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April 27, 2009

Mr. Lek Kadeli

Acting Assistant Administrator

Office of Research & Development

U.S. Environmental Protection Agency

Ariel Rios Building

1200 Pennsylvania Avenue, N. W., Mail Code: 8101R

Washington, DC 20460

Via Electronic Mail: [kadeli.lek@epa.gov](mailto:kadeli.lek@epa.gov)

Dear Mr. Kadeli,

The National Association of Clean Water Agencies (NACWA) is concerned that the ongoing Integrated Risk Information System (IRIS) evaluation of inorganic arsenic [Toxicological Review of Inorganic Arsenic (CASRN 7440-38-2)] is not following established Agency procedures, nor adhering to EPA's standards for due consideration of external and internal peer-review comments by technical experts. NACWA believes the Agency is not providing sufficient opportunity for public comment and is acting inconsistently with recent policy statements from the Administrator.

As EPA described the IRIS process in a recent *Federal Register* notice, the IRIS risk assessment process consists of eleven steps and these steps are consistent with past IRIS practice:

*... (1) Publication of an annual Federal Register announcement of EPA's IRIS agenda and call for scientific information from the public on selected chemical substances; (2) a comprehensive search of the current scientific literature; (3) development of a draft IRIS health assessment utilizing state of the art scientific methods and guidelines; (4) internal EPA review of the draft assessment; (5) interagency review of the draft assessment; (6) public comment followed by independent external peer review of the draft assessment; (7) a public external peer review meeting related to the draft assessment; (8) preparation of a final IRIS assessment that reflects public comments and independent expert review; (9) interagency review of the final assessment; (10) EPA review and clearance of the final assessment; and of the final IRIS assessment on the IRIS database (<http://www.epa.gov/iris>). ...” (72 Fed. Reg. 72715)*

It is our understanding that EPA is striving to post a final IRIS assessment for inorganic arsenic by May, despite the fact that it has failed to:

1. Provide a public comment opportunity on the draft assessment;

2. Give appropriate consideration to comments from independent expert reviewers consulted by the agency (e.g., EPA-SAB-07-008, June 28, 2007); or
3. Provide for full and open interagency review of the final assessment.

While NACWA has not had an opportunity to review the recent revisions to the assessment of cancer risk of inorganic arsenic from oral exposure, we understand that the working draft of the IRIS evaluation proposes a dramatic increase in the cancer slope factor (CSF). This increase in the CSF is substantial in comparison to both the currently posted IRIS assessment and the partial draft assessment that was provided to the Science Advisory Board (SAB) for its review. According to a widely circulated copy of the draft final document, entitled *IRIS Evaluation for Inorganic Arsenic*, the current IRIS cancer slope factor of 1.5 per mg/kg/day will increase to 30.5 per mg/kg/day, a 20 fold increase. Such a dramatic increase in the current slope factor (CSF) could have overwhelming implications on a wide range of regulatory endpoints.

NACWA's members manage thousands of pounds of sewage sludge or biosolids on a daily basis in accordance with the 40 CFR Part 503 regulations. These regulations require that biosolids not exceed specific levels of key pollutants, including arsenic, for various management methods, including land application of treated biosolids, disposal and incineration. A change in the arsenic CSF would likely lead to a review of and possible change in EPA's Part 503 pollutant levels. NACWA believes that EPA must act cautiously to ensure that all of its existing procedures are being followed to provide ample opportunity for review and comment for a decision that could have extraordinary regulatory burden and cost implications.

EPA Administrator Jackson has pledged to ensure that Agency decisions are made in an open and transparent manner, most recently in an April 23 memo to EPA staff. Given this strong commitment to transparency and science-based decision-making, we request that the agency:

1. Provide an opportunity for public comment on the entire draft inorganic risk assessment;
2. Engage the Science Advisory Board 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.

These steps are consistent with the Agency's existing policies and principles and would ensure thorough involvement of the public and key stakeholders in the decision-making process.

Thank you in advance for your prompt attention to this matter. Please contact me at [chornback@nacwa.org](mailto:chornback@nacwa.org) or 202/833-9106 if you have any questions. We look forward to discussing next steps toward an IRIS assessment for inorganic arsenic that fully reflects public comment and an appropriate internal and external peer review.

Sincerely,



Chris Hornback  
Senior Director, Regulatory Affairs

NACWA Letter on IRIS Assessment for Inorganic Arsenic

April 27, 2009

Page **3** of **3**

cc: Michael Shapiro, Acting Assistant Administrator, EPA/OW  
Kevin Neyland, Acting Administrator, OMB/OIRA