

National Drinking Water Advisory Council

August 9, 2000 Executive Summary of Arsenic in Drinking Water Stakeholder Meeting

[Final Agenda](#)

Background

On August 9, 2000, the U.S. Environmental Protection Agency (EPA) held a one-day stakeholders meeting in Reno, Nevada, to present elements of the June 22, 2000 proposal and to answer questions about the proposed Arsenic and Clarifications to Compliance and New Source Contaminants in Drinking Water Rule. Over 140 people attended in person and about 40 people joined by phone.

Welcome by James Taft, the Acting Director for the Standards and Risk Management Division. While EPA will write down and consider views expressed at the meeting, he encouraged people to submit comments in writing to the Docket for the rulemaking record. Although EPA missed the statutory date for the proposal, the Office of Water is striving to meet the statutory deadline to issue the final rule by January 1, 2001. EPA agrees with the National Academy of Sciences that existing research supports lowering the current standard of 50 parts per billion (ppb). EPA's risk characterization identified the level which would be no more risky than one excess death in 10,000 persons. Although the feasible level (measurable and treatable) is 3 ppb, EPA is proposing 5 ppb and also asking for comments on 3 ppb, 10 ppb, and 20 ppb.

Mr. Taft recognized that people have concerns about the data and science supporting the health effects assessment as well as EPA's analysis of the costs and benefits. Asking for comment on so many concentrations is unusual and reflects uncertainties about the health effects. Although EPA does not accept the drinking water supply industry cost estimate, the Agency is continuing to meet with industry to discuss it. Although some believe that EPA has already chosen the final MCL, that is not true. EPA is very interested in getting the points of view of the attendees and other commenters.

Regulatory History and SDWA Statutory Process. The presentation highlighted preamble material found on pages 38892-38896, the discussion of risk characterization on page 38902, and sections XIII and XIV. EPA has a statutory requirement to identify how it reconciled inconsistencies in scientific data used in the proposal, and people can comment on how well EPA met this requirement. EPA is adding comments to the rulemaking docket that people submitted after the pre-publication copy of the proposal went on the arsenic web page on May 25, 2000. That added twenty-eight days to the "official" 90-day comment period, which started the date of publication, June 22, 2000, and ends September 20, 2000.

Over 95% of the nation's school children are served by CWSs. The current arsenic MCL does not apply to the 20,000 non-transient, non-community water systems (NTNCWSs). The proposal estimates that less than one half of one percent of all students would be exposed to arsenic above 5 µg/L if NTNCWSs continue to be unregulated. However, depending on the comments received, NTNCWSs could be fully regulated in the final rule.

The Regulatory Impact Analysis in the docket is also available electronically and on the arsenic web page. The Small Business Advocacy Review panel report is in the docket. Although EPA found no socioeconomic bias or disproportionate risks to children, the Agency invites comment on these positions and submission of any peer-reviewed data on early life exposure risks. The Health Risk Reduction and Cost Analysis is section XIII of the preamble.

- Several stakeholders voiced concerns that the Agency will not have enough time after the close of comments (9/20/00) to fully consider comments before issuing the final rule. They expect EPA will receive many important, substantial comments on this proposal that may not be addressed if the final rule meets the statutory deadline (1/1/01).
- Some stakeholders pointed out that the uncertainties surrounding interpretation of the health effects data also affect the benefits, which tends to weaken the support for the costs. In addition, the statute limits the conditions under which EPA can raise an existing MCL, even if subsequent scientific information validates a higher MCL. Stakeholders asked the Agency to consider a phased approach: set an arsenic standard in the 20 ppb range and revisit it when better information is available, which would also provide better cost information for revisions.
- Stakeholders asked how they can challenge the proposal and final rule. EPA encouraged them to submit comments on the proposal. [The procedures for challenging the final regulation can be found in sections 1448 and 1449 of the Safe Drinking Water Act.]

MCLG Development, Risk Characterization, and Health Advisory. EPA calculated a theoretical noncarcinogenic MCLG of 3-30 ppb (using the method in the Final Rule for Phase V on pgs. 31781-31784 of the July 17, 1992 *Federal Register* (57 FR 31776)). The presentation covered a review of the 1996 proposed carcinogen risk assessment guidelines, exposure, NRC report, on-going peer review of health effects section of the proposal. The proposed health advisory would be available soon after the final rule is issued, to give guidance to the public prior to the effect dates 3-5 years after promulgation.

- One stakeholder noted that the proposal does not quantify skin cancer risks. Another stakeholder asked how the risk, extrapolated below arsenic concentrations with observed health effects, can be explained to the public.
- Stakeholders wondered if EPA could justify basing compliance on a weighted average from changing exposures caused by limited seasonal well usage.
- Several stakeholders felt that international studies do not prove that arsenic causes adverse health effects at levels seen in the U.S., due to different factors. Taiwan had humic acids in the drinking water which intensify peripheral vascular disease. Although Chile and Argentina had no humic acids, those populations still had increases in peripheral vascular disease.
- Several stakeholders believe application of the Taiwan data to the U.S. is inappropriate and, at a minimum, the Agency should more effectively account for the various uncertainties that the NRC pointed out in their March 1999 report (i.e., differences in diet, health status, and selenium levels).
- Some stakeholders believe that finding no lung and bladder cancer in Utah studies supports their view that using Taiwan risk data is overly protective for the U.S. Human studies can only detect risks of 1 in 100, which is much higher risk than EPA accepts.
- Stakeholders asked why EPA is setting the standard for total arsenic and using a linear extrapolation if the mode of action is probably nonlinear. Inorganic arsenic is the primary form found in drinking water, and in the body, arsenic (V) is converted to arsenic (III). Both have a similar level of cellular toxicity. Inorganic arsenic (V) is converted to mono-methyl arsenic (III) in the body, which reacts with proteins and possibly with DNA. A zero MCLG is protective of a possible linear mode of action.

Treatment Decision Tree, Costs, Variances, Affordability. EPA derived treatment costs from 3 models, the W/W Cost Model, the Water Model, and the Very Small Systems model to model flows between 200 and 0.015 million gallons a day. In some instances, the models were modified to be more reflective of current market conditions based on comments from stakeholders. For membrane technologies, EPA used published operating cost data. Results of case studies support EPA's assumption

that residuals will not be subject to regulation as hazardous waste. Since we proposed small system compliance technologies, we did not list variance technologies. EPA requests comment on its affordability criteria and approach to measure the cumulative cost of rules

- Stakeholders asked EPA to consider cost of purchasing condemned land from homeowners, increased staff needed to maintain point of use devices (POUs), and initiating use of chemicals; as well as: limited affordability due to local median incomes, water bills higher than the national estimates, and lack of increased funding available through loans and grants. Discharge to a POTW includes the cost of expanding the sewer for hook up.
- Some stakeholders believe that the Agency underestimated costs of sending brine wastes to POTWs and disposing of sludges that are hazardous wastes.

Benefits, Proposed MCL Options, and NODA. Uncertainties in shape of the dose-response curve, use of grouped exposure data, selenium and arsenic levels in diet could overestimate risk. Survival rate applied to Taiwan and incomplete identification of health effects besides bladder cancer underestimate risk in U.S. The Notice of Data Availability for lung cancer risks will be available within a month in order that commenters can understand how it affects the proposed rule. Excess deaths in Taiwan from lung cancer associated with arsenic appear to be about the same as the arsenic-related deaths from bladder cancer.

- Stakeholders were not satisfied with EPA's approach under 1412(b)(6) to comparing costs and benefits and exercising its discretionary authorities to move to a higher level MCL. Several believed costs would support setting MCL much higher than 5 ppb. Others believed that unquantified benefits would support an MCL lower than 5 ppb.

National Occurrence Estimates. From the 25-State database EPA derived system, regional, and national estimates for community water systems and NTNCWSs. Analysis of data from the U.S. Geological Survey showed no change over time in well measurements although draw down could affect results. The attendees raised no concerns with these analyses or the underlying rationale.

Analytical Methods and Development of the PQL. EPA is proposing to remove approval of inductively coupled plasma-atomic emission spectroscopy (ICP-AES) analytical methods for arsenic, because the detection limits are too high to support the new MCL options. Laboratory capacity appears to be sufficient at the practical quantitation level of 3 ppb with acceptance limits of $\pm 30\%$. No one mentioned any concerns after the presentation.

Monitoring and Implementation Issues. Stakeholders have already asked if rounding to the nearest 0.001 mg/L must follow the illustrated "even/odd" protocol that would round 0.0055 mg/L to 0.006 mg/L and 0.0045 mg/L to 0.004 mg/L. Applications for monitoring waivers need to provide data below the new MCL, which can be done using existing test methods. EPA is taking comments on the draft compliance guidance available at <http://www.epa.gov/safewater/ars/implement.html>.

- Some stakeholders believe EPA's basis for excluding NTNCs is not clear and compelling; others would like the Agency to apply NTNC exclusions to existing rules for metals to be consistent. Another noted that requiring monitoring and reporting by NTNCs could confuse the public; it may be more appropriate to exclude them entirely.
- The Agency should consider allowing running quarterly averages as a compliance approach for chronic toxicity contaminants.

Consumer Confidence Report, Public Notification, and Next Steps. The existing consumer confidence rule (CCR) requires providing the public with health information if arsenic is detected between 25 and 50 ppb. If arsenic is detected, the annual report must provide the MCL, highest detected level, range, and likely source of contamination. The proposal will require that reports provide health effects language starting in the report covering 2001 for detections above the new MCL, which will not be

effective until three to five years after the final rule is promulgated, depending on system size. The existing public notification, with reporting arsenic MCL violations within 14 days, will continue as late as May 6, 2002 in States with primacy. Tier 2 will require notice within 30 days for the new, lower MCL violations and NTNCWSs exceeding the new MCL effective 3-5 years after the final MCL is issued. People can call the Safe Drinking Water Hotline to ask for copies of the proposal and/or electronic (if available) or hard copies of the technical support documents for occurrence, analytical methods, treatment, risk, and the regulatory impact analysis.

**Final Agenda
Stakeholders Meeting
Arsenic in Drinking Water
Reno, NV
Wednesday, August 9, 2000**

Meeting times are shown in Pacific Daylight Time (PDT)

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| 8:00-8:20
PDT | Registration & Phone Linkups |
| 8:20-8:30 | Introductions & Meeting Logistics - Ian Kline,
facilitator, Cadmus |
| 8:30-8:40 | Welcome - James Taft, Acting Director, Standards and Risk Management
Division, Office of Ground Water and Drinking Water (OGWDW) |
| 8:40-9:00 | Arsenic Regulatory History and SDWA Statutory Review - Presentation
and Questions - Irene Dooley, OGWDW |
| 9:00-10:00 | MCLG Development, Risk Characterization, and Health Advisory
Presentation - Dr. Charles Abernathy, Office of Science & Technology
(OST)
Facilitated Stakeholder Discussion |
| 10:00-10:20 | Break |
| 10:20-11:15 | Treatment Decision Tree and Costs
Presentation - Amit Kapadia and Jeff Kempic, OGWDW
Facilitated Stakeholder Discussion |
| 11:15-11:45 | Treatment Variances and Exemptions
Presentation - Amit Kapadia and Jeff Kempic, OGWDW
Facilitated Stakeholder Discussion |
| 11:45-1:00 | LUNCH (<i>on your own</i>) |
| 1:00-2:20 | Benefits, Proposed MCL & Options, and NODA
Presentation - Dr. John B. Bennett, OGWDW
Facilitated Stakeholder Discussion |
| 2:20-3:00 | National Occurrence |

**Presentation - Irene Dooley for Dr. Andrew Schulman, OGWDW
Facilitated Stakeholder Discussion**

3:00-3:15

Break

3:15-3:45

**Analytical Methods and Development of the PQL
Presentation- Ms. Wynne Miller, OGWDW
Facilitated Stakeholder Discussion**

3:45-4:30

**Monitoring and State Implementation Issues
Presentation - Ed Thomas, OGWDW
Facilitated Stakeholder Discussion**

4:30-4:50

**Consumer Confidence Report, Public Notification, & Next Steps
Presentation - Irene Dooley, OGWDW
Facilitated Stakeholder Discussion**

4:50-5:00

**Wrap up and adjourn meeting
James Taft, OGWDW
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