

Comments Submitted by Todd Abel on behalf of the Chlorine Chemistry Division of the American Chemistry Council to the SAB Dioxin Review Panel

on

EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments

June 24, 2010

Introduction

Thank you for providing this opportunity to address the Panel. I'd like to talk briefly about the Agency's Reanalysis as it relates to the NAS recommendations, and to suggest some additional charge questions for the Panel's consideration.

Comments Related to Recommendations from the National Academy of Sciences

First, EPA's Reanalysis addresses a number of recommendations put forth by the NAS but fails to adequately consider other important recommendations. Moreover, EPA provides no basis for its decision to respond to some recommendations but not others.

1. With regard to exposure, the NAS suggested that to assess the total magnitude of emissions of dioxin-like compounds, the EPA should utilize a top-down approach to account for observed levels. EPA, however, has not addressed this recommendation. Likewise, the NAS recommended that EPA evaluate the impact of early emission inventory estimates of sources added in more recent assessments so that the overall percentage declines in environmental levels reflect all sources. Such an evaluation would help to confirm the dramatic decreases in TEQs that have occurred over time. In other words, accurate exposure information needs to be generated and incorporated to determine the relevant human exposures at human equivalent intakes. This recommendation has also been overlooked by the Agency.
2. Additionally, the NAS report also made several recommendations regarding the use and application of toxic equivalency factors, or TEFs. Specifically, NAS recommended that EPA adequately address the uncertainties and limitations inherent with the current TEF methodology. It is not clear why the Agency did not address these issues in its response to the NAS. Additionally, it is unclear how a separate ongoing evaluation of TEFs might impact the Dioxin Reassessment.
3. These recommendations, along with others, reflect the time, effort, commitment, and expertise of the NAS Panel. Their end product was a significant document intended to task EPA with accurately characterizing the health effects due to dioxin exposure. Key to the deliberation of EPA's Reanalysis, then, is the NAS evaluation of the Reassessment. With this in mind, to facilitate the Panel's understanding of the NAS recommendations, I would request that the 2006 NAS report entitled *Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment* be included among the review documents accessible to the Panel.

Suggested Charge Questions to the SAB Dioxin Review Panel

In addition to drawing attention to some of the NAS recommendations not considered by the Agency in the Reanalysis, I'd also like to suggest some charge questions that may play a crucial role in ensuring a thorough examination of EPA's Reanalysis:

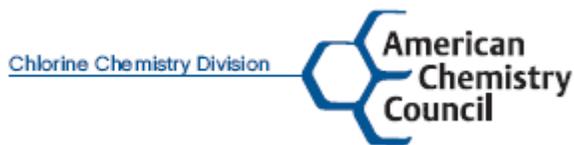
1. With regard to EPA's reference dose (RfD), the Panel should be asked specifically to comment on the key limitations of the epidemiologic studies and any implications they may have for the utility of the RfD EPA has derived using these studies.
2. Further, the Panel should be asked to offer recommendations on other potential studies that may be more appropriate for an RfD determination.
3. The Panel should be asked to comment on the implications of current low exposures regarding the development of a point of departure for an RfD.
4. The Panel should be asked to comment on the use of peak blood concentration and EPA's approach of averaging TCDD blood concentrations over the entire dosing period.
5. The Panel should be asked to comment on the appropriateness of EPA's modification of the Emond *et al.* model and whether such a modification should be peer reviewed prior to its application.

Listening Session

I would also encourage the EPA and the SAB Staff Office to urge each of the SAB Dioxin Review Panel members to join the Listening Session scheduled for July 9th at 9:00 am ET. This Listening Session is part of the IRIS risk assessment process put forth by EPA, and allows stakeholders and interested parties the opportunity to provide insight to the issues under consideration by the SAB Dioxin Review Panel. I would further request that EPA ensure that a transcript and all materials presented during the Listening Session be made accessible to the Panel.

Panel Member

Finally, I would appeal to the SAB Staff Office that they ensure that each member of the SAB Dioxin Review Panel evaluates the Reanalysis with complete and total impartiality. To that end, I am attaching a previously submitted correspondence to the SAB Staff Office requesting the exclusion of a Panel member whose work includes a co-critical study used by EPA to establish a reference dose for TCDD. I implore the SAB Staff Office to re-consider this individual's participation in this Panel, and that this individual be replaced with someone of comparable expertise.



June 11, 2010

VIA E-MAIL AND U.S. MAIL

Anthony F. Maciorowski
Deputy Director
EPA Science Advisory Board Staff Office
US Environmental Protection Agency
(Mailcode 1400F)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Mr. Maciorowski:

On behalf of the American Chemistry Council (ACC), I am writing to bring to your attention an urgent matter regarding the current Science Advisory Board Dioxin Review Panel (SAB Dioxin Review Panel) recently constituted to peer review EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS (Draft Report). In particular, ACC believes that Dr. Paolo Mocarelli's participation on the Panel raises, at a minimum, an appearance of a lack of impartiality. We, therefore, respectfully request that Dr. Mocarelli be excused from the Panel. In his place, we nominate the following scientists with the requisite expertise from which the SAB Staff Office could select a suitable replacement for Dr. Mocarelli:

- Dr. Michael Dourson, Toxicology Excellence for Risk Assessment (TERA)
- Dr. Thomas Gasiewicz, University of Rochester
- Dr. Norbert Kaminski, Michigan State University
- Dr. Michael DeVito, National Institute of Environmental Health Sciences
- Dr. Randall Manning, Georgia Department of Natural Resources

Drs. Dourson, Gasiewicz, and Kaminski were included on EPA's "Short List" for the SAB Dioxin Review Panel so their qualifications have already been vetted by the SAB Staff Office and the public. Drs. DeVito and Manning are well acquainted with the subject matter, having already established themselves as experts in the field of dioxin toxicology.

In its Draft Report, which is the subject of the upcoming SAB Dioxin Review Panel's peer review, EPA relies on Dr. Mocarelli's epidemiology study¹ on the dioxin-exposed Seveso population to establish a reference dose for the non-cancer health effects of dioxin. The reference dose (RfD) represents a significant science policy decision with potentially far-reaching implications. The SAB Panel's deliberations on the basis for the RfD, therefore, demand an impartial panel. As a member of the SAB Dioxin Review Panel, however, Dr. Mocarelli will be reviewing and commenting on his own work that serves as the basis for the proposed RfD. As such, Dr. Mocarelli's presence on the Panel runs headlong into SAB's own panel formation process, as well as EPA's NCEA Policy and Procedures for Conducting IRIS Peer Reviews, and OMB's Final Information Quality Bulletin for Peer Review.

Importantly, ACC did not previously contest Dr. Mocarelli's selection on the SAB Dioxin Review Panel because the Draft Report was only recently issued to the public, long after the SAB Staff Office began its deliberative process of screening candidates.² Thus, neither ACC nor the SAB Staff Office could have fully anticipated the appropriateness of Dr. Mocarelli's appointment to the SAB Dioxin Review Panel.

As explicitly stated in the Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board, "If a conflict exists between a panel candidate's private financial interests and activities and public responsibilities as a panel member, **or even if there is the appearance of partiality**, as defined by federal ethics regulations, the SAB Staff will, as a rule, seek to obtain the needed expertise from another individual."³ There is little doubt that "the appearance of partiality" exists here. Moreover, pursuant to the EPA's Peer Review Handbook (3rd Edition), "each advisory committee member or peer reviewer should be

¹ Mocarelli P; Gerthoux PM; Patterson DG; Milani S; Limonata G; Bertona M; Signorini S; Tramacere P; Colombo L; Crespi C; Brambilla P; Sarto C; Carreri V; Sampson EJ; Turner WE; Needham LL. (2008). Dioxin exposure, from infancy through puberty, produces endocrine disruption and affects human semen quality. *Environ Health Perspect.* 116:70-77. This study is identified as a co-critical study used to develop the reference dose at page 4-27 of EPA's Draft Report.

² 72 Fed. Reg. 61114 (15 October 2008).

³ EPA. 2002. Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board. Office of the Administrator, Washington D.C. EPA-SAB-EC-02-010, page 9. (emphasis added).

evaluated to ensure that an appearance of lack of impartiality does not preclude their participation.”⁴

The Draft Report also “is now considered to be under EPA’s Integrated Risk Information System (IRIS) program.”⁵ Consequently, the peer review of the Draft Report is subject to EPA’s NCEA Policy and Procedures for Conducting IRIS Peer Reviews.⁶ Under these procedures, a re-certification of a peer-review panelist may be requested to determine if there were any changes to the information they previously disclosed that could create either an actual conflict of interest or an appearance of bias or lack of impartiality during the period of performance. As in the case here, “EPA may be informed about a potential emerging conflict of interest situation, including an appearance of bias or lack of impartiality, by a person or organization external to both EPA and the contractor.⁷ ... Resolution may include, but not be limited to, elimination of a particular reviewer from the Panel....⁸

Similarly, the Office of Management and Budget (OMB) Final Information Quality Bulletin for Peer Review states that “... agencies shall adopt or adapt the NAS policy for committee selection with respect to evaluating conflicts of interest” concerning non-federal employees. The National Academy of Sciences (NAS) Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports, states that “... an individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work, or that of his or her immediate employer, is the central purpose of the activity, because that would constitute a conflict of interest, although such an individual may provide relevant information to the program activity.”⁹

⁴ EPA. 2009. U.S. Environmental Protection Agency Peer Review Handbook (3rd Edition). Science Policy Council, Washington, D.C. EPA/100/B-06/002, p. 67. The Handbook suggests the following question to assess a candidate’s suitability to serve on a peer-review panel: Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the Panel or any reason that your impartiality in the matter might be questioned? *Id.*

⁵ 75 Federal Register 28610 (21 May 2010).

⁶ EPA. 2009. NCEA Policy and Procedures for Conducting IRIS Peer Reviews. Office of Research and Development, Washington, D.C.

⁷ *Id.* at 11.

⁸ *Id.* at 12.

⁹ Office of Management and Budget. 2004. Final Information Quality Bulletin for Peer Review. Executive Office of the President, Washington, D.C.

In sum, ACC respectfully requests that the SAB Staff Office replace Dr. Mocarrelli with another expert, such as one of the aforementioned scientists. In light of the fast approaching June 24 public teleconference of the SAB Dioxin Review Panel, we ask that you act promptly upon this request. Thank you for your consideration of this important matter. Please do not hesitate to contact me directly at 703-741-5856 or todd.abel@americanchemistry.com should you have any questions.

Sincerely,

Todd Abel
Manager

cc: Dr. Thomas Armitage, DFO