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Arsenic in Drinking Water: Regulatory Developments and Issues

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Summary

In January 2001, the Environmental Protection Agency (EPA) promulgated a new regulation for arsenic in drinking water, as required by 1996 Safe Drinking Water Act Amendments. The rule set the legal limit for arsenic in tap water at 10 parts per billion (ppb), replacing a 50 ppb standard that was set in 1975, before arsenic was classified as a carcinogen. The arsenic rule was to enter into effect on March 23, 2001, and public water systems were given until January 23, 2006, to comply. When issuing the rule, EPA projected that compliance could be costly for some small systems, but many water utilities and communities expressed concern that EPA had underestimated the rule's costs. Subsequently, EPA postponed the rule's effective date to February 22, 2002, in order to review the science and cost and benefit analyses supporting the rule. In October 2001, EPA affirmed the 10 ppb standard. The compliance date remained unchanged, and the new standard became enforceable for water systems in January 2006.

With the arsenic regulation in place, Congress and EPA have focused on how to help communities comply with the new requirements. In the 109th Congress, bills have been introduced to establish small system grant programs and to provide more compliance flexibility and technical assistance to small systems. This report reviews issues surrounding the arsenic rule and related congressional and EPA actions.

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 typically use surface-water sources, arsenic tends to occur in higher levels more frequently 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 with the rest of the United States, Western states have

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more water systems with levels exceeding 10 ppb; levels in some locations 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. EPA projected that 5.5% of water systems, serving a total of 11 million people, were likely to exceed the 10 ppb level.

The previous 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. 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 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 it 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 a Taiwan study, deserved closer 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 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 were sufficient to add lung and bladder 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

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[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.

States.[2] The NRC added that key studies for improving the scientific validity of arsenic risk assessment were still needed and recommended specific research studies to EPA.

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 systems.[3] EPA gave systems 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.

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]

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.

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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/arsenic/regulations.html].

[4] SDWA does not discuss how EPA should consider cost in determining feasibility; thus, EPA has relied on legislative history for guidance. Congress last discussed this issue 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*, S.Rept. 104-169, Nov. 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 or other means 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 EPA must list variance technologies. A variance technology need not meet the MCL, but must protect public health. A state may then grant a variance to a small system, allowing the system to use a variance technology to comply with a regulation (§1215(e)). EPA did not list variance technologies for arsenic or any other standard because, based on its affordability criteria, EPA has determined that affordable compliance technologies are available for small systems for all standards. Thus, small system variances are not available. If they were, it is not clear that they would be used often. A key issue is that variances allow systems to provide lower-quality water to consumers, and this may raise various issues for communities.

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 currently under consideration are well below the current level: 0.25%; 0.50%; and 0.75%. The revised criteria are also expected to address how to ensure that a variance technology would be protective of public health. According to EPA, the final criteria would apply only to EPA's newly promulgated Stage 2 DBP and future rules, and not to 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 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 2-year extensions, for a total exemption duration of 9 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 note that "unreasonable risk to health" has never been defined, and that states must make a separate finding for each system. Many states have indicated that they plan to grant 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 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 large systems) 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 more research to address the scientific uncertainty regarding the health risks 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 could 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.

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 are expected to exceed the standard are in this category, and most of these systems serve fewer than 500 people. For larger systems, projects 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.

EPA's Science Advisory Board (SAB) raised concerns about EPA's economic and engineering assessment, and concluded that several cost assumptions were likely to be unrealistic and various costs seemed to be excluded. The SAB also suggested that EPA give further thought to the concept of affordability as applied to this standard.[5] Many municipalities and water system representatives also disagreed with EPA's cost estimates. The American Water Works Association (AWWA), 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. EPA issued the final rule on January 22, 2001. 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.

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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.

Legislative Action

Concerned over the potential cost of the revised arsenic standard, especially to rural communities, the 107th Congress directed EPA to review its affordability criteria and how small system variance and exemption programs should be implemented for arsenic (P.L. 107-73, H.Rept. 107-272, p. 175). Congress directed EPA to report on its affordability criteria, administrative actions, potential 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 undertaking to address these directives. Major activities included reviewing the small system affordability criteria and variance process, and 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. To further help with compliance, EPA offered technical assistance to small systems and sponsored research on low-cost arsenic treatment technologies.[8] EPA also issued *Implementation Guidance for the Arsenic Rule*, which includes guidance to help states grant exemptions.

The 108th Congress also expressed concern over the financial impact that the new 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. Conferees also expressed concern that many rural communities would 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 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 have focused on helping economically struggling communities comply with the arsenic rule and other drinking water regulations. Bills have been introduced to provide more regulatory flexibility, financial assistance, and technical assistance. EPA's FY2007 funding bill, as reported by the Senate Committee on Appropriations (H.R. 5386, S.Rept. 109-275), would require the EPA to make available at least $11 million for small system compliance assistance. S. 41 and H.R. 1315 would require states to grant small community water systems exemptions from regulations for naturally occurring contaminants in certain cases. Companion bills, H.R. 2417 and S. 689, would require EPA to establish a grant program to help qualified communities comply with standards, delay enforcement of the arsenic rule until states implement the grant program, and prevent EPA from enforcing a standard during the grant application process. H.R. 4495 would give small systems two more years to comply with the arsenic rule. S. 1400 (S.Rept. 109-186), the Water Infrastructure Financing Act, would increase funding authority for the drinking water state revolving fund (DWSRF) program and establish a grant program for priority projects, including projects to help small systems comply with standards. S. 2161 would prevent the enforcement of regulations for small systems unless EPA has identified a variance technology and sufficient DWSRF funds are made available. S. 2161 also would require EPA to develop new affordability criteria related to small system variances. (For information on potential sources of federal financial assistance, 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].