



**American Water Works
Association**

The Authoritative Resource on Safe Water SM

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March 26, 2009

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Sue Shallal
Science Advisory Board
U.S. Environmental Protection Agency
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RE: Peer Review Draft, Integrated Risk Information System (IRIS) Toxicological
Review of Inorganic Arsenic (Docket ID No. EPA-HQ-ORD-2010-0123)

Dear Ms. Shallal,

In April 2009, the American Water Works Association (AWWA) and the Association of Metropolitan Water Agencies (AMWA) jointly asked EPA to take appropriate steps to assure that the Integrated Risk Information System (IRIS) Toxicological Review of Inorganic Arsenic:

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

AWWA believes these steps are consistent with, and critical to, the agency's policies and principles of sound science and transparent government. AWWA was gratified to see that EPA

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has forwarded a peer-review draft of the Toxicological Review of Inorganic Arsenic to the SAB for review and provided an opportunity for public comment.

As the SAB is aware, arsenic is ubiquitous at low levels in the nation's soils and natural waters. For this reason, the hazard assessment has to be sound, particularly at potentially low concentrations in drinking water. As the agency moves from hazard assessment to risk management under the Safe Drinking Water Act (SDWA) and other statutes, the role of uncertainty and how uncertainty is addressed in the hazard assessment amplifies both the projected benefits and costs of potential risk management options. The SAB's careful review of the Peer Review Draft is greatly appreciated.

The SAB was provided three specific charges. In responding to its first charge, to evaluate EPA's treatment of available epidemiology data, AWWA recommends the SAB closely evaluate why the Peer Review Draft continues to rely largely on the Taiwanese dataset, when there has been substantial additional work in the field. We were not able to discern from the draft a clear reason for not incorporating more of the recent epidemiological and toxicological data. With respect to the committee's second charge, to evaluate the agency's modeling effort, AWWA recommends that the committee closely examine the basis for the large increase in anticipated cancer risk reflected in the Peer Review Draft over the previous analysis underlying the Arsenic Rule. The current hazard assessment utilizes essentially the same data as previous work and yet arrives at twice the anticipated cancer risk (see Table 5.6) associated with drinking water exposure.

AWWA strongly advocates for effective research planning to support timely and appropriate regulatory decisions. EPA's Office of Water recently demonstrated a similar interest by publishing its National Water Program Research Strategy (<http://www.epa.gov/waterscience/strategy/>). A recent paper by Seidel and Roberson (Dec. 2009) in *Journal AWWA* found that only one third of the 46 risk assessment, exposure, health effects, and risk management research tasks in EPA's Research Plan for Arsenic in Drinking Water (1998) yielded results that were incorporated into the 2001 arsenic regulation. Of relevance to these comments, only three of the 21 health effects-related research tasks identified in the Research Plan yielded results that were incorporated into the final rule. As demonstrated, a substantial portion of the research that was not completed would have informed that rulemaking. Either completion of the other two thirds of this research, or development and implementation of an updated arsenic research plan needs to be completed prior to the Agency contemplating any potential revisions to the 2001 SDWA arsenic regulation. Further research to improve the agency's understanding of the inorganic arsenic modes of carcinogenic action should be priority research topics as lack of such data leads to the use of the default non-linear, low-dose models, introducing uncertainties in the low-dose extrapolation that constitute a major limitation in past and current hazard assessments.

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AWWA looks forward to the SAB's comments on the Peer Review Draft. Please contact me or Steve Via at AWWA (202-326-6130, svia@awwa.org) if there are any questions regarding arsenic as a regulated drinking water contaminant.

Best regards,

Thomas W. Curtis
Deputy Executive Director
AWWA Government Affairs

Attachment: Seidel, C.; Roberson, A.; Summers, R.; Zearley, T.; Tang, G., 2009. Incorporation of research plan results into regulatory policy. *Jour. AWWA*, 101:12:42- 56.

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