

Stakeholder Meeting Summary - Arsenic in Drinking Water

EXECUTIVE SUMMARY

September 11-12, 1997

Background

In the [1996 amendments to the Safe Drinking Water Act \(SDWA\)](#), Congress directed EPA to expand research and issue a new regulation for arsenic. Other sections of the 1996 amendments emphasize risk communication; use of the best available, peer-reviewed science for decision-making; EPA review and revision, as appropriate, of each primary drinking water regulation every six years; analysis of health benefits likely to occur, including considerations of sensitive populations; and costs of alternative options in the preparation of regulations. The Unfunded Mandates Reform Act of 1995 requires EPA to assess impacts of regulations on governments; consult with State, local and Tribal employees during the preparation of the regulation; and analyze impacts to the private sector. EPA must consult with small business advocacy panels and prepare guidance to assist small entities to comply with new regulations to satisfy the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

Since 1995, the Office of Ground Water and Drinking Water (OGWDW) in EPA has held stakeholder meetings to help refocus priorities in the drinking water program and to improve strong, flexible relationships among EPA, States, Tribes, local governments, and the public. On September 11 and 12, OGWDW convened an arsenic public meeting in Washington, DC to discuss statutory requirements, research activities, regulatory options, policy issues and on-going work. The major meeting objectives were to:

- (1) Outline the health assessment, research, and regulatory history of arsenic,
- (2) Describe EPA's approach for meeting statutory requirements and deadlines for research and rulemaking,
- (3) Present the arsenic research plan,
- (4) Solicit comments on the 1998 external arsenic research grant solicitation topics,
- (5) Review and discuss regulatory development activities for risk assessment, treatment, and risk management, and
- (6) Solicit input on obtaining continued stakeholder involvement.

Summary

The meeting format consisted of presentation of information, questions and answers, and open discussion. Each section below contains a synopsis of the principle issues presented at the meeting, followed by major comments of the participants.

Legislative Requirements. The SDWA stipulates that EPA prepare an arsenic research plan to study the low level health effects of arsenic that will support rulemaking, and to consult with interested entities in carrying out the research. The Act also encourages EPA to enter into cooperative agreements to carry out the studies. Furthermore, EPA must issue a proposed rulemaking by January 1, 2000, and take final action on an arsenic rule a year later. Overall, the 1996 amendments to SDWA revised the rulemaking process to more fully consider both health benefits and costs.

Regulatory History. Efforts spanning 50 years have not resolved the scientific uncertainties about the health effects of arsenic. EPA will use current and future arsenic research, to the extent available, to meet

the statutory deadlines. Therefore existing peer-reviewed research, evaluation of EPA's methodologies for developing standards, stakeholder input, and EPA studies of treatment, analytical methods, occurrence, and cost-benefits will be used to develop the final rule. Focussed long-term arsenic research efforts will be applied in future reviews of the regulation. To meet competing statutory mandates, EPA plans to use a multi-faceted regulatory approach. This will entail near term improvements in the National Primary Drinking Water Regulation to satisfy the statutory deadline. At the same time, EPA and others will vigorously pursue long term research to reduce health assessment uncertainties. Meeting participants discussed how to ensure funding of critical arsenic research, and how to address small system issues during rulemaking.

Regulatory Development. A number of risk management components are considered when developing a drinking water regulation: analytical assessment (test methods, instrument availability, and quantitation levels); occurrence assessment (arsenic concentrations and the number and water source of systems affected); treatment technologies assessment (performance, residuals, water use, and small system needs); and cost/benefit assessment (benefits and costs of regulation). The drinking water standard is set as close to the nonenforceable health goal as feasible, considering analytical method capability, treatment technologies, and regulatory costs. EPA is having its arsenic health risk estimates and research needs peer reviewed and is updating the carcinogen database and cancer assessment guidelines. Stakeholders expressed interest in the margin of safety or uncertainty factor used by EPA to account for sensitive subpopulations and the value of existing epidemiological studies.

Treatment Technology. EPA presented an overview of treatment options and their advantages and disadvantages. Some variations of existing technologies need further research and field testing. Future ORD work will include performance evaluation of full scale systems, oxidation of arsenic, a treatment workshop on the "state of the science," and residual disposal studies. Participants asked EPA to consider state discharge standards, the cost of other drinking water regulations being issued in the same time frame, and the training needs for small systems.

Analytical Methods. Currently approved analytical methods measure total arsenic in the 2 ppb ($\mu\text{g/L}$) range, and enough performance evaluation data exists to support a practical quantitation level. Future ORD research involves speciation analysis in water, food, and urine.

Occurrence. EPA drafted a national arsenic occurrence projection in 1992, but new sources of occurrence data will be available for the rulemaking, including the assembly of a U.S. Geological Survey (USGS) ground water database. Stakeholders were requested to share other occurrence studies and comments on how EPA should combine databases. Participants discussed the strengths and limitations of the existing databases.

Public Participation Process. Preferred approaches included having EPA hold additional stakeholder meetings, schedule in-depth meetings, time arsenic meetings to coincide with other EPA or association meetings, utilize the [OGWDW website](#), contribute to newsletters, and maintain mailing lists as methods for increasing communication.

Arsenic Research Plan and Summary of ORD Research Activities. The arsenic research plan includes short-term and long-term studies of mechanisms of action and levels of human exposure, methods to measure exposures, cancer and non-cancer health effects, and risk management areas. Future research will help select health endpoints for risk assessment and identify the shape of the dose-response curve at low doses. EPA is planning approaches to fill the epidemiological study gaps and studies on modes of action, metabolism, and susceptibility. Participants were interested in speciation studies, the study of noncancer effects, and the role of epidemiology studies for the final rule.

Arsenic Research Grants. EPA is awarding three research grants totaling \$2 million from the 1997 joint request for applications (RFA) on the health effects of arsenic in drinking water. The American Water Works Association Research Foundation and the Association of California Water Agencies is funding two

research projects from the joint RFA. Stakeholders expressed interest in the unfunded proposals, the study of arsenic nutritional essentiality, and the need for research to answer specific questions to assist rulemaking. Topics should allow funding for epidemiological studies and biomarker work. One stakeholder suggested that EPA needed to explain how the research studies relate to setting an arsenic drinking water regulation at a level understandable to the public.

Next Steps. Irene Dooley [(202) 260-9531, dooley.irene@epamail.epa.gov] is the lead contact for the second stakeholder meeting on arsenic in conjunction with the San Antonio meeting. EPA will consider holding a third stakeholder meeting on the west coast in the future. Participants recommended that EPA present an update meeting on arsenic research in early 1998, attempt to leverage resources from other federal agencies, provide more funds for the regulatory process, and solicit comments on the research grant topics at the arsenic specialty conference taking place September 22-24. The full meeting summary will contain more detailed discussions, comments, and questions and answers. It will be placed on the OGWDW webpage Calendar [meeting summaries](#) later this fall.