National Drinking Water Advisory Council

Executive Summary of June 2-3, 1999 Arsenic Stakeholder Meeting

and June 3, 1999 Half-day Conference Call

Background

On June 2-3, 1999, the U.S. Environmental Protection Agency (EPA) held a one-and-a half-day stakeholder's meeting *and a half-day conference call* to give stakeholders the latest information and to solicit feedback regarding the Arsenic in Drinking Water Rule. EPA is scheduled to propose the rule by January 1, 2000; and to promulgate the final rule by January 1, 2001. Since the presentations of the half-day conference call covered the same materials in a condensed version, *additional comments from the call will be reported in italics* in the combined summary below.

SUMMARY

Arsenic Regulatory Review. In 1995 EPA's regulatory cost analysis projected that lowering the MCL into the range of 2 to 20 ppb would cost small households over $1100/household/year compared to less than $100/household/year for households in larger systems. The 1996 Amendments require EPA to prepare a Health Risk Reduction and Cost Analysis (HRRCA) with the proposal. A stakeholder requested that EPA provide access to the arsenic HRRCA as early as possible. Another stakeholder observed that the statute requires research, and this rule will be issued without having all of the results of new research. However, Congress decided on this research-regulatory dual track approach fully informed by EPA, and EPA believes that the MCL can be set based on good science with existing data. A stakeholder remarked that MCLs are used within other EPA regulatory programs which may cause economic impacts not reflected in the HRRCA. EPA's Office of Water sets the MCLG and MCL based on SDWA statutory requirements and considering other program offices' issues, using the Agency workgroup process.

Analytical Methods and PQL. Currently approved analytical methods, including the 1994 methods update and the 1998 proposed revisions, measure total arsenic. Analytical capability is only one aspect considered in setting an MCL, so the MCL is not set purely on the basis of the lowest value that can be measured. The 1999 derivation of a practical quantitation level (PQL) was rounded to 3 µg/L for an acceptance value of 25 and 30%, and a 30% acceptance value would provide more laboratory capacity than having a 25% acceptance value. All approved analytical methods, when revised with the proposed modifications, should be able to meet the PQL and remain on the approved list of methods. The PQL derivation will be peer reviewed.

National Research Council/National Academy of Sciences (NRC/NAS) Report. EPA charged the NRC of NAS to assemble experts to: review EPA's risk characterization work; review current data for use in risk assessment; and identify priorities to fill research gaps. People vary in their metabolic ability to excrete arsenic, and animals respond differently according to species. *Noncarcinogenic effects include effects on the cardiovascular system, gastrointestinal tract, and diabetes.* As a carcinogen, arsenic appears to affect chromosomes and "genetic housekeeping," rather than interacting directly with deoxyribonucleic acid (DNA). Studies confirm skin, bladder, and lung cancer. Applying EPA's 1996 guidelines depicted the lifetime risk of bladder cancer as about one excess case per 1000 at 50 ppb*, derived by extrapolating from observed health effects, which are in the range of 350-410 µg/L.*

Organic arsenic from fish tends to pass unchanged through humans, and methylated forms may be toxic. Stakeholders voiced concern that EPA is regulating all forms of arsenic (total). A stakeholder noted that a

1983 NAS report said that arsenic was an essential nutrient. The 1999 NRC report has not determined arsenic to be an essential nutrient, even though some forms are used as a growth promoter for animals. A form of arsenic is being used to treat leukemia.

EPA's risk characterization will be done in the fall. A stakeholder wanted EPA to make the NRC report available for free. Ordering information for the copyrighted NRC/NAS report can be found at http://www2.nas.edu/whatsnew/29e6.html; and the full report can be read at http://www.nap.edu/readingroom/enter2.cgi?0309063337.html.

MCLG Development, Risk Characterization and Health Advisory. SDWA requires that EPA issue MCLGs, nonenforceable health goals. To do so, EPA follows the 1996 Proposed Carcinogen Risk Assessment Guidelines to develop MCLGs for carcinogens. The risk assessment process evaluates exposure from drinking water, diet, and air. *Skin absorption is minimal.* Arsenic in air accounts for less than 1% of total exposure. Overall, risk characterization considers modes of action; adverse cancer and noncancer health effects; susceptible populations, such as children (required by Executive Order) and aged populations; and the risk assessment. EPA is currently creating a health advisory for arsenic. The purpose of this advisory is to provide guidance for the United States population prior to the effective date of the regulations, which is three to five years after the final rule is published. It will review health effects; explain the risk assessment process used to determine the proposed MCL; and provide treatment technology and analytical methodology. The health advisory should be available in early 2000 on EPA's web site (http://www.epa.gov/waterscience/) or by calling the Safe Drinking Water Hotline at 800-426-4791.

Arsenic Research Plan Update. The Arsenic Research Plan, completed in February 1998 and extensively peer-reviewed both internally and externally, has not changed. It is available at http://www.epa.gov/ORD/WebPubs/final/arsenic.pdf. One of its purposes is to improve the scientific basis for risk assessment and regulatory decisions regarding arsenic. The Plan is also designed to identify critical research for reducing uncertainty and to provide a comprehensive framework to address key research for decisions needed by January 1, 2001 and for long-term risk assessment. In order to regulate arsenic in U.S. drinking water, EPA needs to address the levels of exposure, analytical methods, cancer and non-cancer health effects, the mode of action for arsenic toxicity, and treatment performance. One stakeholder asked if EPA will identify how it is addressing NRC/NAS research recommendations on line. Another stakeholder asked EPA to conduct more health studies of As(III) and As(V) species.

EPA Health Effects Research. For epidemiological research on arsenic, more information is needed on dose-response for internal cancers and noncancer effects; the roles of nutrition, genetics, and other factors; and use of biomarkers to measure exposure, effect, and susceptibility. Ongoing studies include the Utah study (ending in 1999), an evaluation of other U.S. sites (ending in 2000), and a feasibility study in Mongolia (ending in 2001). A collaborative study in Chile is a case-control study of lung and bladder cancer (ended 1998). Another collaborative study in India will examine noncancer effects, including hyperkeratosis and hyperpigmentation. Laboratory studies can improve understanding of the dose response at low doses by understanding the factors that influence toxicity. Mode-of-action research studies the role of arsenic and metabolites in tumor promotion, in modifying DNA methylation, and in producing noncancer effects (such as embryotoxicity in mice). Animal research and development of models can improve studies of metabolism and susceptibility. EPA has no plans in the near term to cut funding of long-term research for arsenic, even though Congress only authorized funding through the year 2000.

The study of reproductive effects in Chile found increased infant mortality when drinking water had high arsenic concentrations (up to 860 µg/L). Another Chilean arsenic study showed a weight decrease and increase in prematurity for infants exposed to 40-50 µg/L vs. those exposed to less than 1 µg/L. Stakeholders asked if other contaminants had been considered. Three U.S. infant studies have indicated increases in spontaneous abortions and heart defects mortality.

In Utah, EPA compared causes of death observed in a county with arsenic medians ranging from 14 to 166 µg/L in the drinking water to the State mortality records. Some heart and kidney diseases, kidney cancer, and prostrate cancer were higher with arsenic exposure; while other diseases were lower. EPA's biomarker study of 30 families in the same county indicated that the arsenic concentration in the drinking water, rather than food, is linked closely to the urine arsenic concentration; and neither age nor gender affected the amount of arsenic excreted in urine.

Arsenic Treatment Technologies and Residuals. Arsenic exists in organic and inorganic compounds, which can be dissolved, particulate, or both. Because As(V) is much more effectively removed than As(III), EPA is studying factors that affect oxidation processes as well as arsenic removal technologies. One point-of-use (POU) pilot program decreased arsenic from 65 µg/L to 5 µg/L, and found that properly maintained systems continued to remove arsenic. A pilot point-of-entry (POE) reduced arsenic from 55-500 µg/L to 5 µg/L. Some stakeholders voiced concern about having hazardous waste treatment residuals after the arsenic MCL is lowered. Historically, EPA has not revised the hazardous waste toxicity characteristic regulation to reflect other MCL changes. *Tested spent activated alumina has not been hazardous waste due to arsenic.*

EPA's Approach to Compliance Forecasts -- Decision Tree and Treatment Variances and Exemptions. EPA identifies the best available technologies (BATs) for larger systems and small system compliance and, if necessary, variance technologies for small systems if there are no affordable compliance technologies. In addition, EPA develops unit cost estimates to develop national cost estimates. The "decision tree" assigns expected percentages of utilization of various treatment options. Stakeholder comments have been incorporated into EPA's analyses, such as operating activated alumina at suboptimal pH for small systems.

EPA is to specify compliance technologies for small systems to achieve compliance with the regulatory standard. Other compliance options include the installation of other technologies (that meet the MCL), restructuring through interconnection with other systems or common management and treatment, and use of an alternative source. Exemptions give the system extra time to come into compliance. When there are no affordable compliance technologies for specific system size/source water quality combinations (based on national level affordability criteria), EPA will specify variance technologies. A variance technology is an affordable technology that maximizes contaminant reduction and protects public health but may not achieve compliance with the MCL. Therefore, more process-control monitoring may be required for a variance technology than for a compliance technology.

If EPA lists variance technologies for a small system size category, States apply system-level affordability criteria to individual systems when granting small system variances under Section 1415(e). The small systems' National Drinking Water Advisory Council (NDWAC) Working Group developed options that States can use for system-level affordability criteria. Technologies that meet the national-level criteria may not be affordable for a specific system within the size category.

National-level affordability criteria can be evaluated by examining user burden and the increase in annual household (hh) water bills as a result of treatment installation ($/hh/year increase). EPA's approach is to (1) develop baseline annual water bills for each size category; (2) develop baseline median household income for each size category; (3) summarize comparative household expenditures as a percentage of median household income; and (4) develop income-based measures of affordability.

EPA has not yet determined if there are any system size/source-water quality combinations for which variance technologies will be identified under the revised arsenic standard. The guidance document *Variance Technology Findings for Contaminants Regulated before 1996*, EPA-815-R-98-003, is available from the Hotline (1-800-426-4791) or at the drinking water treatment webpage: www.epa.gov/safewater/standard/tretech.html.

National Occurrence Estimate. In order to estimate compliance costs and benefits, EPA needs an estimate of the national distribution of mean arsenic concentrations in water systems, the range of arsenic within systems with multiple sources, and the number of systems with at least one source above the proposed standard. The compliance monitoring data for 24 States provides more of this data than EPA or utility industry national surveys. *For instance, EPA's National Inorganics and Radionuclides Survey only reported arsenic concentrations down to 5 µg/L.* EPA explained the statistical approaches used to calculate system means and State distributions. Dividing the country into groups of States allowed EPA to obtain regional estimates, weighted by the number of systems in each region. Preliminary national occurrence estimates were similar to results predicted by an industry survey. EPA estimates for intrasystem variability are still under development. *Formerly, EPA's system average did not account for the distribution of arsenic concentrations among the reported points of entry*. Initial analyses of raw water well data from the U.S. Geographical Survey (USGS) with ten or more samples indicate no changing trends over time; no correlation between well depth and temporal variability; and a fairly constant coefficient of variation.

Cost-benefits Regulatory Issues. EPA's cost analysis acknowledges intrasystem variability, which means not all wells in a system may require treatment to meet the MCL. The Monte Carlo program randomly selects a system, assigns it to the national system average occurrence distribution, and applies the relative standard deviation to assign arsenic concentrations to entry points. For the entry points which are above a particular MCL option, the model assigns a treatment technology according to the percentages in the decision tree, and assigns the costs. The computer program is run many times to estimate total national costs and derive estimates of household cost for the national affordability criterion. Stakeholders noted that the analyzed costs are not the "real"costs for water systems and customers. A stakeholder noted that during treatment optimization, a system will monitor more frequently than required, which will increase analytical costs.

Very large systems serve more than a million people, and may represent 10-20% of all compliance costs. EPA did individual water cost estimates for the 25 very large systems, which use ground water and surface water. At an MCL option of 20 ppb, EPA projects that two systems would be impacted; at 10 ppb and 5 ppb, three systems; and at 2 ppb, five. The systems are reviewing EPA's draft cost estimates. EPA allocates cost on a retail population basis.

SDWA requires EPA to identify quantifiable and non-quantifiable health risk reduction benefits and to identify incremental benefits and costs of MCL options considered. EPA guidelines will guide this work, as well as recommendations from the National Drinking Water Advisory Council (NDWAC) benefits working group. The Value of a Statistical Life (VSL) measures the willingness of people to pay to avoid immediate death, and it is multiplied by the reduction in number of *premature* fatal cancers associated with each MCL option level to quantify benefits of reducing fatal cancers. Non-fatal benefits are being calculated from Cost of Illness studies for skin, bladder, and lung cancer and the Willingness to Pay (WTP) to avoid illness. Currently EPA does not adjust monetized benefits over time. Some stakeholders believe that the Agency should do so and to acknowledge that reducing the MCL does not immediately reduce health effects due to arsenic. Some also want EPA to consider life expectancy so a younger person's life is worth more than an older person's life.

Monitoring and State Implementation Issues. Currently arsenic monitoring is described in §141.23(l). Non-transient, non-community water systems (NTNCWS) are not required to monitor for arsenic; an MCL exceedance triggers three samples within a month until two consecutive samples are less than the MCL; and no waivers from regulation are presently permitted. EPA plans to propose that arsenic move to the standardized monitoring framework for other inorganics found in §141.23(c), which includes NTNCWS. Furthermore, an MCL exceedance would trigger quarterly monitoring until reduced by the State; and nine-year monitoring waivers would be possible. The effective date of the arsenic MCL is three years after promulgation (approximately January 1, 2004). All systems would be required to receive a complete initial sampling by December 31, 2004. If capital improvements were deemed necessary, systems could apply to the State for a two-year extension. EPA could extend the effective date for all or some systems on a national basis and consider use of grandfathered data to satisfy compliance and to issue waivers.

Stakeholders favored EPA giving the 2-year capital extension to small systems. In addition, a stakeholder noted that systems would be monitoring more often than required while optimizing added treatment. While EPA's test procedures measure to 8 ppb or less, some States have not reported data below 50 ppb, which affects the value of grandfathered data. EPA is also considering changes to the State primacy revision application process for the arsenic MCL. A stakeholder said the Drinking Water Revolving Fund could not fund all new treatments, which EPA should consider when contemplating extensions.

Wrap up. EPA has the necessary information to revise the present arsenic standard in time to meet the statutory deadline. Some components of the regulatory process are established (the PQL, analytical methods, the decision tree, and monitoring requirements), while others are still being developed (*e.g.*, occurrence, MCLG, and costs and benefits of MCL options). The Small Business Advocacy Review (SBAR) Panel completed its process last month, and its report will be part of the official record for this rulemaking. It is doubtful that portions of the rule would be released for public comment before the proposal deadline of January 1, 2000 because of time constraints. The proposal must be completed by late August so that the three-month OMB review can occur on schedule, as well as EPA's internal review.