



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.

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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 Review, 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.

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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



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 24, 2010

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Mr. Todd Abel
Chlorine Chemistry Division
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209

Dear Mr. Abel:

This letter is in response to your letter sent to me by e-mail on June 11, 2010 on behalf of the American Chemistry Council concerning the Science Advisory Board (SAB) Dioxin Review Panel. You specifically requested replacing Dr. Paolo Mocarelli with one of five other scientists included on the EPA "Short List" of candidates. Your request is based on your view that Dr. Mocarrelli is not an impartial reviewer, because his dioxin epidemiology research study was used to establish a reference dose for the non-cancer health effects of dioxin in EPA's draft document.

As you know, the SAB Staff Office considered 63 experts for potential service on the Dioxin Review Panel, and solicited public comments on these candidates. The SAB Staff Office Director, Dr. Vanessa Vu, made her decisions for service based on all relevant information, including ethics information. The final Dioxin Review Panel membership was announced on November 5, 2009.

Thank you for your interest in the work of the SAB.

Sincerely, 

Anthony F. Maciorowski, Ph.D.
Deputy Director
Science Advisory Board Staff Office