Order Code RS20672
Updated July 1, 2008

CRS Report for Congress

Arsenic in Drinking Water: Regulatory Developments and Issues

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

Summary

The Safe Drinking Water Act Amendments of 1996 directed the Environmental Protection Agency (EPA) to update the standard for arsenic in drinking water. In 2001, EPA issued a new arsenic rule that set the legal limit for arsenic in tap water at 10 parts per billion (ppb), replacing a 50 ppb standard set in 1975, before arsenic was classified as a carcinogen. The arsenic rule was to enter into effect on March 23, 2001, and water systems were given until January 2006 to comply. EPA concluded that the rule would provide health benefits, but projected that compliance would be costly for some small systems. Many water utilities and communities expressed concern that EPA had underestimated the rule's costs significantly. Consequently, EPA postponed the rule's effective date to February 22, 2002, to review the science and cost and benefit analyses supporting the rule. After completing the review in October 2001, EPA affirmed the 10 ppb standard. The new standard became enforceable for water systems in January 2006.

Since the rule was completed, Congress and EPA have focused on how to help communities comply with the new standard. In the past several Congresses, numerous bills have been offered to provide more financial and technical assistance and/or compliance flexibility to small systems; however, none of the bills has been enacted.

Background

Sources of arsenic in water include natural sources, particularly rocks and soils, and also releases from its use as a wood preservative, in semi-conductors and paints, and from mining and agricultural operations. Elevated levels of arsenic are found more frequently in ground water than in surface water. Because small communities typically rely on wells for drinking water, while larger cities often use surface-water sources, arsenic tends to occur in higher concentrations more frequently in water used by small communities.

In the United States, the average arsenic 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 with the rest of the United States, Western states have more water systems with levels exceeding 10 ppb; levels in some locations in

the West exceed 50 ppb. Parts of the Midwest and New England also have some water systems with arsenic levels exceeding 10 ppb, but most systems meet the new standard. When issuing the rule, EPA estimated that roughly 4,000 (5.5%) of regulated water systems, serving a total of 13 million people, were likely to exceed the 10 ppb standard.

The previous 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 caused the agency to miss the 1989 deadline. 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 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 a 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 required to conduct the study in consultation with the National Academy of Sciences. 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 1999 and recommended that the standard be reduced, but it did not recommend a particular level. The NRC affirmed that the 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 a Taiwan study, deserved greater scrutiny. The NRC explained that the data in the study lacked the level of detail needed for use in dose-response assessment. The Council also reported that research suggested 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 were sufficient to add lung and bladder cancers to the types of cancers caused by ingestion of inorganic arsenic; however, the NRC noted that few data addressed the risk of ingested arsenic at lower concentrations, which would be more representative of levels found in

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

the United States. The NRC concluded that key studies for improving the scientific validity of risk assessment were needed, and recommended specific studies to EPA.[2]

EPA's 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 water systems. The agency gave the water utilities five years to comply (the maximum amount of time allowed under SDWA). EPA estimated 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, would need to take measures to meet the standard.[3]

Standard-Setting Process. In developing standards under the Safe Drinking Water Act, 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).[4] EPA's determination of whether a standard is feasible typically has been based on costs to large water systems (serving more than 50,000 people). Less than 2% of community water systems (roughly 750 of 54,000 systems) are this large, but they serve roughly 56% of all people served by community systems.[5]

Variances and Exemptions. Congress has long recognized that the technical and cost considerations associated with technologies selected for large cities often are not applicable to small systems. In the 1996 amendments, Congress expanded SDWA variance and exemption provisions to address small system compliance concerns.

---

[2] National Research Council, *Arsenic in Drinking Water*, National Academy of Sciences, National Academy Press, Washington, DC, 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/arsenic/regulations.html].

[4] For a more detailed discussion of these and other SDWA provisions, see CRS Report RL31243, *Safe Drinking Water Act: A Summary of the Act and Its Major Requirements*, by Mary Tiemann.

[5] SDWA does not discuss how EPA should consider cost in determining feasibility; thus, EPA has relied on legislative history for guidance. The Senate report for the 1996 amendments 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*, S.Rept. 104-169, November 7, 1995, p. 14.) Systems serving 10,000 or more people serve about 80% of the population served by community water systems.

The *small system variance* provisions require that for each rule establishing an MCL, EPA must list technologies that comply with the MCL and are affordable for three size categories of small systems. If EPA does not list affordable compliance technologies for small systems, then it must list variance technologies. A variance technology need not meet the MCL, but must be protective of public health. If EPA lists a variance technology, a state then may grant a variance to a small system, allowing the system to use a variance technology to comply with a regulation. EPA has not identified variance technologies for arsenic or any other standards because, based on its current affordability criteria, EPA has determined that affordable compliance technologies are available for all standards. Thus, small system variances are not available.

Congress took issue with EPA's assessment that small system variance technologies were not merited for the arsenic standard, and in 2002, directed EPA to review the criteria it uses to determine whether a compliance treatment technology is affordable for small systems. In March 2006, EPA proposed three options for revising its affordability criteria (71 *FR* 10671). Under the current affordability criteria, EPA considers a treatment technology affordable unless the average compliance cost exceeds 2.5% of the area's median household income. Based on this measure, EPA determined that affordable technologies are available for all SDWA standards. The proposed options under consideration are well below the current level: 0.25%, 0.50%, and 0.75% of an area's median household income. EPA also stated that it expects to address in the revised criteria the issue of how to ensure that a variance technology would be protective of public health. According to EPA, the final criteria would apply only to the new Stage 2 Disinfectants/Disinfection Byproducts Rule and future rules, and not to the arsenic rule.

Exemptions potentially offer a source of compliance flexibility for small systems. States may grant temporary exemptions from a standard if, for certain reasons (including cost), a system cannot comply on time. The arsenic rule gives systems five years to comply with the new standard; an exemption allows another three years for qualified systems. Systems serving 3,300 or fewer persons may receive up to three additional two-year extensions, for a total exemption duration of nine years (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 have noted that "unreasonable risk to health" has never been defined, and that states must make a separate finding for each system. Many states have granted few or no exemptions.

Balancing Costs and Benefits. 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 costs are not justified, then it 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 large systems) was 3 ppb, but that the benefits of that level did not justify the costs. Thus, EPA proposed a standard of 5 ppb. Also, EPA 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." The final rule applies to schools and similar non-community water systems.

Anticipated Benefits and Costs. In the final rule, EPA estimated that reducing the standard to 10 ppb could prevent roughly 19 to 31 bladder cancer cases and 5 to 8 bladder cancer deaths each year. The agency further estimated that the new standard could prevent 19 to 25 lung cancer cases and 16 to 22 lung cancer deaths each year, and provide other cancer and non-cancer health benefits that were not quantifiable.

Regarding the cost of meeting the 10 ppb standard, EPA estimated that for systems that serve fewer than 10,000 people, the average cost per household could range from $38 to $327 per year. Roughly 97% of the systems that were expected to exceed the standard are in this category, and most of these systems serve fewer than 500 people. For larger systems, projected water cost increases range from $0.86 to $32 per household. The estimated national, annualized cost of the rule is approximately $181 million.

EPA's Science Advisory Board (SAB) had raised concerns about the rule's economic and engineering assessment, and concluded that several cost assumptions were likely to be unrealistic and other costs seemed to be excluded. The SAB also suggested that EPA give further thought to the concept of affordability as applied to this standard.[6] Many municipalities and water system representatives also disagreed with the agency's cost estimates. The American Water Works Association (AWWA), while supporting a stricter standard, estimated that the new rule would 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 treatment residuals and the estimated number of wells affected. The AWWA projected that the rule could cost individual households in the Southwest, Midwest, and New England as much as $2,000 per year.[7]

Arsenic Rule Review. EPA issued the final rule on January 22, 2001. In March 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, 2001, 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 subsequent 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 determined 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."[8] The NDWAC concluded that EPA had 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 affirmed 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 comply.

---

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

[7] AWWA, January 17, 2001. See [http://www.awwa.org].

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

Legislative Action

Since the arsenic standard was revised, Congress repeatedly has expressed concern over the cost of this regulation, especially to small, rural communities. The 107th Congress directed EPA to review its affordability criteria and how the small system variance and exemption programs should be implemented for arsenic (P.L. 107-73, H.Rept. 107-272, p. 175). The conferees directed the agency to report on its affordability criteria, administrative actions, funding mechanisms for small system compliance, and possible legislative actions. In 2002, EPA submitted its report to Congress, *Small Systems Arsenic Implementation Issues*, on actions EPA was taking to address these directives. Major activities included developing and implementing a small community assistance plan to improve access to financial and technical assistance, improve compliance capacity, and simplify the use of exemptions. EPA also has sponsored research on low-cost arsenic treatment technologies and has issued guidance to help states grant exemptions.

The 108th Congress again expressed concern over the financial impact that the revised standard could have in many communities. In the conference report for the omnibus appropriations act for FY2005 (P.L. 108-447, H.Rept. 108-792), Congress provided $8.2 million for arsenic removal research. The conferees expressed concern that the new requirements could pose a "huge financial hardship" for many rural communities. Congress directed EPA to report on the extent to which communities were being affected by the rule and to propose compliance alternatives and make recommendations to minimize costs. This report is pending.

In the 109th Congress, legislative efforts focused on helping economically struggling communities comply with the arsenic rule and other drinking water regulations. Bills were offered to provide more regulatory flexibility, financial assistance, and technical assistance, especially to small systems. One reported bill, the Water Infrastructure Financing Act (S. 1400, S.Rept. 109-186), would have increased funding authority for the drinking water state revolving fund (DWSRF) program and established a grant program for priority projects, including projects to help small systems meet standards. Among other bills, S. 2161 proposed to prevent enforcement of regulations for small systems unless EPA had identified a variance technology and sufficient DWSRF funds were made available. S. 2161 also proposed to require EPA to develop new affordability criteria related to small system variances. H.R. 1315 and S. 41 would have required states to grant small community water systems exemptions from regulations for naturally occurring contaminants in certain cases. None of the bills was enacted.

Similar legislation has been offered in the 110th Congress. Several bills would promote small system compliance by providing technical assistance, financial assistance, and/or compliance flexibility. H.R. 2141 would require states to grant exemptions to eligible small systems for rules covering naturally occurring contaminants. S. 1933 would authorize a small system grant program. S. 1429 (S.Rept. 110-242) and H.R. 6313 would reauthorize funding authority for small system technical assistance under SDWA. S. 2509 would require EPA to promote the use of affordable technologies (e.g., point-of-use technologies and bottled water), revise its affordability criteria, and provide more compliance assistance for high-priority rules including the arsenic rule. This bill also would require that funds are made available to small systems before enforcement actions are taken. (For more information on this and other issues, see CRS Report RL34201, *Safe Drinking Water Act: Selected Regulatory and Legislative Issues*, by Mary Tiemann.)