

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

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February 20, 2013

The Honorable Bob Perciasepe
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dr. Ken Olden
Director, EPA National Center for Environmental Assessment
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Acting Administrator Perciasepe and Dr. Olden:

Since the National Academy of Sciences (NAS) issued its final report on EPA's IRIS assessment for formaldehyde in April 2011, we have been closely monitoring the Agency's ongoing efforts to implement meaningful reforms to its IRIS process. The NAS report went beyond simply discussing issues with the Agency's formaldehyde assessment¹ – it addressed the systemic and continuing deficiencies with EPA's IRIS development process while issuing broad recommendations for improvements. The report contains a strong call for fundamental reform:

The committee is concerned about the persistence of problems encountered with IRIS assessments over the years, especially given the multiple groups that have highlighted them, and encourages EPA to address the problems with development of the draft [recommendations] that have been identified.²

Following these recommendations, Congress directed EPA to have NAS conduct a more comprehensive review of the IRIS program. This NAS review will provide EPA with more

¹ National Research Council, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde, Apr. 2011, p163: ("The committee offers a roadmap for changes in the development process if EPA concludes that such changes are needed. The term *roadmap* is used because the topics that need to be addressed are set out, but detailed guidance is not provided because that is seen as beyond the committee's charge.")

² National Research Council, Review of Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde, Apr. 2011, p13.

detailed recommended improvements which – if implemented properly – should ensure future assessments are based upon the best available science and methodologies for reviewing scientific information.

The Agency has publicly stated their intention to improve the IRIS process to include more transparency and public participation, and increase the timeliness of high quality assessments. These are important and encouraging pledges. However, as EPA crafts reforms to the IRIS assessment process, the Agency must remain mindful that the NAS IRIS panel is simultaneously conducting its comprehensive review and will issue further recommendations.

Many crucial aspects of EPA's announcements remain unclear, and we are concerned that without proper communication from EPA, the NAS is reviewing a moving target. For example, as of February 5, 2013, EPA's IRIS TRACK website lists 57 substances, all at various stages in the IRIS development process. While EPA has included updated schedules for 14 substances, the timeframe for completion of the remaining 43 assessments is currently listed as TBD (to be determined). It also appears that EPA has introduced additional language in describing the steps in its IRIS process. Currently, several substances are listed in the "Draft Development (hazard identification)" step; however, the current IRIS process does not provide sufficient information on what is entailed in the hazard identification step or if there are additional sub-steps in the "Draft Development" stage.

EPA has also stated that they will not delay assessments already in progress and that they will continue with the IRIS development process for chemicals. Despite this pledge, the Agency recently re-evaluated the draft inorganic arsenic assessment and initiated plans to restart the development process from the problem formulation, planning and scoping stage, essentially starting the assessment over from scratch. While we agree that the 2009 draft inorganic arsenic assessment would benefit from the announced reforms, we are discouraged the Agency is moving forward with other assessments without communicating to stakeholders what specific improvements the Agency will take to ensure these assessments are also scientifically sound and credible.

EPA's expressed commitment to improving the IRIS process is encouraging; yet we remain concerned by the Agency's questionable level of transparency regarding what and how these changes will improve the assessments of substances currently in development and the timelines associated with completing these assessments. While EPA recently submitted materials to the NAS, including descriptions of some chemical specific examples, the Agency is silent on any opportunities for the public to engage and comment on these materials. Additionally, we remain concerned that many draft assessments are likely to have analytic biases, omitted data, and insufficiently independent and comprehensive peer review. At a minimum, they certainly have not had the benefit of the public engagement opportunities and transparent decision making EPA has now pledged for future assessments.

Furthermore, we are concerned by recent reports which could be signaling a significant setback in the credibility of EPA's peer review process. As you know, we consider peer review to be a critical step to ensure the integrity of EPA's work. Unfortunately, a newly leaked copy of the Agency's guidance entitled "Conflicts of Interest Review Process for Peer Reviews of IRIS Assessments and Other EPA Documents" seems to suggest that EPA could be considering capitulating to requests by environmental groups in barring qualified experts from peer review

panels. To be clear, tenuous ties to the regulated community signal no more of a conflict of interest than having similar connections to environmental advocacy groups who often raise money by attacking American industry and frequently receive grants from the very agencies whose work they review.

EPA policies on peer review panels should clearly address both conflict of interest and bias, recognizing that these are separate matters and are to be dealt with differently. Under U.S. law, affiliation alone is not a conflict of interest (*see* 18 U.S.C. § 208). In selecting candidates, the EPA policy must ensure fair representation on the peer review panel and a diversity of scientific perspectives relevant to the subject. Questions as to financial arrangements, sources of contracts and grants, honoraria, and expert witness work (for plaintiff or defendant) are equally applicable to individuals affiliated with academic institutions, research organizations, governmental organizations, and non-governmental organizations. We are further disappointed that although this draft guidance has been shared with the media and commented on by “Agency sources,” EPA has denied Congressional requests to review the document.

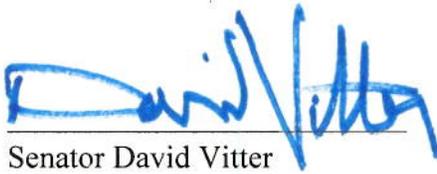
It is critical that EPA apply IRIS reforms to all draft assessments. Those assessments which have had significant revisions based on previous public comments and peer review recommendations should be released as revised draft assessments to the public and for peer review. In this manner, EPA’s actions to address the significant shortcomings in earlier drafts will be transparent to stakeholders and can be verified by independent experts. We are interested in receiving detailed information on how EPA will ensure that current draft assessments under development will benefit from proposed reforms. Please answer the following questions:

1. How many chemicals and substances were under development in IRIS on the date the NAS issued its review of the draft formaldehyde assessment? Please list the names and CAS numbers of these chemicals and substances.
2. Although IRIS TRACK was partially updated in February 2013, for a number of substances, the details remain unclear. For each listed chemical and substance, please list the specific steps EPA plans to conduct to complete each assessment and the timeframe expected for completion. Please note each opportunity for public comment, public engagement, release of a draft assessment, revised assessment or intermediate work product for public comment and review, independent peer reviews, and EPA’s responses to public and peer review comments.
3. For each chemical and substance, please describe why the proposed steps will be adequate to address the NAS reform recommendations in the formaldehyde report and any specific procedural and analytic flaws in the current state of the assessment.
4. What are EPA’s plans for public review of the Agency’s newly developing policy entitled “Conflicts of Interest Review Process for Peer Reviews of IRIS Assessments and Other EPA Documents?” Please include a copy of this document, even if it is in draft form, in your reply.

5. Please describe the steps EPA will take to engage the public and also obtain stakeholder comment on the materials submitted to the NAS in January 2013 regarding EPA's progress, plans, and chemical specific examples for IRIS implementation. Please also describe any specific steps EPA is taking to ensure that any public comments received will also be considered by the NAS committee.

Thank you for your consideration. Due to the ongoing importance of this issue, we respectfully request a thorough response by March, 8, 2013.

Sincerely,



Senator David Vitter
Ranking Member
Senate Committee on Environment
and Public Works



Senator Mike Crapo
Ranking Member
Subcommittee on Superfund
Toxics and Environmental Health



Senator James M. Inhofe
Ranking Member
Subcommittee on Oversight