



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

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OFFICE OF CONGRESSIONAL
AND INTERGOVERNMENTAL RELATIONS

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman

I am responding to your March 13, 2008, letter to U.S. Environmental Protection Agency (EPA or Agency) Administrator Stephen L. Johnson requesting information generally about EPA's process for conducting independent external peer reviews of its draft science reports. Your inquiry focuses particularly on the February 2007 peer review of the four draft human health assessments for the polybrominated diphenyl ethers (PBDEs), as well as several other external peer reviews that were conducted either by EPA's Science Advisory Board (SAB) or by an independent external contract mechanism. To provide context for this response, the following background on the procedure for conducting independent peer reviews for Integrated Risk Information System (IRIS) human health assessments, particularly the PBDE assessment, and the role of EPA's SAB and its process to assure independent external peer review may be useful.

Introduction

EPA takes very seriously its responsibility to have its scientific documents externally peer reviewed by an independent panel of experts to ensure that the Agency's scientific reports are held to the highest possible standards. The Agency makes every effort to assure that the scientists serving on these independent peer review panels are fully vetted for any actual or potential conflicts of interest. This rigorous process is designed to assure that the Agency's peer reviews are independent, open, transparent, and of the highest scientific quality.

The Polybrominated Diphenyl Ethers Peer Review for the EPA's Integrated Risk Information System (IRIS) Program

Your letter requests information specifically about the peer review for the polybrominated diphenyl ethers (PBDE) draft assessments. This independent external peer review was conducted for EPA by the Department of Energy's Oak Ridge Institute for Science and Education (ORISE) under an interagency agreement. ORISE selected a pool of potential reviewers who were experts in science areas identified by EPA. All

potential reviewers were expected to have broad expertise in toxicology, including human health assessment, an understanding of EPA guidance, and familiarity with the IRIS database. Curriculum vitae for each of the proposed panel members were provided to EPA for review to assure that the proposed panelists had the necessary scientific expertise.

Before assembling the final peer review panel, ORISE performed an evaluation to determine the existence of actual or potential conflicts of interest, including the appearance of a lack of impartiality for each proposed panel member, and resolved issues of actual or potential conflicts of interest or an appearance of a lack of impartiality. Standard practice in most, if not all, independent peer review processes involves the vetting of potential peer reviewers for financial conflicts of interest. EPA, however, is also concerned about whether or not potential reviewers could begin their tenure as peer reviewers with a lack of impartiality. This is because, in the case of a draft IRIS human health assessment, EPA wants reviewers to base their technical review of the draft IRIS assessment on the merits of the document before them and not on any previously publicly expressed opinions on the toxicity of the chemical under review.

ORISE required each prospective panel member to fill out a form disclosing any potential conflicts of interest and lack of impartiality and sign the form certifying that full disclosure was made. ORISE then provided a signed certification to EPA concluding that there were no unresolved actual or potential issues among the panel members. Additionally, the ORISE contractor then selected and secured contractual arrangements with a subset of the proposed pool. The panelists were provided with draft IRIS documents, a charge that identified the scientific issues and questions pertinent to the review, and a Web link to the e-docket system that allowed the panelists to review written comments submitted by the public. Prior to the face-to-face peer review meeting, the contractor requested re-certification from the panelists on whether there were any changes to the information previously disclosed that could create either an actual or potential conflict of interest or an appearance of a lack of impartiality during the period of performance. One of the questions on the ORISE conflict of interest form is, "Have you made any public statements or taken positions on or closely related to the subject chemical or topic under review?"

On February 16, 2007, the ORISE manager asked Dr. Deborah Rice, the Chair of the PBDE peer review panel, whether anything on her conflict of interest form had changed. Dr. Rice affirmed that there was no change and she did not disclose a potential conflict of interest or potential for lack of impartiality. Dr. Rice had testified on February 15, 2007 before the Maine Legislature in her capacity as a State of Maine employee, in support of a State ban of decabromodiphenyl ether, a PBDE. At the time of the peer review meeting neither EPA nor the ORISE manager was aware of her testimony. After the final peer review report was delivered to EPA, this testimony was brought to the attention of the Agency. EPA considered the aforementioned testimony, including statements attributed to the Chair, and determined that a potential appearance or actual lack of impartiality existed. While Dr. Rice was not officially dismissed from the panel, the Agency decided to remove her comments from the final peer review report as a result

of the determination. Dr. Rice, however, was fully engaged in the scientific discussions at the peer review meeting itself. At this time the final PBDE assessments are undergoing final interagency review prior to posting on the IRIS database.

As to Dr. Rice, EPA has a high esteem for this respected scientist. The circumstances regarding her tenure as Chair of the PBDE peer review panel were unfortunate and could have been avoided. If EPA had known in advance that Dr. Rice had made statements to the Maine legislature about one of the PBDEs, which EPA determined presented an appearance of a lack of impartiality, she would not have been asked to serve on this panel. EPA, however, would not in any way limit Dr. Rice's involvement in future EPA peer review activities if her scientific credentials were appropriate for review of a specific environmental contaminant. In fact, since the PBDE peer review, Dr. Rice has served as a peer reviewer on a different IRIS draft chemical assessment.

SAB Peer Review Process

The SAB provides the EPA Administrator with outside, independent advice on scientific, engineering, economics, and social sciences that impact the technical basis for EPA policy positions or environmental decision making. The SAB operates as an EPA Staff Office reporting directly to the Administrator and manages EPA requests for advice and peer review, and provides technical assistance to the SAB. As required under the Federal Advisory Committee Act (FACA), the SAB Staff Office is responsible for ensuring that the membership of SAB committees and panels is balanced in the points of view represented for the function of the committee.

The SAB panel formation process involves: (a) public nomination of experts; (b) publication of names and short biographies of nominated experts for public comments; (c) SAB staff review of public comments and ethics information submitted by prospective panelists, and relevant information gathered by staff; and (d) publication of the SAB Staff Office Director's decision regarding the membership of the panel. Prospective panel members are required to submit a Confidential Financial Disclosure Report and responses to supplemental questions related to any appearance of a lack of impartiality. The selection criteria for panel membership include: balance and breadth of relevant scientific and technical expertise, knowledge, and experience needed to address the charge; absence of financial conflict of interest; and absence of an appearance of a lack of impartiality. Panel members are also required to complete ethics training before participation in an advisory activity.

Prior to panel establishment, the SAB Staff Office determines whether a candidate may have a financial conflict of interest or an appearance of a lack of impartiality. The SAB Ethics and FACA Policy Officer and the SAB Deputy Ethics Official (who is the SAB Staff Office Director) carefully review the Confidential Financial Disclosure Reports and the responses to supplemental questions related to an appearance of a lack of impartiality as submitted by the candidates as well as public comments and information independently gathered by staff. The SAB Staff Office applies all applicable ethics

definitions (e.g., 5 C.F.R. 2635 – Standards of Ethical Conduct for Employees of the Executive Branch) when reviewing the ethics information.

Your letter also questions whether EPA had altered any submissions to the SAB from experts or consultants due to conflict of interest concerns. Preparation of an SAB draft report is a collaborative process involving all panel members under the direction of the panel chair with the assistance of the SAB Designated Federal Officer. Comments from individual members may also be included in an appendix for the Agency's consideration. Individual comments, however, do not represent the consensus view of the panel, and they are not subject to change by the Designated Federal Officer. At every major stage of report development, a public draft copy of the SAB report is made available on the SAB Web site. The chartered SAB (the parent committee) reviews and approves reports prepared by its panels (or subcommittees) in a public forum. Public comments are welcome at all stages during the preparation and approval of a given SAB report. The SAB Staff Office has no records of any instances in which the Designated Federal Officer unilaterally altered the substance of a panel member's submissions for any reason, including conflict of interest, lack of impartiality, or appearance of lack of impartiality.

Other Conflict of Interests Concerns

Your letter questions whether the participation of nine other individuals on various peer review panels raised conflict of interest concerns. The SAB Staff Office had determined that six of the aforementioned individuals did not present a financial conflict of interest or an appearance of a lack of impartiality prior to panel establishment. These individuals have extensive knowledge and experience in conducting research of chemical-induced toxicities including those associated with ethylene oxide or acrylamide. In general, they received research funding from many different organizations. The other three peer reviewers mentioned in your letter served on a panel convened by ORISE. These three reviewers were chosen based on their scientific expertise and history of publications and presentations in the field required for this review. No reasons to dismiss them from consideration for membership on a peer review panel were noted.

Request for Documents

Finally, your request seeks eight categories of documents. EPA respects your very strong interest in this issue and is committed to providing the Committee information to the extent possible and consistent with our Constitutional and statutory obligations. Please find enclosed copies of documents responsive to your request. EPA has identified important confidentiality interests in a number of these documents because they contain non-public information about EPA's deliberations or the personal privacy of individuals, including information that may be protected from public disclosure under the Privacy Act. EPA has identified these documents by copying them on paper with a legend that reads: "Internal, deliberative document of the U.S. Environmental Protection Agency; disclosure authorized only to Congress for oversight purposes." Through this accommodation, EPA does not waive any confidentiality interests in these documents or

similar documents in other circumstances. EPA respectfully requests that the Committee protect the documents and the information contained in them from further dissemination. Specifically, should the Committee determine its legislative mandate requires further distribution of this confidential information outside the Committee, we request that such need first be discussed with the Agency to help ensure the Executive Branch's confidentiality interests are protected to the fullest extent possible.

In addition to the aforementioned concerns, EPA has identified heightened privacy interests in the confidential financial disclosure forms for panel members. The privacy concerns are heightened for these documents because, as you know, appointees to the panel are required to disclose all their personal financial information on conflict of interest forms. Broadly disseminating this non-public information could jeopardize an individual's personal finances and could lead to a chilling effect on future panel candidates' willingness to serve, thereby making it more difficult for EPA to seat the most qualified reviewers. In an effort to accommodate the Committee's interest in this issue, however, EPA is prepared to make these non-public documents available for review by Committee members or staff.

If you have any questions or wish to arrange inspection of the financial disclosure forms, please contact me, or your staff may contact Reynold Meni in my office at (202)-564-3669.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chris Bliley', with a long horizontal line extending from the end of the signature.

Christopher P. Bliley
Associate Administrator

Enclosures

cc: The Honorable Joe Barton, Ranking Member