



Office of Advocacy

---

Date: May 3, 2000

To: Jere Glover, Chief Counsel

From: Kevin Bromberg

Subject: Draft Arsenic Proposal (3/01/00 Draft); EPA Risk Analysis Underestimates Range of Uncertainty and Likely Exaggerates Risk; Supports Adoption of 10 or 20 ppb MCL

The arsenic sensitivity analysis of the costs and benefits addresses a very small range of uncertainty, in contrast to the large uncertainties cited in the National Research Council (NRC) report. The NRC report recommends that 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 report also notes that it was not providing a formal risk assessment, and urged the agency to complete its own analysis. Despite these recommendations, EPA chose to select data that showed variation in risk by only a factor of two, utilizing estimates solely from the higher Poisson modeling exercise. The NRC report cites uncertainties from a large number of assumptions that individually approach and exceed a factor of one hundred.

The 3/1/00 preamble states at page 260, "[a]dditional sources of uncertainty are also found in the NRC Report. Such uncertainties include the shape of the dose-response curve, the contribution of the arsenic exposure from food, and the choice of model when conducting arsenic risk assessment." On pages 216 through 219, the preamble includes mention of the following additional uncertainties: linearity assumption, dietary arsenic, selenium availability, Weibull vs. Poisson modeling, selection of village well data, and well groupings of the exposure measurements. Regarding the selection of village well data, "[a]t 10 ppb [the EPA draft proposed standard], the variation in estimated risk is even more marked (ranging from 0.002 to 0.254 per 1,000)." NRC at 238. The group modeling alone introduces an additional potential error of a factor of 100 at 10 ppb (Table 10-9, NRC at 241). However, instead of employing a range of uncertainty that encompasses a "fairly broad feasible range of assumptions" [NRC at 251], EPA instead chose to use only four values using only from the Poisson distribution assumption (with the risk estimates higher than the biologically-based Weibull distribution), and which reflected a total variation of a factor of two.

"EPA selected four of these distributions as representative of the risks and uncertainty involved (selecting relatively high and relatively low estimates)." Preamble at 186. Including the 95% confidence limits, the risk per 1,000 at 50 ppb varied from 0.73 to 1.58. In contrast, one factor discussed above alone would account for a 100-fold variation. It appears that the risk reductions, according to EPA's calculation could easily be lower by much greater than a factor of 100, using NRC's own figures, which EPA does not dispute.

Considering the fact that there is a reasonably large probability that EPA's risk estimates are high, if not extremely high, based on a confluence of several conservative assumptions (including linearity of dose response, different nutrition, diet and selenium

levels in Taiwan study population), there is a stronger basis for the regulatory options of 10 and 20 ppb than the preamble suggests. Further, significant adverse health effects have not been noted in any study based in the United States with low arsenic concentrations. The only potentially significant study in the United States (Utah study) fails to show a dose-response for bladder cancers, in contrast to the Taiwan study (involving higher arsenic exposures) that is the basis of the NRC risk estimates. The NRC report states that the only known plausible mechanisms for arsenic to act as a carcinogen would dictate that arsenic act in a sublinear fashion, i.e., as a threshold chemical. This threshold could be in the neighborhood of 10 or 20 ppb. Additional research is ongoing to further reduce the uncertainties in the arsenic risk assessment. Further, at higher MCLs, the cost of treatment would be more in line with the potential benefits, and EPA could exercise its discretionary authority under SDWA section 1412(b)(6) to align the MCL so that the benefits would justify the costs.

Under EPA's current calculations of monetized benefits at 5 ppb, the costs of \$380 million could outweigh the benefits of \$64-\$725 million. Utilizing the greater range of uncertainty, as recommended by the SBREFA panel and NRC would cause the benefits uncertainty range, at least at the lower end, to expand considerably downward by at least a factor of one hundred. This provides the basis for EPA selection of a regulatory option of 10 ppb or above, including the option of 20 ppb.

EPA is also apparently concerned that many millions of people could face unusually high risks (above  $10^{-4}$ ) if a standard of 20 ppb were adopted (see preamble at 188). However, that calculation is predicated on an estimate that is very uncertain. It may be equally likely that the number exposed to this risk is less than one hundredth or one thousandth of the EPA estimate.

In summary, the current risk evidence supports an MCL of 10 or 20 ppb under the discretionary authority under SDWA section 1412(b)(6) to adopt an MCL that is justified by the costs.