Guest Editorial: The IRIS Assessment of Inorganic Arsenic: Is Science Being Hijacked?

By Lynn L. Bergeson

The arsenic IRIS assessment exemplifies the current administration's unwillingness to walk its own talk on transparency and scientific integrity.

Early in her role as the EPA Administrator, Lisa P. Jackson expressed her now familiar mantra that regulatory initiatives

Indeed, IRIS program reforms are as recurrent as the flu and, sadly, often inspire a similar response.

must be "transparent" and risk assessments must be conducted to "ensure the highest levels of scientific integrity." This particular recital was in Administrator

Jackson's May 21, 2009, memorandum, "New Process for Development of Integrated Risk Information System Health Assessments," which outlines IRIS process reforms.

IRIS stakeholders have witnessed more than their share of IRIS reforms. Indeed, IRIS program reforms are as recurrent as the flu and, sadly, often inspire a similar response. The hope, however, was that these reforms would be different and that Administrator Jackson's public commitment to transparency and scientific integrity would surely transcend the realm of political expedience and embrace the defining imperatives of any credible assessment process – transparency and scientific integrity.

The EPA's rush to judgment on the inorganic arsenic IRIS assessment suggests otherwise. In late 2008, a widely circulated copy of the draft IRIS assessment revealed that the current IRIS oral cancer slope factor (CSF) of 1.5 per mg/kg/day would increase to 30.5 per mg/kg/day, a staggering 20-fold increase. The draft sent shock waves through a wide swath of industry sectors, as the IRIS CSF is relied upon by an overwhelming majority of risk assessors for soil cleanup purposes, where already unacceptable risks estimated for naturally occurring levels of arsenic in soil will become even more unacceptable, but also for purposes of drinking water standards and health advisories for

seafood and other food items. Strenuous advocacy resulted in the EPA's commitment to subject the draft assessment to Science Advisory Board (SAB) review.

On February 19, 2010, the 575-page draft IRIS assessment was published and confirmed many stakeholders' worst fears. The draft includes a CSF of 25.7 per mg/kg/day, a 17-fold increase over the current standard. The EPA nominally allowed 60 days, or until April 20, to provide comment. On March 1, 2010, the EPA announced the SAB would conduct an "expedited" review of the draft assessment. The notice provided that only comments submitted by March 29, or within 38 days, are "guaranteed" to be read by SAB members.

This appallingly short comment period violates the EPA's own Public Involvement Policy and betrays Administrator Jackson's repeated commitment to transparency and scientific integrity. In this instance, the process the EPA provided to review complex science is so blunted there can be no transparency or scientific integrity. Moreover, the process has hijacked the science, exposed the folly of the Administration's commitment to scientific integrity, and perverted the SAB process.

The author is Managing Director of the Washington, D.C. law firm of Bergeson & Campbell, P.C., and President of The Acta Group, L.L.C. and The Acta Group EU, Ltd, in Washington, D.C. and Manchester, UK. Bergeson & Campbell is counsel of record for a stakeholder in the IRIS proceeding on inorganic arsenic. She can be reached at lbergeson@lawbc.com.

BY THE WAY...

Manufacturers worldwide cannot afford the losses in market share that would result should they fail to comply with REACH.

Source: Wilson, M. and M. Schwarzman. 2009. Environ. Health Perspect. August. 117(8): 1202-1209.

In the next issue:

Current Controversies in Non-Cancer Dose-Response: The End of Thresholds?

Data Mining: Potential and Pitfalls

Weigh the Evidence! But How Much Does Evidence Weigh?

Guest Editorial: Tailoring Risk Assessment to End Use

Look for *Trends* on the Web at: www.gradientcorp.com

Copyright © Gradient 2010

Photocopying for personal use is permitted.



Produced by: Gradient

20 University Road

Cambridge, Massachusetts 02138

Phone: (617) 395-5000 Fax: (617) 395-5001

Internet: trends@gradientcorp.com

Printed on recycled paper with soy inks

