs and incremental benefits and costs be addressed in the rule in analyzing regulatory alternatives to ensure appropriate consideration by decision makers and the public?

(2) How should latency be addressed in the benefits estimates for the final rule when existing literature does not provide specific quantitative estimates of latency periods associated with exposure to arsenic in drinking water?

(3) Should reduction/elimination of exposure be evaluated as a separate benefits category, in addition to or in conjunction with mortality and morbidity reduction?

(4) How should health endpoints (other than bladder and lung cancer) be addressed in EPA's analysis, when existing literature does not provide specific quantification, to ensure

appropriate consideration by decision makers and the public?

(5) How should uncertainties be addressed in EPA's analysis to ensure appropriate consideration by decision makers and the public?

G. What Process Is EPA Planning for Review of Financial, Technical, and Planning Tools for Small Systems?

1. Small System Review Process

As part of its overall review of the arsenic rule, EPA wishes to reassess the financial, technical, and planning tools available to help small systems achieve compliance. SDWA provides special consideration for small systems in a number of areas and also created the Drinking Water State Revolving Fund (DWSRF) to help systems, including small systems, comply with the provisions of the Act. The DWSRF provides low interest loans, and allows forgiveness of principal for communities identified by the States as disadvantaged. The Agency believes that State capacity development strategies offer a useful framework within which to address small system issues. The Agency seeks comment to help it reassess the financial, technical, and planning tools available to small systems and determine what, if any, additional steps the Agency should take to facilitate compliance with a revised arsenic standard.

2. List of Small System Issues

a. Affordability, availability of financial assistance, and treatment technology. Extensive concerns have been raised regarding the ability of households served by small systems to afford compliance with a revised arsenic standard. In the January 2001 rule, the Agency attempted to address many of these concerns. The preamble of the January 2001 rule emphasized the framework established by SDWA to consider affordability and the tools available to help address affordability concerns. These tools include financial assistance; and extended compliance time frames through exemptions. SDWA also provides for small system variances, but EPA determined in the January 2001 rule that affordable small system compliance technologies are available for all categories of system size, so this option is not available for the new arsenic standard published in the January 2001 rule.

The January 2001 preamble points out that about \$1 billion/year is being made available to large and small systems through the Drinking Water State Revolving Fund (DWSRF), and about \$780 million/year is being made

available through the water and waste disposal program of the Rural Utilities Service (RUS) of the Department of Agriculture. EPA also noted that almost one quarter of the DWSRF loans have been made to systems States classified as disadvantaged (66 FR 6796 at 7020).

Treatment technology is another issue around which small system concerns have clustered. The major concern voiced in this regard has been that small systems may not be able to apply the lower cost compliance technologies identified by EPA. The most significant issue relates to the application of Point-of-Use (POU) technology. Under the arsenic rule, EPA has designated POU technology as an affordable compliance technology. The Agency recognizes that application of POU technology for compliance is not presently a common practice and water systems would face a number of challenges in implementing such an approach. EPA's probability decision trees (Exhibits A-7 through A-22 in the Economic Analysis (EPA 2000g)) assigned POU technologies to approximately 5% of systems serving fewer than 500 in the decision tree. The Agency believes that customers may be quite supportive of a POU solution once they understand the cost-savings it offers based upon pilot studies and information that EPA has analyzed.

b. SDWA Capacity Development Framework. SDWA recognized that small systems would find it more challenging than large systems to achieve the public health protection goals of the Act. In amending SDWA in 1996, Congress found that effective protection of public health requires water systems with adequate managerial, technical, and financial capacity. Congress further found that compliance with the requirements of SDWA continues to be a concern at public water systems experiencing technical and financial limitations; and Federal, State, and local governments need more resources and more effective authority to attain the objectives of SDWA. In response to these findings, Congress included in the amendments a number of provisions designed to help EPA and the States address the needs of small systems, including, for the first time, the State Revolving Loan Fund for assisting drinking water systems in complying with standards.

These provisions included new flexibility for EPA in setting standards and compliance time frames; explicit authority to allow Point-of-Use technologies for compliance; broader and more flexible authority for issuing exemptions to provide systems with additional time to comply; small system variances in cases where EPA

determines that affordable small system compliance technologies are not available; and financial assistance through a new drinking water State revolving fund. In order to help focus these and other tools on helping systems develop managerial, technical, and financial capacity, Congress created a strong incentive for States to develop a "capacity development strategy." States were given broad flexibility in designing their strategy, but were required to consider a number of issues including how they would use the authority and resources of SDWA or other means to assist systems in complying with regulations and to encourage the development of partnerships between systems to enhance their capacity.

All States have developed strategies consistent with the SDWA framework. EPA believes that implementation of a revised arsenic standard will be the first major test of these strategies. SDWA clearly anticipated that systems would need to enhance their technical, financial, and managerial capacity in order to achieve the public health protection objectives of the law. The extensive concerns which have been voiced about systems ability to meet a revised arsenic standard serve to confirm the need for such enhancements.

Successful implementation of a revised standard will require that States focus on developing system capacity by fully utilizing the flexibilities available under SDWA. In particular, the Agency believes that appropriate use of these three provisions will be essential:

(1) DWSRF assistance, including principal forgiveness for disadvantaged communities and set-aside funds to assist systems through a State's capacity development strategy.

(2) Exemptions to allow additional time for systems that demonstrate the need for such time to achieve compliance. Such systems of any size can be granted an additional 3 years beyond the compliance date for the revised MCL to achieve compliance, while systems serving <3300 persons can be granted up to 6 additional years beyond that date. This extra time can be used to obtain financial assistance or undertake restructuring or other changes to achieve compliance.

(3) Application of Point-of-Use (POU) technology.

States may wish to utilize their capacity development strategy as a framework within which to plan the most effective utilization of all of the tools available. In addition to the SDWA provisions discussed previously, another important tool is financial assistance available through the United

States Department of Agriculture's Rural Utilities Service.

3. Request for Small Systems Comment

EPA invites comments on all aspects of small system compliance with a revised arsenic standard. In particular, the Agency seeks comment on the following issues:

(1) What additional guidance, information, or other assistance, if any, do States need to help them develop and apply system-level affordability criteria (for prioritizing use of drinking water revolving funds in a State; and for determining whether or not to grant exemptions)?

(2) Will exemptions allowing needy systems additional time to achieve compliance be a useful tool? What guidance, information, or other assistance, if any, should EPA make available to States and or systems relative to exemptions?

(3) To what extent can systems lower their compliance costs or enhance their ability to comply by forming partnerships with other systems or otherwise restructuring their operations? What barriers (physical and/or institutional) exist to the formation of these partnerships? What guidance, information, or other assistance, if any, should EPA make available to States and or systems to assist in the formation of system-level partnerships?

(4) What challenges or barriers exist to adoption of POU technology? What do EPA and or the States need to do to facilitate application of POU technology?

(5) What additional guidance, information, or other assistance do States need to help them refine their capacity development strategies to facilitate compliance with a revised arsenic standard?

III. Process To Be Employed After Technical Reviews and Public Comment

A. How Will EPA Notify the Public of Results of the Technical Reviews and the Nature of the Public Comments?

As previously noted, the findings of the expert review panels will be made publicly available. In addition, EPA will publish a notice with a summary of these findings for public comment. The purpose of the notice will be to provide EPA's perspective on the findings of the review of the costs, benefits, and science underlying the arsenic rule. In addition, the notice will summarize comments received on this proposal and EPA's perspective on those comments. Finally, the notice will provide an indication of how the Agency plans to synthesize this

new information with respect to final decisions on the arsenic in drinking water rule. EPA expects that the notice will be published in the Fall of 2001.

B. What Process Will EPA Use To Make Final Decisions on the Rule?

The process of making final decisions on the arsenic in drinking water regulation will involve legal, regulatory, policy, and scientific considerations. The results of the expert panels' reviews and public comment will be significant and important sources of information that will be fully considered by the Agency as it makes a final decision. In making a final decision, EPA will also exercise judgment and discretion based on the record and all applicable legal, regulatory, and policy requirements. EPA expects to make a final decision on how to proceed with the arsenic rule by February 22, 2001, after considering the reviews and public comments.

IV. Administrative Requirements

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866, [58 **Federal Register** 51735 (October 4, 1993)] the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that the January 22, 2001, rule is a "significant regulatory action" because it will have annual costs of more than \$100 million. Because this proposal is an extension of a rulemaking published on January 22, 2001 (66 FR 6976), and is based on the record for that rulemaking, EPA has complied with this Executive Order through the economic analyses prepared for the January 22,

2001, rulemaking. Those analyses were reviewed by OMB. In addition, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public record for W-99-16-VI.

B. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternative definition(s) in the **Federal Register** and taking comment (5 U.S.C. 601(3)-(5)). In addition to the above, to establish an alternative small business definition, agencies must consult with the Small Business Administration's (SBA) Chief of Counsel for Advocacy.

For the purposes of assessing the impacts of today's rule on all three categories of small entities, EPA considered small entities to be systems serving 10,000 or fewer customers. In accordance with the RFA requirements, EPA proposed using this alternative definition for all three categories of small entities in the **Federal Register** (63 FR 7605 at 7620; February 13, 1998), requested public comment and consulted with SBA regarding the alternative definition as it relates to small businesses. In the preamble to the final Consumer Confidence Reports (CCR) regulation (63 FR 4511; August 19, 1998), EPA stated its intent to establish this alternative definition for regulatory flexibility assessments under the RFA for all drinking water regulations and has thus used it in this proposed rulemaking.

As noted in the previous section, this proposal is an extension of, and relies on the record of, a previous rulemaking concerning the same regulatory options. In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the original proposed rule, published in the **Federal Register** on June 22, 2000 (EPA

2000b), and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the regulated small entities in accordance with section 609(b) of the RFA. A detailed discussion of the Panel's advice and recommendations is found in the Panel Report (EPA 1999). The June 2000 proposed rule presented a summary of the Panel's recommendations (65 FR 38888 at 38963).

As required by section 604 of the RFA, EPA also prepared a final regulatory flexibility analysis (FRFA) for the January 2001 rule (EPA 2001a). The FRFA and the January 2001 arsenic rule's preamble (66 FR 6976 at 7047) addressed the issues raised by public comments on the IRFA, which was part of the regulatory impact analysis for the proposed rule (65 FR 38888 at 38962; EPA 2000b). The FRFA (EPA 2000j) is available for review in the docket. The previous analyses encompass all of the options proposed again today, and as a result, EPA is relying on those analyses for compliance with the RFA for this proposal.

C. Unfunded Mandates Reform Act (UMRA) of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, Tribal, and local governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the

UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that the January 22, 2001, rule contains a Federal mandate that may result in expenditures of \$100 million or more for State, Tribal, and local governments, in the aggregate, or the private sector in any one year. Because today's proposal is an extension of the January 2001 arsenic rulemaking and discusses only those options which were fully analyzed in the previous rulemaking, EPA is relying on the record of the January, 2001 rule to provide the analyses required by UMRA. A detailed description of this analysis is presented in EPA's Economic Analysis of the arsenic rule (EPA 2000g) which is included in the Office of Water docket for the arsenic rule, and summarized in the January 2001 preamble (66 FR 6976 at 7049). Through targeting mailing of this notice to entities on the arsenic mailing list, we will continue to solicit State, local, and Tribal access and dialog on the arsenic rule. EPA will also develop a small government agency plan.

D. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule were previously submitted for approval to the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* As noted in previous sections, today's proposal is an extension of a previous rulemaking which analyzed the same options presented today. As a result, EPA is relying on the PRA analyses prepared for the January 2001 rulemaking and its proposal for compliance with the PRA for this rule. OMB has already reviewed and approved the information collection request (ICR) in the previous rulemaking and assigned OMB control number 2040-0231. This action does not impose any additional information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

E. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note)

directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

EPA's analysis of the NTTAA's application to this rulemaking is described in the June 22, 2000, proposal at 65 FR 38971-38972 and the January 22, 2001, preamble at 66 FR 7051. EPA requests comment on this analysis.

F. Executive Order 12898: Environmental Justice

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agencies' missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. The Agency has considered environmental justice related issues concerning the potential impacts of this action and consulted with minority and low-income stakeholders.

In the preamble to the June 2000 proposal (65 FR 38888 at 38972), EPA noted arsenic concerns raised during the March 12, 1998, environmental justice stakeholder meeting. The issues raised included confusion over units of measure of test results (*i.e.*, ppb and $\mu\text{g}/\text{L}$), effects on sensitive subpopulations (*e.g.*, incidence of diabetes in Tribal communities), infeasibility of regional consolidation, affordable treatments for small systems, increased access to funding, considering regional needs in standard setting, more training, and protection of low income communities. The Agency took these issues into consideration during the development of the January 2001 arsenic rule and the response-to-comments document. The public is invited to comment on EPA's analysis of environmental justice as it relates to today's proposal (which was discussed in the June 2000 proposal and January 2001 rule) and to recommend additional methods to address environmental justice concerns with the approach for treating arsenic in drinking water.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045: "Protection of Children From Environmental Health Risks and Safety Risks" (62 FR 19885; April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This proposed rule is not subject to Executive Order 13045 because the Agency does not have reason to believe that the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. Nonetheless, EPA evaluated the environmental health and safety effects of arsenic in drinking water on children as part of the January 2001 rule and its proposal. The public is invited to submit or identify any new peer-reviewed studies and data that assess results of early life exposure to arsenic via ingestion.

H. Executive Order 13132, Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255; August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, imposes substantial direct compliance costs, and is not required by statute (unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation). EPA also may not issue a regulation that has federalism implications and that preempts State

law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation. If EPA complies by consulting, Executive Order 13132 requires EPA to provide to OMB in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

EPA has concluded that this proposed rule will have federalism implications; these are the same federalism implications discussed and analyzed in the June 2000 and January 2001 arsenic rules. EPA provided the Office of Management and Budget (OMB) with a federalism summary impact statement (FSIS) in the preamble to the proposed and final rules. EPA provided the FSIS on page 7052 of the January 2001 rule (66 FR 6976).

I. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249; November 6, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and the Indian tribes."

This proposed rule may have tribal implications. It may have substantial direct compliance costs on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and the Indian tribes, as specified in Executive Order

13175. As a result of administrative review of the regulation published on January 22, 2001, the Environmental Protection Agency (EPA) is requesting additional comments on the regulatory options via this proposal. In developing the January 2001 rule, EPA consulted with Tribal governments to permit them to have meaningful and timely input into its development, as described in the preamble (66 FR 6976 at 7052). In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and tribal governments, EPA specifically solicits additional comment on this proposed rule from tribal officials.

J. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with sections 1412 (d) and (e) of SDWA, the Agency discussed or submitted possible arsenic rule requirements to the Science Advisory Board, National Drinking Water Advisory Council (NDWAC), and to the Secretary of Health and Human Services and requested comment from the Science Advisory Board on the arsenic rule, as described in the January 2001 preamble (66 FR 6976 at 7053). In addition, the April 23, 2001 proposed rule (66 FR 20580) outlines the additional consultations planned with NDWAC. EPA will continue contacts with the Department of Health and Human Services during the arsenic rule review process.

K. Likely Effect of Compliance With the Arsenic Rule on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of SDWA as amended requires that, in promulgating a National Primary Drinking Water Regulation (NPDWR), the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial capacity of public water systems. EPA provided the analysis performed to fulfill this statutory obligation for the January 2001 rule (EPA 2000a). During this reconsideration process, EPA will review the capacity issues further.

L. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355; May 22, 2001), provides that agencies shall

prepare and submit to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, a Statement of Energy Effects for certain actions identified as "significant energy actions." Section 4(b) of Executive Order 13211 defines "significant energy actions" as "any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) that is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action."

We have not prepared a Statement of Energy Effects for this proposed rule because this rule is not a significant energy action, as defined in Executive Order 13211. While this rule is a significant regulatory action under Executive Order 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

V. References

- Chiou, H.-Y., S.-T. Chiou, Y.-H. Hsu, Y.-L. Chou, C.-H. Tseng, M.-L. Wei, and C.-J. Chen. 2001. Incidence of transition cell carcinoma and arsenic in drinking water: A follow-up study of 8,102 residents in an arsenic-endemic area in Northeastern Taiwan. *American Journal of Epidemiology*. 153:411-418.
- Frey, M. M. and M. A. Edwards. 1997. Surveying Arsenic Occurrence. *Journal of the American Water Works Association*. 89(3):105-117.
- Frey, M., J. Chwirka, S. Kommineni, and Z. Chowdhury. 2000a. "Cost Implications of a Lower Arsenic MCL". May 5, 2000. American Water Works Association Research Foundation, Denver, CO.
- Frey, M., J. Chwirka, S. Kommineni, and Z. Chowdhury. 2000b. "Update Cost Implications of a Lower Arsenic MCL". October 10, 2000.
- Morales, K.H., L. Ryan, T.-L. Kuo, M.-M. Wu and C.-J. Chen. 2000. Risk of internal cancers from arsenic in drinking water. *Environmental Health Perspectives* 108:655-661.
- National Research Council. 1999. *Arsenic in Drinking Water*. Washington, DC. National Academy Press.
- US EPA. 1996. Proposed Guidelines for Carcinogenic Risk Assessment; Notice. **Federal Register**. Vol 61, No. 79, p. 17960. April 23, 1996.
- US EPA. 1998a. National Primary Drinking Water Regulations: Consumer Confidence Reports. Final Rule. **Federal Register**. Vol. 63, No. 160, p. 44512. August 19, 1998.

- US EPA. 1998b. Benefits Working Group Report to the National Drinking Water Advisory Council, unpublished. October 29, 1998.
- US EPA. 1999. Analytical Methods Support Document for Arsenic in Drinking Water. Prepared by Science Applications International Corporation under contract with EPA. December 1999. EPA-815-R-00-010. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2000a. Estimated Per Capita Water Ingestion in the United States: Based on Data Collected by the United States Department of Agriculture's (USDA) 1994-1996 Continuing Survey of Food Intakes by Individuals. Office of Water, Office of Standards and Technology. EPA-822-00-008. April 2000.
- US EPA. 2000b. National Primary Drinking Water Regulations; Public Notification Rule; Final Rule. **Federal Register**. Vol. 65, No. 87, p. 25982. EPA 815-Z-00-001. May 4, 2000. Available on web at www.epa.gov/safewater/pn.html.
- US EPA. 2000c. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Proposed Rule. **Federal Register**. Vol. 65, No. 121, p. 38888. EPA 815-Z-00-004 June 22, 2000. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2000d. SAB Report from the Environmental Economics Advisory Committee (EEAC) on EPA's White Paper "Valuing the Benefits of Fatal Cancer Risk Reduction. EPA-SAB-EEAC-00-013. July 27, 2000.
- US EPA. 2000e. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Notice of Data Availability. **Federal Register**. Volume 65, Number 204. October 20, 2000. Page 63027-63035. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2000f. Arsenic Proposed Drinking Water Regulation: A Science Advisory Board Review of Certain Elements of the Proposal. EPA-SAB-DWC-1-001. December 12, 2000. Available on web at www.epa.gov/sab.
- US EPA. 2000g. Arsenic Economic Analysis. Prepared by Abt Associate for Office of Ground Water and Drinking Water. EPA 815-R-00-026 December 2000. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2000h. Arsenic Occurrence in Public Drinking Water Supplies. Prepared by ISSI for EPA Office of Ground Water and Drinking Water. EPA 815-R-00-023. December 2000. Available online at www.epa.gov/safewater/arsenic.html.
- US EPA. 2000i. Arsenic Technologies and Costs for the Removal of Arsenic from Drinking Water. EPA 815-R-00-028. December 2000. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2000j. Arsenic Response-to-Comments Document for W-99-16-III. December 2000.
- US EPA. 2000k. Final Regulatory Flexibility Analysis (FRFA) for the Final Arsenic Rule. December 29, 2000.
- US EPA. 2000l. SAB Report on EPA's White Paper, Valuing the Benefits of Fatal Cancer Risk Reduction. EPA-SAB-EEAC-00-013. July 27, 2000. Available on web at www.epa.gov/sab/eeacf013.pdf.
- US EPA. 2001a. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule. **Federal Register**. Vol. 66, No. 14, p. 6976. EPA 815-Z-01-001. January 22, 2001. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2001b. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule; delay of effective date. **Federal Register**. Vol. 66, No. 57, p. 16134. March 23, 2001. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2001c. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Notice of proposed rulemaking. **Federal Register**. Vol. 66, No. 78, p. 20580. April 23, 2001. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2001d. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Notice; request for nominations to the Arsenic Cost Working Group of the National Drinking Water Advisory Council. Vol. 66, No. 87, p. 22661. May 4, 2001. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2001e. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final rule; delay of effective date. **Federal Register**. Vol. 66, No. 99, p. 28342. May 22, 2001. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2001f. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Notice [of NDWAC Arsenic Cost Working Group meeting]. Vol. 66, No. 99, p. 28161. May 22, 2001. Available on web at www.epa.gov/safewater/arsenic.html.
- US EPA. 2001g. Arsenic Response-to-Comments Document for W-99-16-IV. May 2001.
- US EPA. 2001h. Meetings of the Arsenic Cost Working Group of the National Drinking Water Advisory Council; Notice of Public Meeting. Vol. 66, No. 116, p. 32617. June 15, 2001.
- US EPA. 2001i. EPA Science Advisory Board; Notification of Public Advisory Committee Meetings. Vol. 66, No. 127, p. 34924. July 2, 2001.
- WH. 2001. Memorandum for the Heads and Acting Heads of Executive Departments and Agencies. **Federal Register**. Vol. 66, No 66, pg. 7702. January 24, 2001. Available on web at www.epa.gov/safewater/arsenic.html.
- US GS. 2000. Focazio, M., A. Welch, S. Watkins, D. Helsel & M. Horn. A retrospective analysis of the occurrence of arsenic in ground water resources of the United States and limitations in drinking water supply characterizations. Water Resources Investigations Report: 99-4279. May 2000. Available on web at: <http://co.water.usgs.gov/trace/arsenic>.

List of Subjects in 40 CFR Parts 141 and 142

Environmental protection, Chemicals, Indian lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: July 13, 2001.

Christine Todd Whitman,
Administrator.

[FR Doc. 01-18093 Filed 7-18-01; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 98-67; DA 01-1555]

Provision of Improved Telecommunications Relay Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document solicits additional comment on the provision of improved Telecommunications Relay Service (TRS). Title IV of the Americans with Disabilities Act (ADA) requires the Commission to promulgate regulations on TRS, to make available to Americans with hearing or speech disabilities telecommunications services that are functionally equivalent to those available to individuals without disabilities.

DATES: Comments are due on or before July 30, 2001 and reply comments are due on or before August 6, 2001.

ADDRESSES: Federal Communications Commission, 445 12th Street, S.W., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Dana Jackson, (202) 418-2247 (voice), (202) 418-7898 (TTY). This document is available to individuals with disabilities requiring accessible formats (electronic ASCII text, Braille, large print, and audio) by contacting Brian Millin at (202) 418-7426 (voice), (202) 418-7365 (TTY), or by sending an email to access@fcc.gov.

SUPPLEMENTARY INFORMATION: The Bureau is issuing this document to seek comment on WorldCom's Petition and additional issues associated with IP Relay. Comments already submitted in response to WorldCom's petition will be