

Appendix C

**Arsenic and Clarifications to
Compliance and New Source
Contaminants Monitoring:
Delay of Effective Date;
Final Rule (66 FR 28342)**

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Environmental Protection Agency

40 CFR Parts 9, 141, and 142

**[WH-FRL-6983-8]
RIN 2040-AB75**

National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring: Delay of Effective Date

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; delay of effective date.

SUMMARY: Today's action delays the effective date of the arsenic in drinking water regulation published on January 22, 2001 (66 FR 6976), to February 22, 2002. The effective date for the arsenic regulation was previously delayed 60 days on March 23, 2001 (66 FR 16134), to May 22, 2001. The effective date for clarifications to compliance and new-source contaminants monitoring in the January 22 arsenic regulation remains unchanged as January 22, 2004.

On March 20, 2001, EPA's Administrator publicly announced that the Agency would take steps to reassess the scientific and cost issues associated with the arsenic rule published on January 22, 2001, and seek further public input on important issues with that rule. On April 23, 2001, EPA published in the Federal Register (66 FR 20580) a proposal to delay the effective date of the arsenic rule for an additional nine months in order to conduct reviews of the science and costing analysis and make the results available for public review. Today's action extends the effective date for the arsenic rule from May 22, 2001, to February 22, 2002, in order to conduct the reviews described in the April 23, 2001 Federal Register (66 FR 20580). For now, the current standard of 50 : g/L remains the applicable arsenic drinking water standard until the 2006 compliance date for the January 2001 final rule.

DATES: As of May 22, 2001, the effective date of the National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, amending 40 CFR parts 9, 141 and 142, published in the Federal Register on Monday, January 22, 2001, at 66 FR 6976 and delayed on Friday, March 23, 2001, at 66 FR 16134, is further delayed for nine months, from the scheduled effective date of May 22, 2001, to a new effective date of February 22, 2002, except for the amendments to Secs. 141.23(c)(9), 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(f)(22), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) which are effective on January 22, 2004. The amendment to Sec. 141.6 in this rule is also effective February 22, 2002.

ADDRESSES: You can review copies of the public comments received on the proposed nine-month extension of the effective date, EPA responses, and all other supporting documents in docket W-99-16-IV at the U.S. EPA Water Docket (4101), East Tower Basement room 57, 401 M Street, SW., Washington, DC 20460.

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 and copies of arsenic documents. For technical inquiries, contact: James Taft, (202) 260-5519, e-mail: taft.james@epa.gov. Contact the Water Docket at (202) 260-3027 to review the supporting documents and public comments on the proposed nine-month extension as well as EPA's responses to those comments.

SUPPLEMENTARY INFORMATION: Availability of Docket. For an appointment to review the docket for this nine-month extension of the effective date, 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-IV. 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.

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 Sec. 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 Sec. 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." Entities potentially regulated by this action are community water systems and non-transient, non-community water systems. 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 or mixed ground water and surface water.
State, Tribal, and Local Government	State, Tribal, or local government-owned/operated water supply systems using ground water or mixed ground water and surface water.
Federal Government	Federally owned/operated community water supply systems using ground 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 Secs. 141.11 and 141.62 as revised by the January 22, 2001 (66 FR 6976) arsenic rule.

Abbreviations Used in This Rule

Sec. --section
: g/L--micrograms per liter, same as ppb
APA--Administrative Procedure Act
BAT--Best available technologies
CCR--Consumer confidence reports (Subpart O)
CFR--Code of Federal Regulations
CWS--Community water system
EPA--U.S. Environmental Protection Agency
FACA--Federal Advisory Committee Act
FR--Federal Register

MCL--Maximum Contaminant Level
 MCLG--Maximum Contaminant Level Goal
 mg/L--milligrams per liter
 NAS--National Academy of Sciences, private entity chartered in 1863 to advise the government
 NCWS--Non-community water system
 NDWAC--National Drinking Water Advisory Council, chartered under FACA to advise EPA
 NPDWR--National primary drinking water regulation
 NRC--National Research Council, operating arm of NAS
 NTNCWS--Non-transient non-community water system
 NTTAA--National Technology Transfer and Advancement Act
 OMB--Office of Management and Budget
 POTWs--Publicly owned treatment works (treat wastewater)
 ppb--parts per billion, same as : g/L
 PRA--Paperwork Reduction Act
 PWS--Public water systems
 RFA--Regulatory Flexibility Act
 SBREFA--Small Business Regulatory Enforcement Fairness Act
 SDWA--Safe Drinking Water Act
 TDS--Total dissolved solids
 UMRA--Unfunded Mandates Reform Act
 U.S.--United States
 WHO--World Health Organization

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I. Background and History

A. What is in EPA's January 22, 2001, Final Rule and What Requirements Will Be Affected by a Delay in the Effective Date?

1. Final Arsenic Regulations

In the Monday, January 22, 2001, **Federal Register** (EPA 2001a), EPA issued final regulations for arsenic and clarifications to compliance and new-source contaminants monitoring (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) and an enforceable Maximum Contaminant Level (MCL) for arsenic of 0.01 mg/L (i.e., 10 micrograms per liter (: g/L)). Until the January 2001 arsenic regulation becomes effective, the existing arsenic regulation (i.e., no MCLG and an MCL of 50 : g/L) issued December 24, 1975 (40 FR 59566) remains in effect. (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 : g/L in this preamble.) As part of the January 2001 arsenic regulation, EPA also listed the approved analytical methods to measure compliance, the best available technologies (BAT) and small system technologies that could achieve compliance with the MCL, and the public reporting requirements (changed by revising the MCL to 10 : g/L). The January 2001 rule contained an effective date of March 23, 2001, and a compliance date for this final arsenic regulation of January 22, 2006, five years after publication for all systems.

2. Clarifications for Monitoring and Compliance for New Systems and New Sources

On January 22, 2001 (66 FR 6976), EPA also published regulations for inorganic, volatile organic, and synthetic organic contaminants (EPA, 2001a), and these regulations are not affected by today's action. Sections 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), and 141.24(h)(11) covered the clarifications for monitoring and compliance when a system fails to collect the required number of samples. Sections 141.23(c)(9), 141.24(f)(22), 141.24(h)(20), and 142.16(k) recognized the State-specified time period and sampling frequency for new public water systems and systems using a new source of water for demonstrating compliance with drinking water regulations.

EPA's review of the arsenic rule does not include a review of the clarifications to compliance and new source compliance monitoring regulations issued on January 22, 2001 (66 FR 6976). Therefore, the "effective date for purposes of compliance" for these regulations remains January 22, 2004, as specified in the January 2001 rule in Sec. 141.6(k).

While provisions of the January 2001 final rule will move arsenic into the standardized monitoring framework for inorganics (i.e., Secs. 141.23(a)(4)(i), (a)(5), (c), (i)(1), (i)(2), and (k)(2), (k)(3)), the compliance date for the revised arsenic regulations remains January 23, 2006. Until then, the revisions to Sec. 141.11(a) and (b) retain the existing monitoring and compliance requirements of Sec. 141.23(l)--(p) for arsenic.

3. Primacy Requirements

Section 1413(a)(1) of the Safe Drinking Water Act (SDWA), as amended in 1996, requires States with primary enforcement responsibility to adopt drinking water regulations that are no less stringent than EPA's regulations. By statute, States are required to do so no later than two years after EPA promulgates national primary drinking water regulations unless EPA provides up to a two-year extension. Specifically, States will be required to specify the initial monitoring requirements for new PWSs and new sources (Sec. 142.16(k)) mentioned in the previous section. In addition, States will have to adopt the wording for submitting more information for newly regulated contaminants per Sec. 142.16(e) and less information than now required for revising primacy for an existing contaminant per Sec. 142.16(j).

EPA is reviewing the final arsenic regulation, and may ultimately decide to revise the MCL published on January 22, 2001. EPA is also aware of the practical implications of such possible decisions on State primacy requirements and State schedules for implementing these changes. As a result, EPA will be working closely with States in this regard and will be addressing the issue of State primacy requirements in more detail in future Federal Register actions.

4. Changes in Consumer Confidence Reports (CCR) for Arsenic

The January 2001 revisions to the CCR rule that included new reporting requirements for arsenic will be delayed until February 22, 2002. The final rule issued for the consumer confidence rule (63 FR 44512) on August 19, 1998, at Sec. 141.154(b) required CWSs that detect arsenic between 25 : g/L and 50 : g/L to include an informational statement about EPA's review of the arsenic standard beginning with the report for calendar year 1998 (see Sec. 141.152(a)). Section 141.153(d)(4) requirements stipulate that if arsenic is detected, the CCR must list the MCL (i.e., 50 parts per billion (ppb)), the highest contaminant level used to determine compliance, the range of detected levels (specified in Sec. 141.153(d)(4)(iv)), and likely source(s) of contamination. Section 141.153(d)(6) requires that, for any data indicating violations of the arsenic MCL (i.e., 50 parts per billion (ppb)), the CCR must explain the length of the violation, actions taken to address the violation, and the potential adverse health effects described in appendix A to subpart O.

The final arsenic rule (EPA 2001a) issued on January 22, 2001 (66 FR 6976), made two changes to the annual consumer confidence reports for arsenic. The January 2001 arsenic rule changed the informational reporting for arsenic in Sec. 141.154(b) to require additional information for CWSs that detected between 5 : g/L and 10 : g/L starting with the calendar year 2001 report (due July 1, 2002). The January 2001 rule (66 FR 6976) also added Sec. 141.154(f) to require reporting of health effects information for systems that detect arsenic between 10 : g/L and 50 : g/L beginning with the report due July 1, 2002 and ending January 22, 2006, before the new MCL becomes effective for compliance purposes.

Because of the review of the January 2001 arsenic rule, the reporting requirements in Secs. 141.154(b) and (f) relating to arsenic will also need to be reconsidered and may, at the least, need to be amended to delay the due date for reporting. EPA will be considering changes to these CCR requirements for arsenic as part of the forthcoming arsenic rulemaking discussed in section II of today's preamble.

The effect of today's 9-month delay of the effective date is that, for the CCR reports for calendar year 2001, CWSs will continue to implement the CCR requirements for arsenic contained in the August 19, 1998 rule until February 22, 2002, rather than any of the new requirements of the January 22, 2001 rule.

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

On March 20, 2001, the Administrator announced plans to seek independent reviews of the science and cost estimates supporting the arsenic standard. The March 23, 2001, Federal Register notice (66 FR 16134) delayed the effective date for parts of the arsenic rule by 60 days, from March 23, 2001, to May 22, 2001 (EPA, 2001b). That delay was in accordance with the memorandum of January 20, 2001, from the Assistant to the President and White House Chief of Staff, entitled "Regulatory Review Plan," published in the Federal Register on January 24, 2001 (66 FR 7702).

C. What Did EPA Propose on April 23, 2001?

On April 23 (66 FR 20580), EPA proposed (EPA, 2001c) a further delay of the effective date for parts of the arsenic rule, until February 22, 2002, to allow additional time for reconsideration of specific aspects of the arsenic rule as explained in the next section. EPA accepted public comments during a 14-day comment period on the proposed delay of the effective date.

D. Why Did EPA Propose Further Review of the Arsenic Rule?

Consistent with the Administrator's public announcement on March 20, the purpose of proposing a 9-month delay to the effective date was to allow additional time for review of the science and costing analyses underlying the arsenic in drinking water rule. 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 and benefit 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.

II. What Will Be the Process for Reviewing the Arsenic Rule?

A. Overview

EPA considered a number of possible mechanisms for conducting the necessary reviews of the underlying science and cost of compliance estimates associated with the arsenic in drinking water rule, and is also considering establishing a third mechanism to review the benefits of the rule. The Agency's criteria for conducting the reviews are to ensure that reviewers are recognized experts in their fields and are as impartial and objective as possible; that the reviews can be completed quickly; and that the results of the review be made publicly available for comment. At present, EPA is using two distinct mechanisms for the review and will continue to consider other steps to ensure timely and thorough review of the standard.

- Review of Health Effects of Arsenic and Consideration of Key Issues Associated with the Risk Analysis: National Academy of Sciences' National Research Council.

- Review of Process for Developing Cost of Compliance Estimates: Specially convened subgroup of the National Drinking Water Advisory Council.

In the case of the National Research Council, EPA is relying on the same independent judgment, objective analysis, and scientific expertise that is reflected in the March 1999 NRC report (NRC, 1999), entitled, "Arsenic in Drinking Water" in reviewing the Agency's interpretation and application of existing arsenic research as well as new studies of arsenic health effects science that have been published since the 1999 report. With regard to costing issues, the National Drinking Water Advisory Council has a charter, under the Federal Advisory Committee Act, to advise the Agency on an array of drinking water issues associated with implementing the national drinking water program and has previously provided recommendations to the Agency in the development of the arsenic in drinking water rule.

As its next step in the process for review of the arsenic MCL, EPA plans to release a proposal requesting comment on a range of arsenic MCLs from 3 : g/L to 20 : g/L. The purpose of this proposal is to provide for additional public comment on the range of arsenic MCLs and the science, cost and benefit and other analysis related to the arsenic rule. EPA will also provide the public an opportunity to comment on the results of the independent science and cost reviews. EPA then plans to analyze the results of these reviews together with any public comment on the range of arsenic MCLs to reach a final decision on how to proceed with regard to the arsenic MCL. As it becomes available, further information on this process will also be available on EPA's arsenic in drinking water webpage at www.epa.gov/safewater/arsenic.html and from the Safe Drinking Water Hotline phone: (800) 426-4791, or (703) 285-1093, e-mail: Hotline-sdwa@epa.gov.

B. Approach to Review of Health Science

Under a cooperative agreement with EPA, on May 21 the National Academy of Sciences (NAS) will convene a subcommittee of the National Research Council's (NRC) Committee on Toxicology to prepare a report updating the scientific analyses, uncertainties, and findings of the 1999 NRC report "Arsenic in Drinking Water." Specifically, the subcommittee will review 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. The subcommittee will address 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 plans to produce a consensus report in August 2001. The subcommittee will hear presentations from government agencies, industry, and other interested or affected parties. Notices of meetings open to the public are to be posted on the website www.national-academies.org. EPA has asked NRC to make its final report publicly available, and the report will be available in EPA's arsenic rulemaking record.

C. 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 has asked the NDWAC to convene a panel of nationally recognized technical experts to review the cost of compliance estimates associated with the final arsenic rule. In particular, the working group is to review the costing methodologies, assumptions, and information underlying the costs applicable for various categories of water system sizes as well as the aggregated national estimate of system costs underlying the final arsenic rule. As a part of this review, the group should evaluate significant alternative costing approaches or critiques where there is adequate information upon which to evaluate the basis for such alternate estimates or approaches.

Working group members will be asked to attend a series of meetings (approximately three) over the summer of 2001, participate in discussion of key issues and assumptions at these meetings, and review work products of the working group. EPA has asked NDWAC to ensure the working group prepares a report and makes a recommendation to the full NDWAC based on their review of the national cost estimates. The NDWAC, in turn, would submit a report and 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. The report and the final recommendations of the NDWAC will be made available for public review and comment by EPA and will also be available in the arsenic rulemaking record.

III. Response to Comments

A. Comments Specific to the Proposal To Further Delay the Effective Date of the January 22, 2001, Arsenic Rule Until February 22, 2002

The Agency received over 12,000 comments on the April 23, 2001, proposal to delay the effective date of the January 22, 2001, final rule (66 FR 6976) another nine months until February 22, 2002, to allow additional time for reconsideration of the provisions of this final rule. The majority of the comments came from private citizens sending electronic mail (i.e., e-mail). Many of these commenters did not support the extension and cited several reasons for their position: their concerns about the health hazards posed by arsenic in drinking water and the consequences of a delayed effective date on implementation deadlines; their belief that the decade or more of scientific reviews, public hearings, and other deliberations that supported the revised arsenic MCL were sufficient and that additional time is not warranted; and their belief that the standard published on January 22, 2001, is appropriate and should not be delayed further since the 10 : g/L MCL conforms with the standard set by other entities, such as the World Health Organization (WHO). A few commenters believed that the 14-day comment period on the April 23, 2001, proposal was too short to obtain meaningful comment.

Other commenters, most of whom represented the drinking water industry, small system water providers, and States, believed that a short delay to re-examine some of the consequences of the final rule was warranted, especially to carefully consider the financial impact on small systems (i.e., systems serving populations of 10,000 or fewer). These commenters supported a comprehensive and independent review of the underlying science (health studies used and interpretations of these studies) and costing associated with the arsenic final rule. These commenters strongly supported the Agency's plan to use NAS (NRC) and NDWAC expert panels.

The following sections respond to the comments that were specifically directed towards the issue of whether or not to delay the effective date. Section III.B. provides a more general response to the many issues raised by the commenters that were not directly tied to the delay of the effective date.

1. Health Concerns

The overwhelming number of commenters expressed concern about a nine-month delay of the effective date of the revised arsenic rule, due in part to concerns about immediate health impacts due to a delay in implementation of the rule. EPA does not believe that this short delay of the effective date will result in health effects of any kind for several reasons. First of all, the delay EPA issues today is very short; EPA has committed to reviewing the science and cost issues related to the revised final arsenic rule as expeditiously as possible and no later than early next year. Second, the compliance date for the revised arsenic rule was five years in the future even under the January 2001 rule so that there would have been no immediate implementation of the new standard in any case. Moreover, EPA does not anticipate that this short delay will mean a delay in these compliance deadlines.

2. Adequacy of Existing Scientific Research

Many commenters expressed their belief that extensive research supports the 10 : g/L MCL published in the January 2001 rule and that there is an insufficient technical and procedural basis for reconsidering the rule. Many of these commenters urged the Agency to simply allow the effective date to occur on May 22, 2001, without impediment. The Agency understands these concerns, but wishes to allow time for serious reconsideration of the arsenic standard published on January 22, 2001. A relatively short delay of the effective date provides flexibility for fully reconsidering the rule and a full range of options consistent with SDWA section 1412(b)(9) (concerning review and revisions of existing drinking water regulations). While the Agency agrees that the January 2001 rule was supported by extensive data and analysis, the Agency also agrees with other commenters who argued that this rule is very important and the issues of cost and science that are central to the rulemaking deserve one final review before concluding this rulemaking. Thus, EPA believes that the ultimate decision to be made in early 2002 will be strengthened by allowing additional public comment and a review by expert panels from NAS and NDWAC. This review includes a reconsideration of the 3, 5 and 10 : g/L MCLs suggested by the commenters who oppose the extension. The nine-month period provides a unique opportunity for independent, expert panels to review the Agency's actions in the final rule in connection with both the underlying science and the Agency's compliance cost assumptions and methodologies contained in the final January 2001 rule. This review also provides an opportunity to examine information that has only recently become available. In particular, the Agency is aware of many scientific articles that have become available since the original report of the NAS (NRC 1999) committee published in March 1999.

3. Comparison of January 22, 2001, Standard to WHO Recommended Standard

Several commenters expressed concerns that the Agency may, as a result of a nine-month delay of the effective date, revise the January 22, 2001, standard to a less stringent standard that would not comport with the WHO recommended standard of 10 : g/L. In this regard, the Agency noted in the preamble of the January 2001 final rule (66 FR 7025) that the nonenforceable WHO guideline was not set using the same health endpoints, feasibility of implementation, or other risk management factors that are mandated under SDWA. Because the U.S. drinking water standard for arsenic was not developed using the basis employed in setting the WHO guideline, the Agency specifically noted in the 2001 final rule that a possible future change in the WHO value would not necessarily require a revision to EPA's MCL. For the same reasons, the Agency's MCL is not dependent on arsenic standards established by the European Union, or other countries or international organizations. In any case, the Agency has made no commitment to revise the standard to a concentration more or less stringent than the January 22, 2001, level.

4. Adequacy of Comment Period

The Agency believes that the fourteen-day comment period was sufficient to allow public comment on the very narrow issue of whether or not to provide a short delay of the effective date. Because (1) the issue is so narrow and the implications so minor in light of the five-year compliance period and the length of the delay; (2) the rule had just been issued a few months ago after many months of public input; (3) there has been intense public attention already devoted to this rulemaking; and (4) there is an urgency to the upcoming May 22 deadline, the Agency did not feel that it was necessary to have a longer comment period. Indeed, the number of comments received (over 12,000) greatly exceeded the 1,000 or so comments received on the June 2000 rule that proposed a range of new MCLs for arsenic. The Agency helped facilitate this strong and diverse response with prior publicity and a targeted mailing. Prior to publication of the April 23, 2001, proposal, EPA widely publicized the proposed rule indicating EPA's intention to seek a delay, and performed a direct mailing to approximately 1,000 individuals and organizations who had expressed interest in the arsenic rulemaking.

5. Procedural Concerns

One commenter suggested that the Agency is obliged to provide an opportunity for a public hearing(s) on the proposed regulation to delay the effective date, in accordance with section 1412(d) of SDWA before taking final action on the proposal. Section 1412(d) states that EPA must provide opportunity for public hearing prior to promulgation of regulations under section 1412 of SDWA and consult with NDWAC. Today's action is merely a short delay of the effective date of a recently published national primary drinking water regulation (NPDWR). As such, it is, in essence, a continuation of the rulemaking process to revise the arsenic rule first commenced several years ago. The whole purpose of this delay is to allow for additional public input and NDWAC consultation. The Agency does not believe that it is necessary or appropriate to provide for extensive public comment hearings and consultations on the issue of whether to have further public debate and consultation. Indeed, EPA provided several opportunities for public involvement, including hearings and consulted with NDWAC prior to issuance of the January 22, 2001, NPDWR and will provide an opportunity for a public hearing in developing a final decision of whether and how to revise the January rule, based upon the findings of expert review panels. As discussed earlier, EPA's review includes working with NDWAC on some of the most controversial aspects of the January rule. As a result, while EPA does not believe that it makes sense to hold a public hearing for today's action, the Agency has fully complied with this provision throughout this extended rulemaking on arsenic and will continue to provide public hearing opportunities and hold NDWAC consultations before taking any action to withdraw, modify or supercede the January 2001 rule.

Another procedural question raised by some commenters was whether or not the Agency had met its obligations pursuant to SDWA and Public Law 106-377 (fiscal year 2001 appropriations act for EPA), requiring the Agency to promulgate a final rule by June 22, 2001. These commenters contended that a delay of the effective date would result in the Agency missing that deadline and urged the Agency to allow the rule to go into effect on May 22, 2001. The Agency believes that, independent of the statutory deadline for promulgation, EPA has the authority to establish appropriate effective dates.

6. Review of Underlying Costs and Health Effects Associated With the Rule

Several commenters expressed support for delaying the effective date in order to undertake the necessary scientific and technical reviews. The Agency agrees with the sentiment that additional time for technical reviews of elements of the rule is warranted. The Agency also believes that it is also important to recognize that the economic impact of the 80% decrease in the 50 : g/L MCL to 10 : g/L affects about 4,000 PWSs, many of whom serve populations of less than 3,300. Thus, the per capita cost of the final MCL could be significant at some affected PWSs. The independent review proposed by EPA provides more time to develop a mitigation strategy, and the re-opening of the comment period allows the public to participate in this process and suggest other options.

The Administrator announced her intention to review the cost and science underlying the rule on March 20, 2001. The delay of the effective date for parts of the final arsenic rule by nine months will provide the Agency and the public the benefit of the results of reviews by independent expert panels and allow for additional comment by affected individuals and entities. The reviews will be comprehensive and independent, as suggested by commenters. The results will be a significant and important source of information for the Agency to consider as it makes a final decision. There will be no adverse health impacts resulting from this short delay of the effective date within the five-year compliance period. For these reasons, the Agency in today's rule delays the effective date of the January 22, 2001, final rule until February 22, 2002.

B. Comments Not Specific to the Proposal To Further Delay the Effective Date of the Final Rule

Some commenters also commented on issues not specific to the April 2001 proposal to delay the effective date of the final arsenic rule by nine months. Some of these commenters resubmitted or

referenced the same or similar comments that had been submitted in response to the June 22, 2000, proposed rule. A summary of these extra comments follows. EPA does not intend to provide a comprehensive response to these comments because they are not germane to the specific rule issued today. However, many of these issues will be discussed in an upcoming proposal as well as in a future notice providing the results of the reviews of the expert panels referred to earlier.

1. Consumer Confidence Reports

Several commenters disagreed with the consumer confidence reporting (CCR) rule requirements in the revised arsenic rule. Because of the high public awareness about arsenic as a potentially toxic contaminant and carcinogen that may occur in drinking water, the commenters are concerned that these new requirements will unnecessarily alarm consumers. The commenters also noted that one of the reporting requirements is set at 10% of the current 50 : g/L MCL. One commenter believes that the 5 : g/L reporting limit is appropriate, because of the consumer right to know about contamination of their drinking water.

Based on the recent interest and awareness of the general public with arsenic in drinking water, the Agency understands that the requirement for a system to provide health information for arsenic contamination well below the current MCL of 50 : g/L that is in effect until January 22, 2006, requires further analysis and discussion. The Agency will study this issue during the nine-month review of final rule and consider public comment that may be received during that review. The Agency plans to make a final decision whether to revise the arsenic CCR requirements as part of its decision making on whether or not to revise the MCL.

2. Adverse Impacts on Small Systems

Several commenters supporting the delay until February 22, 2002, also noted that the 2001 final rule requires treatment changes that are too costly. Commenters were concerned about costs for small systems. Two commenters also noted that timely compliance with the 2006 date was in jeopardy, because systems affected by the 10 : g/L MCL cannot begin treatment or other changes until the Agency takes final action on the results of the review of the final rule.

The Agency appreciates the support for the delay to allow a review of costs and other issues associated with implementation of the 2001 final rule. The Agency will be further considering concerns raised by commenters with respect to the issue of how to address the impact of the nine-month delay on the compliance dates in the final rule. The statute sets out specific requirements for establishing and extending compliance dates and EPA will comply with these provisions in confirming or revising the January 2001 rule.

Many comments on the April 23, 2001, document were limited to a statement that the costs of the January 2001 rule were too high, or could not be borne within the 2006 time frame. A few commenters resubmitted their comments on the June 2000 proposed rule. These comments on the proposed rule were more detailed and cited specific issues, such as point-of-use devices, feasibility of treatment in arid climates, landfill and waste disposal, wastewater treatment burdens on publicly owned treatment works (POTWs), and impacts of chloride and total dissolved solids (TDS).

Although the Agency has not yet decided whether or how to change the provisions of the January 22, 2001, final rule, the issue of the costs of small system treatment technologies is within the purview of the forthcoming NDWAC review of the cost models used in the final rule. Subsequent to additional public comment on this and other issues, and to the NDWAC expert panel review, the Agency will again address the issues of costs to small systems.

3. Selection and Instruction of the Expert Panels

Several commenters provided detailed suggestions about how to select members and charge the expert panels in the review of the arsenic final rule. Commenters requested that the charge to the panel be

very broad and include all of the issues described in the preamble of the final rule. The Agency appreciates the suggestions for charging the expert panels, and is providing the public with several ways to participate in the review of the final arsenic rule process. For example, on May 4, 2001 (66 FR 22551), EPA requested nominations of individuals to serve on the cost working group of NDWAC (EPA, 2001c). This document provided an opportunity to advise EPA on the selection of this expert panel. In addition, many of these issues will be discussed in the future proposed rule that will request comment on a range of arsenic MCLs and provide for additional public comment on the range of science and cost issues related to the arsenic rule (66 FR 20582, April 23, 2001). In the April 2001 document, the Agency noted that the results of the independent science and cost reviews will be made public along with further information on the review process. Finally, much of this information will be available on EPA's drinking water webpage at www.epa.gov/safewater/arsenic.html and from the Safe Drinking Water Hotline. Similarly, on April 17, 2001, the NAS provided notice about its charge to the new arsenic committee on its web site and solicited comment on the provisionally named members of the committee.

The Agency believes there is still a strong basis to specify an arsenic MCL significantly less than the current 50 : g/L standard. Although the Agency will ask for a review of the 3-20 : g/L range proposed in the June 22, 2000, proposed rule, the public may provide evidence to support a higher drinking water arsenic standard.

4. Use of a Sublinear Dose Response Relationship

Some commenters resubmitted their comment on the June 2000 proposal that the dose-response relationship for arsenic health effects should use a sublinear model rather than the model used by EPA to specify the final MCL and MCLG. These commenters believed that a sublinear model would lead to derivation of a higher MCL and possibly a non-zero MCLG.

Although the Agency has not yet decided whether or how to change the provisions of the January 22, 2001, final rule, the nonlinear dose relationship mentioned by commenters is within the purview of the forthcoming NAS review of the science supporting the final rule. Subsequent to this expert panel review, and to public comment on this and other issues, the Agency will determine whether to adopt a nonlinear dose relationship to calculate an MCLG and MCL for arsenic.

IV. Administrative Requirements

A. Executive Order 12866 Regulatory Planning and Review

Under Executive Order 12866 (58 FR 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 this rule is not a "significant regulatory action," and, as such, has not been submitted to OMB for review under the Executive Order.

B. 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 final rule is not subject to Executive Order 13045 because it is not economically significant and 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.

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.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. This is because the rule imposes no enforceable duty on any State, local or tribal governments or the private sector. Thus today's rule is not subject to the requirements of section 202 and 205 of the UMRA. For the same reason, EPA also has determined that this action contains no regulatory requirements that might significantly or uniquely affect small governments. This action does not impose any requirement on anyone. Thus, there are no costs associated with this action. Therefore, today's rule is not subject to the requirements of section 203 of UMRA.

D. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. This action does not impose any requirements on anyone and does not voluntarily request information. The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the January 22, 2001,

regulations, 40 CFR parts 9, 141 and 142 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2040-0231.

E. 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 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 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, 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.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This action does not impose any requirements on anyone, including small entities, it merely extends the effective date of the January 2001 rule.

F. 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.

This final rulemaking does not impose any new technical standards.

EPA's analysis of the NTTAA's application to the arsenic rulemaking is described in the June 22, 2000, proposal at 65 FR 38971-38972 and the January 22, 2001, final rule at 66 FR 7051.

G. 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."

This final rule does not have federalism implications. It will not 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, as specified in Executive Order 13132. This rule does not establish or change any requirements. Thus, Executive Order 13132 does not apply to this rule.

H. 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 Indian tribes."

This final rule does not have tribal implications. It will not have substantial direct effects 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 Indian tribes, as specified in Executive Order 13175. As a result of administrative review of the final regulation published on January 22, 2001, the Environmental Protection Agency (EPA) is delaying the effective date for the drinking water regulation for arsenic. The purpose is to reassess the scientific and cost issues and seek further public input, as well as to fully review the support available for small systems. This delay does not impose any burden on tribes or tribal governments. Thus, Executive Order 13175 does not apply to this rule.

I. 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. Today's action does not establish or change any requirements and therefore does not have any environmental justice implications.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will become effective upon publication.

K. Administrative Procedure Act (APA)

Section 553(d) of the Administrative Procedure Act, 5 U.S.C. 553(d), generally requires that a substantive rule not become effective prior to 30 days after publication. However, that section allows

rules to be effective immediately if the rule relieves a restriction or for other good cause found by the Agency and published with the rule. Today's effective date delay is immediately effective. EPA believes that this action is justified because there is no need to delay the effective date of a rule that merely delays an effective date. This rule has little, if any, substantive impact. Thus, EPA believes that this action is consistent with Section 553 of the APA.

V. References

NRC. 1999. Arsenic in Drinking Water. Washington, DC. National Academy Press. U.S. EPA. 2000. 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. June 22, 2000.

U.S. 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. January 22, 2001.

U.S. 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.

U.S. 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.

WH. 2001. Memorandum for the Heads and Acting Heads of Executive Departments and Agencies. Federal Register. Vo. 66, No. 16, p. 7702. January 24, 2001.

List of Subjects in 40 CFR Part 141

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

Dated: May 17, 2001.

Christine Todd Whitman,
Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency takes the following actions:

PARTS 9, 141, AND 142--[DELAY OF EFFECTIVE DATE]

1. To delay the effective date of the amendments to 40 CFR parts 9, 141, and 142 published January 22, 2001 (66 FR 6976), and delayed on March 23, 2001 (66 FR 16134), from May 22, 2001, to February 22, 2002, except for the amendments to Secs. 141.23(c)(9), 141.23(i)(1) and (i)(2), 141.24(f)(15), (f)(22), (h)(11) and (h)(20), and 142.16(e), (j), and (k), which are effective January 22, 2004.

PART 141--NATIONAL PRIMARY DRINKING WATER REGULATIONS

2. To amend 40 CFR part 141 as follows:

A. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11.

Subpart A--[Amended]

B. Paragraph (j) of 40 CFR 141.6, as added at 66 FR 7061, January 22, 2001, and amended at 66 FR 16134, March 23, 2001, is further amended by revising the last sentence to read follows:

Sec. 141.6 Effective dates.

* * * * *

(j) * * * However, the consumer confidence rule reporting requirements relating to arsenic listed in Sec. 141.154(b) and (f) are effective for the purpose of compliance on February 22, 2002.

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[FR Doc. **01-12878 Filed 5-21-01**; 8:45 am]

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