



Office of Advocacy

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**To: John Spotila, Administrator
Office of Information and Regulatory Affairs, Office of Management and Budget**

From: Jere Glover, Chief Counsel, Office of Advocacy, Small Business Administration

Subject: Draft Arsenic Proposal – Inclusion of Regulatory Alternative of 20 ppb for Comment ; Proposal of 10 ppb instead of 5 ppb

As you are probably aware, SBA, OMB and EPA participated in a SBREFA panel regarding arsenic in drinking water last summer. Considerable questions have been raised about the costs and benefits of lowering the arsenic standard (Maximum Contaminant Limit) from the current 50 ppb to EPA's draft proposal of 5 ppb. This proposal greatly surprised the water utilities, who were expecting an MCL no lower than 10 ppb. Such a proposal, by EPA's own estimate would cost almost \$400 million annually, to address a problem for which there is no direct evidence of a significant health hazard at the lower concentrations found in the U.S. Costs to households in the smallest systems (under 100 persons served) would exceed \$300 per year. At 5 ppb, EPA estimates an annual cost of \$380 million annually. At 20 ppb, the cost would be \$65 million annually, and the rule would affect many fewer small systems. EPA is requesting comment on the options of 3, 5 and 10 ppb, but not 20 ppb.

I. Regulatory Alternative: MCL at 20 ppb

Relying upon the review of the scientific evidence addressed by the National Research Council (NRC) report, we strongly recommend that EPA include the 20 ppb regulatory option for comment, and propose 10 ppb as the preferred option. The preamble does not clearly explain why the 20 ppb option is not included for comment, although the option is included in the regulatory analysis. **(1)** The sensitivity analysis of the risk reduction benefits uses a very narrow range of uncertainty, in contrast to the large range of uncertainties cited in the NRC report on arsenic. It was "important to emphasize again that the results are not to be interpreted as a formal risk assessment, or as an endorsement of these data for the use of risk assessment for arsenic in drinking water." NRC at 230. "Regardless of the data set that is ultimately used for the risk assessment, the subcommittee recommends that a range of feasible modeling approaches be explored. The final calculated risk should be supported by a range of analyses over a fairly broad feasible range of assumptions. Performing a sensitivity analysis ensures that the conclusions do not rely heavily on one particular assumption." NRC at 251. The agency does not comply with this directive. Despite this very specific recommendation and a parallel recommendation by the SBREFA panel, EPA inexplicably selected only a narrow range of a factor of two, utilizing estimates solely from the higher risk Poisson models. The NRC report cites uncertainties from a large number of assumptions that individually approach and exceed a factor of one hundred (see accompanying staff memorandum). At a minimum, EPA needs to revise its analyses to reflect the "fairly broad feasible" range of assumptions.

Once EPA increases the range of uncertainty, which would reduce the low end estimate of potential benefits, by more than a factor of one hundred, the 20 ppb option warrants serious consideration by EPA for the final rule. Even under EPA's current analysis, the costs of \$380 million could outweigh EPA's estimate of benefits of between \$64-\$725 million (using EPA's 3% interest rate). In our view, the costs and benefits would be more closely aligned at 20 ppb than at 5 ppb, EPA's current choice for the MCL.

Furthermore, over the next six years, EPA will continue to study the effects of arsenic, under its current research plan. As the SBREFA panel stated, it would be poor public policy to set a standard that was too low, require water utilities to make the considerable investment in treatment capacity, only to learn too late that the arsenic effects at low levels were considerably smaller or nonexistent. Indeed, the NRC scientists indicated that the "several modes of action that are considered plausible" would predict that a threshold would exist for arsenic, above which there would be no effect. NRC at 173. This threshold could exist above 5 or 20 ppb. Allowing the public to comment on the 20 ppb option would be sound public policy, consistent with the Safe Drinking Water Act and the requirements of the Regulatory Flexibility Act to consider all reasonable regulatory options that meet statutory goals, while reducing small business burdens.

II. Recommend: MCL at 10 ppb

As a final note, we also urge the agency to propose a standard of 10 ppb, instead of 5 ppb, in light of the previous discussion. These cost impacts on small rural systems are dramatic, and the state of the science and the available evidence do not justify the imposition of these costs on rural America.

ENDNOTE

1. There is a discussion on page 212 of the 3/1/00 draft preamble, indicating that the agency historically has sought to establish risk levels where less than 10% of the exposed population faced a risk exceeding 10^{-4} , but the preamble does not address this point in the discussion of the choice of MCL. If one only considers the small range of uncertainty posed by EPA, the 20 ppb would fall outside this range (see p.187), estimating that 9-24% of the population would exceed this estimate. However, if one assumes, for example, that the risk is overestimated by a factor of ten or more, we would expect this estimate to fall well below 10% of the population.