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Arsenic in Drinking Water: Regulatory Developments and Issues

Mary Tiemann
Specialist in Environmental Policy
Resources, Science, and Industry Division

Summary

In 1996, Congress directed the Environmental Protection Agency (EPA) to issue a new standard for arsenic in drinking water by January 2001. Congress also directed EPA, with the National Academy of Sciences (NAS), to study arsenic's health effects to reduce the uncertainty in assessing health risks associated with exposure to low levels of arsenic. EPA had adopted an interim standard of 50 parts per billion (ppb) in 1975. In 1999, the NAS concluded that the standard did not achieve EPA's goals for public health protection and recommended that it be tightened as soon as possible.

On January 22, 2001, EPA issued a final rule and set the standard at 10 ppb, with an effective date of March 23, 2001; water systems were given until January 23, 2006 to meet the standard. EPA projected that compliance could be costly for some small systems, but water utilities and communities expressed concern that EPA had understated the rule's costs. Subsequently, EPA postponed the rule's effective date to February 22, 2002, in order to review the science, costs, and benefits analyses that supported the rule. In October 2001, EPA announced that the standard will be 10 ppb. The rule became effective on February 22, 2002, and the compliance date for water systems remained unchanged. EPA and Congress are now focusing on how to help communities comply with the new rule by January 23, 2006. This report reviews the arsenic rule and subsequent EPA and congressional actions. It will be updated.

Regulatory Background

Arsenic is a widely distributed, naturally occurring element in the Earth's crust and is present in trace amounts in all living organisms. Higher levels of arsenic tend to be found more frequently in ground water than in surface water. Because small water systems typically rely on wells for drinking water, while the largest systems typically rely on surface-water sources, arsenic tends to occur in higher levels more often in water used by small communities. In the United States, the average level measured in ground-water samples is less than or equal to 1 part per billion (ppb, or micrograms per liter (μg/L); however, higher levels are not uncommon. Compared to the rest of the United States,

Western states have more water systems with levels exceeding 10 ppb, and levels exceed 50 ppb in some locations. Parts of the Midwest and New England also have some water systems with arsenic levels exceeding 10 ppb, but most systems have lower levels. EPA projects that 5.5% of water systems, serving 11 million people, are likely to exceed the10 ppb level. Sources of arsenic in water include natural sources, releases from its use as a wood preservative, in semi-conductors and paints, and from agriculture and mining.

The current federal drinking water standard for arsenic, 50 ppb, was set by the U.S. Public Health Service in 1942. EPA adopted that level and issued an interim drinking water regulation for arsenic in 1975. This standard was based on estimated total dietary intake[1] and non-cancer health effects. In 1986, Congress amended the Safe Drinking Water Act (SDWA), converted all interim standards to National Primary Drinking Water Regulations, and included arsenic on a list of 83 contaminants for which EPA was required to issue new standards by 1989.

EPA's extensive review of arsenic risk assessment issues had caused the Agency to miss the 1989 deadline for issuing a new standard. As a result of a citizen suit, EPA entered into a consent decree with a new deadline for the rule of November 1995. EPA continued work on risk assessment, water treatment, analytical methods, implementation, and occurrence issues but, in 1995, decided to delay the rule in order to better characterize health effects and assess cost-effective removal technologies for small utilities.

Arsenic and the 1996 SDWA Amendments

In the 1996 SDWA Amendments (P.L. 104-182), Congress directed the EPA to propose a new drinking water standard for arsenic by January 1, 2000, and to promulgate a final standard by January 1, 2001. Congress also directed EPA to develop, by February 1997, a comprehensive research plan for arsenic to support the rulemaking effort and to reduce the uncertainty in assessing health risks associated with low-level exposures to arsenic. EPA was directed to conduct the study in consultation with the National Academy of Sciences and others. Congress authorized appropriations of $2.5 million for each of fiscal years 1997 through 2000 for arsenic studies. In 1996, EPA requested the National Research Council (NRC) to review the available arsenic toxicity data base and to evaluate the scientific validity of EPA's risk assessments for arsenic.

The NRC issued its report in March 1999, and recommended that the standard be reduced, but did not recommend a particular level. The NRC reported that available data provided ample evidence for EPA's classification of inorganic arsenic as a human carcinogen, but that EPA's dose-response assessment, which was based on the Taiwan study, deserved closer scrutiny. The NRC explained that the data limitations of the study for use in dose-response assessment were due to insufficient detail, as the study contained only a summary of data. The Council also reported that research suggests that arsenic intake in food is higher in Taiwan than in the United States, further complicating efforts to use the data for arsenic risk assessment. Based on findings from three countries where individuals were exposed to very high levels of arsenic (several hundreds of parts per billion or more), the NRC concluded that the data are sufficient to add lung and bladder

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[1] Food is a significant source of arsenic. The NAS estimates that, in the United States, inorganic arsenic intake from food is comparable to drinking water containing 5 ppb arsenic.

cancers to the cancers caused by ingestion of inorganic arsenic; however, the NRC noted that few data address the risk of ingested arsenic at lower concentrations, which would be more representative of levels found in the United States. The Council concluded that while a nonlinear dose-response curve is most probable for arsenic (i.e., at some low dose, arsenic would not be toxic), the available research was inadequate to rule out linearity (i.e., any dose might have an adverse effect).[2] The NRC added that studies of critical importance for improving the scientific validity of arsenic risk assessment were still needed, and recommended research studies to EPA.

EPA's Proposed and Final Arsenic Rule

In June 2000, EPA published its proposal to revise the arsenic standard from 50 ppb to 5 ppb and requested comment on options of 3 ppb, 10 ppb, and 20 ppb. EPA stated that the proposal relied primarily on the NRC analysis and some recently published research, and that it would further assess arsenic's cancer risks before issuing the final rule. As proposed, the standard would have applied only to community water systems. Non-transient, non-community water systems (e.g., schools with their own wells) would have been required only to monitor and then report if arsenic levels exceeded the standard. In the final rule, published on January 22, 2001 (66 *FR* 6976), EPA set the standard at 10 ppb and applied it to non-transient, non-community water systems as well as community systems. Water systems have until January 23, 2006, to comply.[3] EPA estimates that 3,000 (5.5%) of the 54,000 community water systems, and 1,100 (5.5%) of the 20,000 non-transient, non-community water systems will need to take measures to meet the standard. Most of these systems serve fewer than 500 people.

Standard-Setting Process. In developing standards, EPA is required to set a maximum contaminant level goal (MCLG) at a level at which no known or anticipated adverse health effects occur and that allows an adequate margin of safety. (EPA sets the MCLG at zero for carcinogens (as it did for arsenic), unless a level exists below which no adverse health effects occur.) EPA must then set an enforceable standard, the MCL, as close to the MCLG as is "feasible" using the best technology, treatment, or other means available (taking costs into consideration). EPA's determination of whether a standard is "feasible" typically is based on costs to systems serving more than 50,000 people. Less than 2 % of community water systems (753 of the 54,352 systems) are this large, but they serve roughly 56% of all people served by community systems.[4]

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[2] National Research Council, *Arsenic in Drinking Water*, National Academy of Sciences, National Academy Press, Washington, D.C., 1999, pp. 7, 22.

[3] See EPA's *Technical Fact Sheet: Final Rule for Arsenic in Drinking Water*, available online at [http://www.epa.gov/safewater/ars/ars_rule_techfactsheet.html].

[4] SDWA does not discuss how EPA should consider cost in determining feasibility; thus, EPA has relied on legislative history for guidance. Congress most recently discussed this matter in the Senate report for the 1996 Amendments. The report states that "[f]easible means the level that can be reached by large regional drinking water systems applying best available treatment technology. ... This approach to standard setting is used because 80% of the population receives its drinking water from large systems and safe water can be provided to this portion of the population at very affordable costs."(U.S. Senate, *Safe Drinking Water Amendments Act of 1995*, Report of the Committee on Environment and Public Works on S. 1316, S.Rept. 104-169, Nov. 7, 1995, p. 14.) About 80% of the population is served by systems serving 10,000 or more

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Variances and Exemptions. Congress recognized that the technical and cost considerations associated with technologies selected for large cities often are not applicable to small systems. The 1996 Amendments require that each rule establishing an MCL must list technologies or other means that comply with the MCL and are affordable for three size categories of small systems. The amendments also directed EPA to identify variance technologies for small systems, if no affordable compliance technology is listed. A variance technology need not meet the MCL, but must protect public health. EPA has not identified variance technologies for this or any other rule, because the Agency has determined that affordable compliance technologies are available for small systems. Thus, *small system variances* are not available for the arsenic rule.

States may grant temporary *exemptions* from the standard if, for certain reasons (including cost), a system cannot comply on time. The arsenic rule gives systems 5 years to comply with the new standard; an exemption allows another 3 years for qualified systems. Systems serving 3,300 or fewer persons may receive up to 3 additional 2-year extensions, for a total exemption duration of 9 years (and a total of 14 years to achieve compliance). In the final rule, EPA noted that exemptions will be an important tool to help states address the number of systems needing financial assistance to comply with this rule and other SDWA rules (66 *FR* 6988). However, to grant an exemption, the law requires a state to hold a public hearing and make a finding that the extension will not result in an "unreasonable risk to health." Because the exemption process is complex, states have seldom granted them. State officials note that "unreasonable risk to health" has never been defined, and that states must make a separate finding for each system. Thus, it is uncertain whether states will be able to, or choose to, grant many exemptions.

Balancing Costs and Benefits. Another 1996 SDWA provision requires that, when proposing a rule, EPA must publish a determination as to whether or not the benefits of the standard justify the costs. If EPA determines that the benefits do not justify the costs, then EPA may set the standard at the level that maximizes health risk reduction benefits at a cost that is justified by the benefits. EPA determined that the "feasible" arsenic level (for systems serving more than 50,000 people) is 3 ppb, but that the benefits of that level would not justify the costs. Thus, EPA proposed a standard of 5 ppb. Also, EPA had proposed to require non-transient, non-community water systems (e.g., schools) only to monitor and report (as opposed to treating), largely because of cost-benefit considerations. In setting the standard at 10 ppb, EPA cited SDWA, stating that this level "maximizes health risk reduction benefits at a cost that is justified by the benefits." EPA also applied the final rule to non-transient, non-community water systems.

Anticipated Benefits and Costs. In the proposed rule, EPA noted the need for additional research to address the scientific uncertainty concerning the health effects and risk associated with arsenic ingestion; nonetheless, EPA estimated that the rule would generate a range of health benefits. In the final rule, EPA estimated that reducing the standard to 10 ppb will prevent roughly 19 to 31 bladder cancer cases and 5 to 8 bladder cancer deaths each year. EPA further estimated that the new standard could prevent 19 to 25 lung cancer cases and 16 to 22 lung cancer deaths each year. EPA estimated that the rule would provide numerous other cancer and non-cancer health benefits that were not quantifiable.

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[4] (...continued)
people.

Regarding the cost of meeting the 10 ppb standard, EPA estimated that, for small systems (serving fewer than 10,000 people), the average cost per household ranges from $38 to $327 per year. Roughly 97% of systems expected to exceed the standard are small systems. For large systems, water cost increases range from $0.86 to $32 per household. EPA estimated the total national, annualized cost for the rule to be about $181 million. In its role of providing an expert assessment of the proposal, EPA's Science Advisory Board (SAB) raised a number of concerns about EPA's economic and engineering assessment and reported that several of EPA's cost assumptions were likely to be unrealistic and various costs seemed to be excluded. The SAB also suggested that EPA should give further thought to the concept of affordability as applied to this standard.[5]

Many municipalities and water system representatives have disagreed with EPA's cost estimates. The American Water Works Association (AWWA), for example, while supporting a reduced standard, estimated that the new rule will cost $600 million annually and require $5 billion in capital outlays. The AWWA attributed differences in cost estimates partly to the costs of handling arsenic-contaminated residuals and the estimated number of wells affected. AWWA projected that the rule could cost individual households in the Southwest, Midwest and New England as much as $2,000 per year.[6]

Arsenic Rule Review. On January 22, 2001, EPA issued a final rule. On March 23, 2001, the Administrator delayed the rule for 60 days, citing concerns about the science supporting the rule and its estimated cost to communities. On May 22, EPA delayed the rule's effective date until February 22, 2002, but did not change the 2006 compliance date for water systems (66 *FR* 28342). At EPA's request, the NRC undertook an expedited review of EPA's arsenic risk analysis and recent health effects research, the National Drinking Water Advisory Council (NDWAC) reassessed the rule's cost, and the SAB reviewed its benefits. EPA also requested public comment on whether the data and analyses for the rule support setting the standard at 3, 5, 10, or 20 ppb (66 *FR* 37617).

The NRC concluded that "recent studies and analyses enhance the confidence in risk estimates that suggest chronic arsenic exposure is associated with an increased incidence of bladder and lung cancer at arsenic levels in drinking water below the current MCL of 50 μg/L."[7] The NDWAC reported that EPA produced a credible cost estimate, given constraints and uncertainties, and suggested ways to improve estimates. The SAB offered ways to improve the benefits analysis. In October 2001, EPA concluded that 10 ppb was the appropriate standard, and announced plans to provide $20 million for research on affordable arsenic removal technologies to help small systems. This research is ongoing.

Legislative and EPA Actions

Many bills were offered in the 107th Congress in response to the arsenic rule and its delay. The conference report to EPA's FY2002 appropriations act, P.L. 107-73 (H.Rept. 107-272) prohibited EPA from using funds to delay the rule; required EPA to review its affordability criteria and how small system variance and exemption programs should be implemented for the new arsenic rule; and urged EPA to recommend procedures to grant

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[5] Science Advisory Board, *Arsenic Proposed Drinking Water Regulation: A Science Advisory Board Review of Certain Elements of the Proposal*, EPA-SAB-DWC-01-001, Dec. 2000, p. 4.

[6] AWWA, January 17, 2001. See [http://www.awwa.org/Advocacy/pressroom/pr/010111.cfm].

[7] National Research Council, *Arsenic in Drinking Water: 2001 Update*, NAS, p. 14.

more time for small communities in cases where compliance by 2006 poses an undue economic hardship. Conferees directed EPA to report on its review, potential funding mechanisms for small community compliance, and possible legislative actions that, if taken by the Congress, "would best achieve appropriate extensions of time for small communities while also guaranteeing maximum compliance" (H.Rept. 107-272, p. 175).

EPA's March 2002 Report to Congress summarized agency activities that addressed these directives. Major activities included (1) reviewing the small system affordability criteria and variance process; (2) developing a small community assistance plan to improve access to financial and technical assistance, improve compliance capacity, and simplify the use of exemptions; and (3) implementing a $20 million research and technical assistance strategy.[8] EPA has completed a number of efforts to help states and water systems meet the requirements of the arsenic rule. In August 2002, EPA issued *Implementation Guidance for the Arsenic Rule*, which includes guidance to help states grant exemptions. EPA has offered technical assistance and training to small systems, and is sponsoring research on low-cost treatment technologies for removing arsenic from drinking water. Also, EPA is working with small communities to maximize loans and/or grants under SDWA and U.S. Department of Agriculture water infrastructure programs.

The 108th Congress evidenced concern over the financial impact that compliance with this standard may present for communities. In the conference report for the omnibus appropriations act for FY2005 (P.L. 108-447, H.Rept. 108-792), conferees expressed concern that many rural communities will be unable to meet the new requirements which could pose a "huge financial hardship." The conferees directed EPA to report by August 2005 on the extent to which communities will be impacted by the arsenic rule, and to propose compliance alternatives and make recommendations to minimize costs. The conference report included $8.2 million for arsenic removal research. Other bills would have created grant programs to help small systems comply with the arsenic rule and other SDWA standards, increased funding for the Drinking Water State Revolving Fund (DWSRF) program, and authorized research on affordable arsenic removal technologies.

In the 109th Congress, the Rural Community Arsenic Relief Act has been reintroduced (S. 41) to require states to grant small nonprofit water systems exemptions from regulations for naturally occurring contaminants, in certain circumstances.

EPA's effort to revise the arsenic standard generated considerable debate as to what standard best reduces health risks at a cost that is justified, particularly for small towns, where most elevated arsenic levels occur. This rule also provoked a range of policy responses and illustrated some of the challenges and uncertainties associated with risk, cost, and benefit analyses. Nonetheless, the National Academy of Sciences concluded that while studies for improving the accuracy of arsenic risk assessment are still needed, recent analyses suggest that the risks for cancer incidence are greater than previously thought. Consequently, EPA retained the standard of 10 ppb, and Congress affirmed that standard. Now, as the January 23, 2006, deadline nears, Congress and EPA are focusing on helping communities achieve compliance with the new standard. (See also CRS Issue Brief IB10118, *Safe Drinking Water Act: Implementation and Issues*. For federal financial assistance information, see CRS Report RL30478, *Federally Supported Water Supply and Wastewater Treatment Programs*.)

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[8] For details, see EPA's *Report to Congress: Small Systems Arsenic Implementation Issues*, March 2002, available at [http://www.epa.gov/safewater/arsenic.html].