

June 4, 1999

Ms. Carol M. Browner
Administrator
United States Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Administrator Browner:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel convened for EPA's rulemaking on the National Primary Drinking Water Regulation (NPDWR) for Arsenic (Arsenic in Drinking Water Rule). EPA currently regulates arsenic at 50 parts per billion (ppb), which was set as a National Interim Primary Drinking Water Regulation in 1975 and converted to a NPDWR in 1986, subject to revision by 1989. When EPA failed to meet the statutory deadline, a citizens' group filed suit and the Agency entered into a consent decree to issue the regulation. EPA held internal workgroup meetings throughout 1994, addressing risk assessment, treatment, analytical methods, arsenic occurrence, exposure, costs, implementation issues, and regulatory options before deciding in early 1995 to defer the regulation in order to conduct additional research to better characterize health effects and treatment costs.

Congress amended the Safe Drinking Water Act (SDWA) in 1996, requiring EPA to propose a NPDWR for arsenic by January 1, 2000, and issue a final regulation by January 1, 2001. In addition, EPA must review the new regulation by 2007 at the latest, and revise it, if appropriate, based on new data and information. The 1996 SDWA amendments also directed EPA to develop a comprehensive arsenic research plan by February 1997 to assess health risks associated with exposure to low levels of arsenic. The subcommittee on Arsenic in Drinking Water of the Committee on Toxicology of the National Research Council (NRC) in the National Academy of Sciences (NAS) reviewed EPA's risk assessment of arsenic. NRC submitted its review in March 1999.

On March 30, 1999, EPA's Small Business Advocacy Chairperson (Thomas E. Kelly) convened this Panel under section 609(b) of the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). In addition to its chairperson, the Panel consists of the Director of the Standards and Risk Management Division of the Office of Ground Water and Drinking Water within EPA's Office of Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Chief Counsel for Advocacy of the Small Business Administration (SBA).

It is important to note that the Panel's findings and discussion are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process as well as from public comment on the proposed rule. Any options the Panel identifies for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, protective of public health, environmentally sound and consistent with SDWA.

Panel Findings and Discussion

Under the RFA, the Panel is to consider four regulatory flexibility issues related to the potential impact of the rule on small entities (i.e., small businesses and non-profit organizations): (1) the type and number of small entities to which the rule will apply; (2) record keeping, reporting and other compliance requirements applicable to small entities; (3) the rule's interaction with other Federal rules; and (4) regulatory alternatives that would minimize the impact on small entities consistent with the stated objectives of the statute authorizing the rule. The Panel's most significant findings and discussion with respect to each of these issues are summarized below. To read the full discussion of the Panel findings and recommendations, see Section 9 of the report.

Number of Small Entities

The Panel notes that EPA maintains the national Safe Drinking Water Information System (SDWIS) database, which is the inventory of all public water systems in the United States. In addition, the Panel notes that EPA is revising the draft 1992 estimates by using arsenic compliance monitoring data from 23 States, with support of data from other studies, to establish a more accurate and scientifically defensible occurrence and exposure distribution. Therefore, the Panel believes that EPA will have very good information about the number and type of systems impacted by the arsenic rule.

Potential Reporting, Record Keeping, and Compliance Requirements

Treatment Technologies, Waste Disposal, and Cost Estimates

EPA has developed preliminary cost estimates for three technologies that are applicable for treating arsenic at small ground water systems (reverse osmosis, activated alumina and ion exchange). These include cost estimates for using these technologies both centrally and in point-of-use (POU) (i.e., at the tap) and point-of-entry (POE) (i.e., where drinking water enters the home) forms. This information indicates that annual costs per household could range from about \$50 to \$950 for small systems. In general, these costs decrease as less stringent MCL options are considered, as the size of the system increases, as the influent sulfate level decreases (for ion exchange), and as the influent

arsenic concentrations decrease. The cost estimates are preliminary, and will be updated prior to proposal.

Significant concerns were raised by most SERs concerning the potentially high cost of treatment and waste disposal for small systems. The Panel recommends that EPA further develop these preliminary treatment and waste disposal cost estimates. The Panel further recommends that EPA fully consider these costs when proposing an MCL and identifying affordable compliance technologies for all system size categories. In this context, the Panel notes the importance, in evaluating the costs of POU/POE devices, of accounting fully for all costs, including costs that may not routinely be explicitly calculated, such as unanticipated repairs, educating customers in their proper use, and responding to customer concerns. The Panel also recommends that EPA develop guidance on treatment technologies applicable to small systems to accompany the final rule. The guidance should highlight the various waste disposal options and the necessary technical and procedural steps for small community water systems to follow in exploring these alternatives.

Small Systems Variance Technologies

There was considerable discussion, both with SERs and among Panel members, about the provisions in the 1996 SDWA amendments that allow for States to grant variances to small community water systems from complying with an MCL if EPA determines that there are no nationally affordable compliance technologies for that system size/water quality combination. Systems receiving such a variance must install an EPA-listed variance technology that makes progress toward the MCL, if not necessarily reaching it. EPA currently uses a threshold of 2.5% of median household income for determining if the total cost of water, including a projection of average household compliance costs for the new rule, is nationally affordable. Only if compliance costs would push average household water bills above this threshold (currently equal to about \$750 per household per year) would EPA allow States to consider granting small system variances.

Two Panel members were concerned that use of such a high threshold, which has so far resulted in no variance technologies being listed for any contaminants, may be counter to Congress' intent that States be permitted to grant variances on a case-by-case basis to small systems that truly cannot afford to comply with a particular drinking water standard. They were further concerned that an approach based on national medians would not allow States to address situations where the impact of installing a new treatment on an individual community was severe, because the community already had high water costs, was composed of low-income households, or needed to treat for multiple contaminants. These Panel members suggested that the affordability criteria used for determining whether to list a small system variance technology be less restrictive, thereby allowing more opportunity for States to make affordability determinations for individual systems by applying State-wide criteria on a case-by-case basis.

EPA would be concerned about an approach involving the use of what it considered to be an inappropriately low national level affordability criteria since it would not, in EPA's view, be supported by its analysis of comparable household expenditures for other goods and services. EPA recognizes that individual water systems may have higher than average treatment costs, fewer than average households to absorb these costs, or lower than average incomes, but believes that the national affordability criteria should be based on characteristics of typical systems and should not address situations where costs might be extremely high or low or excessively burdensome. EPA believes that there are other mechanisms that may address these situations to a certain extent. EPA is also concerned that a less restrictive set of criteria could have the net result of a national level finding that this and many future drinking water rulemakings were unaffordable for small systems -- thus creating, in effect, a two-tiered approach to national rulemakings and public health protection (i.e., one level of public health protection for large systems and another, less protective level for small systems).

Two Panel members were also concerned about EPA's plans to cumulatively account for the effect of various rulemakings on the national-level affordability criteria. Costs incurred to comply with new rules at the affected water systems will be averaged over all of the systems in that size category regardless of whether they are affected by the rules or not. This will understate the effect of new rules on individual systems. While EPA understands the concerns expressed by these Panel members about EPA's approach to the upward adjustment of the baseline in increments as each new drinking water regulation is promulgated, it believes there are a number of mitigating circumstances that will help alleviate cost pressures experienced by small systems. EPA also does not believe alternative approaches to calculating the cumulative impact of rules are appropriate since they could very quickly and inappropriately utilize the available small system "budget." This would likely render all technologies for future rules as "unaffordable" from a national standpoint.

The two Panel members were also concerned that the cumulative approach is based on chronological order rather than on risk. They were concerned that small systems might receive variances for high risk contaminants because the available expenditure margin had been used up on lower risk contaminants. The Panel recommends that EPA consider revising its approach to national affordability criteria to address this concern, to the extent allowed by statutory and regulatory requirements.

Monitoring

The Panel notes that EPA plans to revise the arsenic monitoring requirement to be consistent with the Standardized Monitoring Framework (SMF) for inorganic contaminants (IOCs), in which States may grant monitoring waivers to water systems if they find that the system is unlikely to violate the MCL during the term of the waiver. The Panel supports EPA's proposal to move arsenic into the SMF for IOCs, in order to allow waivers. The Panel further recommends that EPA consider allowing States to use recent compliance monitoring data, where they will meet analytical requirements and

have reporting limits sufficiently below the revised MCL, to satisfy initial sampling requirements or to obtain a waiver.

Analyzing Arsenic Species

On the basis of the information provided, one SER commented that EPA's analytical methods should distinguish between organic and inorganic forms of arsenic. This SER noted that drinking water systems containing almost entirely organic forms of arsenic may analytically violate the MCL due to the presence of organic arsenic. While EPA agrees that the available data indicate that organic arsenic forms appear to be much less toxic than inorganic arsenic, EPA believes that testing for total arsenic will rarely affect compliance costs. The Panel recommends that EPA continue to explore whether or not to make a regulatory distinction between organic and inorganic arsenic based on compliance costs and other considerations.

Relevance of Other Federal Rules

The Panel notes the valid substantial concern of a number of SERs about impending total costs of compliance with upcoming rules, including the ground water, disinfection by-products, radon, and uranium rules. The Panel recommends that EPA encourage systems to be forward-looking and test for the multiple contaminants to determine if and how they would be affected by the upcoming rules. To the extent permitted by law, the Panel urges EPA to consider establishing standards and compliance periods over a period of time that permits systems to engage in long-range water treatment planning to avoid unnecessary replacement of water treatment systems to meet new requirements. Furthermore, the Panel recommends that EPA provide guidance to small systems, to accompany the final rule, to assist them in making treatment decisions to address multiple contaminants in the most cost-effective manner.

Regulatory Alternatives

The Panel finds that the preliminary cost figures provided by EPA could place a very large burden on small systems, particularly those that serve less than 500 people. These potentially high costs appear to be the most important concern to the majority of the SERs. The Panel therefore recommends that, in developing a new arsenic proposal, and particularly in determining at what level to set the MCL, EPA take cognizance of the scientific findings, the large scientific uncertainties, the large potential costs, and the fact that the arsenic standard is scheduled for review in the future.

The Panel also notes that the 1996 amendments to the SDWA require that the Agency identify and analyze a comprehensive set of costs and benefits associated with a proposed NPDWR, including consideration of non-quantifiable costs and benefits. In addition, the new statutory provisions allow the Administrator to select an alternative, less stringent MCL for chemical contaminants such as

arsenic when the benefits of a proposed regulation do not justify the costs (SDWA Sections 1412(b)(4)(C) and 1412(b)(6)(A)). Executive Order 12866, which was issued on October 4, 1993, directs regulatory agencies, to the extent permitted by law and where applicable, to assess both the costs and benefits of any intended regulation, and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs. The Panel recommends that EPA give full consideration to the provisions of the Executive Order and to the option of exercising the new statutory authority under SDWA Sections 1412(b)(4)(C) and 1412(b)(6)(A) in the development of a National Primary Drinking Water Regulation for arsenic. In doing so, EPA should take into account both quantifiable and non-quantifiable costs and benefits of the standard and the needs of sensitive sub-populations, and give due consideration to the impact of the rule upon small systems.

Another important rule development consideration with the potential for significant impacts on small entities is the scope of coverage of the rule, in terms of the types and numbers of facilities to which it will apply. The Panel understands that the proposed rule will apply, at a minimum, to Community Water Systems and may apply to Non-Transient Non Community Water Systems (e.g., schools, hospitals, etc.). The Panel recommends that the Agency carefully consider the appropriateness of extending the scope of the rule in this manner.

Other Issues

Arsenic Health Effects and the NRC/NAS Report on Arsenic in Drinking Water

In 1996, EPA asked the National Research Council (NRC) of the National Academy of Sciences (NAS) to review the current state of the science for estimating risks associated with arsenic in drinking water. The NRC's report, issued in March 1999, is based on a more complete database and research findings that have become available since the 1988 EPA risk assessment. The report recommends lowering the current drinking water standard of 50 ppb. The Panel notes that the NRC report stated "EPA did not request, nor did the subcommittee [on arsenic in drinking water] endeavor to provide, a formal risk assessment for arsenic in drinking water." (NRC, 1999) In particular, the Panel understands that the hazard identification and does-response sections of the NRC report were performed in a manner consistent with EPA practice, but realizes that the report did not contain an exposure assessment. The NRC report is one of the elements that EPA will consider in preparing the Health Risk Reduction and Cost Analysis for arsenic required by SDWA.

The subject of the health effects of arsenic in drinking water was of considerable interest to the SERs and the Panel. Several SERs urged the Agency not to use findings from studies from other countries based on arsenic levels atypical of the U.S. to develop a new, more stringent arsenic in drinking water standard. In particular, some SERs observed that the data used in the studies reviewed by the NRC are based upon arsenic exposures of individuals in other countries that are many times

higher (e.g., greater than 300 ppb) than levels typically found in the U.S. (i.e., less than 50 ppb). Preliminary results from a study in Utah, released after the NRC report, did not find elevated levels of lung and bladder cancers in a population exposed to arsenic concentrations in drinking water in the range of 15 to 165 ppb.

The Panel recommends that EPA proceed toward proposing and promulgating a new NPDWR for arsenic within the statutory deadlines. However, the Panel also recommends that the Agency thoroughly consider the SER concerns that the NRC recommendations be examined carefully in the light of the many uncertainties associated with the report's recommendations and any new data that may not have been considered in the NRC report. The Panel also notes that the risk assessment of arsenic in drinking water is one component of the overall rulemaking effort and recommends that EPA fully consider all of the "risk management" components involved in setting a standard to ensure that the financial and other impacts on small entities are factored into its decision-making processes.

The Panel believes EPA should carefully consider all comments received during this outreach process on these and other issues of concern to small entities. A full discussion of the comments received from SERs and Panel recommendations is included in the report.

Sincerely,

/S/

Thomas E. Kelly, Chair
Small Business Advocacy
U.S. Environmental Protection Agency

/S/

Don Arbuckle, Acting Administrator
Office of Information and Regulatory Affairs
U.S. Office of Management and Budget

/S/

Jere W. Glover
Chief Counsel for Advocacy
U.S. Small Business Administration

/S/

William R. Diamond, Director
Standards and Risk Management Division
Office of Ground Water and Drinking Water
Office of Water
U.S. Environmental Protection Agency

Enclosure