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Arsenic in Drinking Water: Recent Regulatory Developments and Issues

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Summary

In 1996, Congress directed the Environmental Protection Agency (EPA) to propose a new standard for arsenic in drinking water by January 1, 2000, and to issue a final standard by January 1, 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 issued the current 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 June 22, 2000, EPA proposed a revised standard of 5 ppb and projected that compliance could be costly for small communities. A question of ongoing scientific debate concerned whether significant adverse health effects occur from ingesting arsenic at very low levels. Because EPA proposed the rule nearly 6 months late, some stakeholders expressed concern that the Agency would not have time to evaluate public comments and complete analyses before issuing a final rule.

On January 22, the final rule, which set the standard at 10 ppb, was published in the *Federal Register* with an effective date of March 23, 2001; public water systems were given until 2006 to meet the new standard. On May 22, EPA extended a previous 60-day delay of the rule's effective date to February 22, 2002 in order to review risk, benefit, and cost issues associated with the rule. The 2006 compliance date for water systems remained unchanged. On October 31, EPA announced that the standard would be 10 ppb. On November 8, Congress approved the conference report to EPA's FY2002 appropriations bill (H.R. 2620), which includes language prohibiting EPA from using the funds to delay the January rule. This report reviews EPA efforts to develop a new arsenic rule and summarizes key provisions and subsequent events.

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 ($\mu\text{g/L}$)); 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 the 10 ppb level. Sources of arsenic in water include natural sources, and 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, still in effect, was based on estimated total dietary intake¹ 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.

In 1989, after reviewing EPA's 1988 risk assessment for arsenic, the EPA Science Advisory Board (SAB) reported that: 1) studies suggesting that arsenic may be an essential nutrient were not definitive; 2) data from Taiwan demonstrated that high doses of arsenic could cause skin cancer; 3) the Taiwan data were inconclusive to determine cancer risk at levels ingested in the United States; and 4) some low levels of arsenic may be detoxified by the body. The SAB recommended that EPA set the standard "using a non-linear dose-response (at some low dose, arsenic would not be toxic)," and that EPA revise its risk assessment.² In 1992, the Advisory Board expressed uncertainty as to whether EPA could obtain enough data to regulate arsenic using a non-linear model.

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

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

² U.S. Environmental Protection Agency. *Arsenic in Drinking Water: Regulatory History*. See Internet website: [<http://www.epa.gov/safewater/ars/ars1.html>].

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 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.³ 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 3 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 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, the available research was inadequate to rule out linearity (i.e., any dose might have an adverse effect).⁴ The NRC added that studies of critical importance for improving the scientific validity of arsenic risk assessment are still needed, and recommended research studies to EPA.

EPA's Proposed and Final Arsenic Rule

On June 22, 2000, EPA published its proposal to revise the arsenic standard from the current level of 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 also 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 (such as schools and offices) 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 the rule to non-transient, non-community water systems as well as to community systems. The rule's general effective date was 60 days after publication; however, public water systems are given until 2006 to comply. On May 22, EPA delayed the rule's effective date to February 22, 2002 (66 *FR* 28342), but did not change the compliance date for systems (see below).

Standard-setting process. In developing standards, EPA is required to set a nonenforceable 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,

³ National Research Council. *Arsenic in Drinking Water*. National Academy Press. Washington, D.C. 1999. p. 22.

⁴ National Research Council. p. 7.

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.⁵

Variations 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 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. For the arsenic rule, EPA did not identify variance technologies because the Agency determined that affordable compliance technologies are available for small systems. Thus, *small system variances* are not available for the arsenic regulation.

States or EPA may grant temporary *exemptions* from the standard if, due to certain compelling factors (including cost), a system cannot comply on time. All systems are required to comply with the new standard in 5 years; an exemption allows an additional 3 years for qualified systems. Systems serving 3,300 persons or fewer may have up to 3 additional 2-year extensions, for a total exemption duration of 9 years (for a total of up to 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).

Balancing costs and benefits. Another 1996 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, EPA may set the standard at the level that maximizes health risk reduction benefits at a cost that is justified by the benefits. For arsenic, EPA determined that the “feasible” level (for systems serving more than 50,000 people) is 3 ppb, but that the benefits of this level would not justify the costs. Consequently, 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.”

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

⁵ SDWA does not discuss how EPA should consider cost in determining feasibility; thus, EPA has relied on legislative history for guidance. Congress most recently expressed its view in this matter in the Senate report accompanying 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. p. 14. Nov. 7, 1995.) EPA estimates that roughly 80% of the population is served by systems serving 10,000 or more people.

risk associated with arsenic ingestion; nonetheless, EPA estimated that the rule would generate various health benefits. In the proposal, EPA estimated that lowering the standard to 5 ppb would prevent about 5 bladder cancer deaths nationwide annually, while a 10 ppb standard would prevent 3 bladder cancer deaths annually. EPA projected that arsenic-related lung cancers and cardiovascular diseases also would be reduced. In the final rule, EPA estimated that, with a 10 ppb standard, the annual number of bladder and lung cancer deaths avoided ranges from 21 to 30. EPA also stated that the rule would provide numerous other cancer and non-cancer health benefits that were not quantifiable.

Regarding the cost of meeting the 10ppb standard, EPA estimated that, for small systems (serving fewer than 10,000 people), the average annual cost per household ranges from \$38 to \$327. 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 proposed rule, 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 that 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.⁶ Many municipalities and water system representatives also disagreed with EPA's 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 projects that the rule could cost individual households in the Southwest, Midwest and New England as much as \$2,000 per year.⁷

EPA statistical estimates indicate 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 new standard. Most of these systems serve fewer than 500 people. (See [http://www.epa.gov/safewater/ars/ars_rule_techfactsheet.html].)

Legislative and EPA Actions

In response to EPA's delay in proposing the arsenic rule, Congress extended the deadline for the final rule from January 1, to June 22, 2001, in EPA's FY2001 appropriations. On January 22, 2001, EPA issued a final rule. On March 23, the EPA 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 public water systems (66 *FR* 28342). At EPA's request, the NAS 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 EPA's Science Advisory Board reviewed its benefits. On July 19, EPA issued a proposal requesting comment on whether the data and technical analyses for the January rule

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. Report available at [<http://www.epa.gov/sab/dwc0101.pdf>].

⁷ AWWA. January 17, 2001. Available at: [<http://www.awwa.org/pressroom/pr/010111.htm>].

support setting the standard at 3, 5, 10, or 20 ppb (66 *FR*. 37617). The risk, cost, and benefits reviews were completed in late summer. The NRC, in its review, 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" ppb. The NDWAC reported that EPA produced a credible cost estimate, given constraints and uncertainties, and offered recommendations to improve estimates. The SAB made recommendations to improve the benefits analysis. EPA studied the reviews, and on October 31 announced that the arsenic standard will be 10 ppb. EPA plans to provide \$20 million over the next 2 years for research and development of more cost-effective technologies to help small systems. EPA also will work with small communities to maximize loans and grants from SDWA and Rural Utilities Service (U.S. Department of Agriculture) programs.

Various bills have been introduced in response to this rule and its delay. The House and Senate added arsenic amendments to their FY2002 appropriations bill for EPA (H.R. 2620). The House version prohibited EPA from using funds to delay the January rule or to issue a rule that sets the standard above 10 ppb. The Senate bill directed EPA to put into effect immediately a standard that protects sensitive subpopulations and that lifts the suspension of the January rule's effective date for new community reporting requirements (the rule requires certain systems to provide additional risk information starting in 2002). On November 8, the House and Senate approved the conference report to H.R. 2620 (H. Rept. 107-272) which: (1) prohibits EPA from using funds to delay the January rule; (2) requires EPA to review its affordability criteria and how small system variance and exemption programs should be implemented for arsenic; (3) urges EPA to recommend procedures to grant more time for small communities in cases where compliance by 2006 poses an undue economic hardship. Also, by March 2002, EPA must report to Congress on its review of the affordability criteria, administrative actions and potential funding mechanisms for small community compliance, and on possible legislative actions. Among other bills, H.R. 1252 would reduce the standard to 10 ppb by 2003, and to 3 ppb by 2006, and authorize grants for small systems; H.R. 1413 would codify the January rule and increase funding for the drinking water state revolving fund program. H.R. 2112 would specify the availability of federal funding programs for arsenic treatment. S. 223 would void the new rule; S. 632 and S. 635 would reinstate the rule, with S. 632 requiring funds to be allotted to states based on arsenic treatment needs. S. 1299 would create a new grant program to help small water systems comply with SDWA standards.

Conclusion

EPA's effort to revise the arsenic standard has been controversial and has generated substantial debate as to what standard best reduces health risks at a cost that is justified, particularly for small towns where most violations are expected. This rule has generated a range of policy responses and illustrates some of the challenges and uncertainties associated with risk, cost, and benefit analyses. However, the NRC has concluded that although studies essential 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 has announced that the standard will be 10 ppb, and Congress has reaffirmed that standard, and the January rule in general. The Agency and Congress now are focusing on providing assistance to small communities to facilitate compliance with the new standard.