



ASSOCIATION OF
METROPOLITAN
WATER AGENCIES

March 26, 2010

Dr. Sue Shallal, Designated Federal Officer
EPA Science Advisory Board
1200 Pennsylvania Avenue, NW
Mail Code 1400 F
Washington, DC 20460

Re: Comments to the USEPA Science Advisory Board on *IRIS Toxicological Review of Inorganic Arsenic (Cancer) (External Review Draft) (75 Federal Register 7477)*

Dear Dr. Shallal:

The Association of Metropolitan Water Agencies (AMWA) appreciates the opportunity to comment on the *IRIS Toxicological Review of Inorganic Arsenic (Cancer) (External Review Draft) (75 Federal Register 7477)*.

INTRODUCTION

Integrated Risk Information System (IRIS) toxicological information is the foundation and cornerstone of all future USEPA risk management actions on arsenic. The hazard, exposure, and risk assessments that will precede any risk management decision to revise the arsenic Maximum Contaminant Level will be based on the toxicological information contained in the IRIS document.

In 2003, USEPA decided to revise the IRIS entry for inorganic arsenic, the first update since 1988. As part of that process USEPA requested a review by the Science Advisory Board (SAB) (2005). In 2007 the SAB completed its report and published its recommendations. Based on these recommendations USEPA revised its original document and is now returning it to the SAB for a second review. EPA has developed specific charges to the SAB, which focus on EPA's responses to the 2007 SAB review.

RECOMMENDATIONS

The 2007 SAB review was not a critical review of the entire document. At that time, the SAB considered expanding its review to the entire document, but in the end decided to focus on responding to the specific charge questions. Consequently, if the SAB review proceeds as proposed in the *Federal Register*, a narrowly focused review will again fail to achieve the degree of review necessary to establish a sound scientific basis for the regulatory process as it pertains to inorganic arsenic.

AMWA recommends that the SAB conduct a thorough independent critical review of the entire document or that EPA revise and expand the charge to the SAB. The SAB's review should examine the techniques, processes, decisions, assumptions and procedures employed by EPA in the development of this document including but not limited to the following questions:

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1. Is the scientific basis for the assumptions and approaches used by USEPA in its low dose extrapolations scientifically sound enough to become the basis for the development of public policy that could have significant economic and social implications?
2. What is the level of specific uncertainty associated with the cancer slope factor?
3. Has the EPA overlooked any epidemiological and toxicological data from other peer reviewed scientific studies in addition to the Taiwanese studies used in the revised toxicological review? There have been many additional studies since the NAS report was released in 2001.
4. Has EPA's analysis of the Taiwanese dataset accounted sufficiently for the confounding factors in these studies such as smoking, drinking water consumption and diet (i.e., the proportion of rice and fish consumed)?

AMWA also recommends two additional areas for SAB review and comment:

- The SAB should identify subject areas for needed research so the USEPA can add these to its research requests to the Office of Research and Development as part of the third Six-Year Review for drinking water regulations.
- While some labs may have the capability to detect arsenic at the concentrations expressed for 10^{-4} risk in drinking water (0.14 $\mu\text{g/L}$ for women and 0.21 $\mu\text{g/L}$ for men), the technology is limiting and therefore there is a higher margin of error. The SAB should comment on the validity of expressing unit risk in drinking water at these levels given the future scientific and policy work that will build upon these unit risk levels.

EPA's 2003 public involvement policy (www.epa.gov/policy2003/policy2003.pdf) states that EPA should distribute materials to make the public aware as soon as such information is available and that "the more complex the issue and greater the potential for controversy or misunderstanding, the earlier the Agency should distribute the materials." This policy also states that the comment period "for public review of unusually complex issues or lengthy documents generally should be no less than 60 days."

AMWA believes that the IRIS toxicological review document for arsenic is both complex and lengthy, and therefore asks that the agency extend the review timeframe for both the SAB and the public. The timeframe for the public to comment and have those comments considered by SAB was less than 60 days. In addition, AMWA asks for assurances from USEPA that all comments submitted to the agency during the comment period be delivered to the SAB for its consideration.

CONCLUSIONS

In a letter dated April 17, 2009, AMWA together with the American Water Works Association requested that USEPA take appropriate steps to ensure that the agency:

1. Provide an opportunity for public comment on the entire draft IRIS inorganic arsenic hazard assessment,
2. Engage the Science Advisory Board (SAB) in an expert review of the entire draft IRIS inorganic arsenic hazard assessment, and
3. Allow for a full and open review of the entire draft IRIS inorganic arsenic hazard assessment within the agency.

This letter reiterates that position and also provides additional recommendations for the SAB's review of this document.

AMWA thanks USEPA for allowing for public comment and SAB review of this document but requests that the agency encourage a fuller review of the document, in keeping with the agency's principles of sound science and transparency.

Sincerely yours,

Diane VanDe Hei
Executive Director

cc: Cynthia Dougherty, EPA/OW/OGWDW
Dr. Paul Anastas, EPA/ORD
Mr. Lek G. Kadeli, EPA/ORD/NCEA
Reeder Sams, EPA/ORD/NCEA