



U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Office of Counsel Legal Review

No Violations Found Regarding Removal of Comments from an External Peer Review

Report No. 09-P-0084

January 16, 2009



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

OFFICE OF
INSPECTOR GENERAL

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MEMORANDUM

SUBJECT: Office of Counsel Legal Review:
No Violations Found Regarding Removal of Comments from an
External Peer Review
Report No. 09-P-0084

FROM: Mark Bialek 
Associate Deputy Inspector General and Counsel

TO: Marcus Peacock
Deputy Administrator

This is in response to your April 10, 2008, letter requesting that the Office of Inspector General (OIG) determine whether the removal of Dr. Deborah Rice's comments from an external peer review panel report regarding the chemical polybrominated diphenyl ethers (PBDE) was consistent with existing federal law, regulations, guidance, and other relevant requirements. The results of our review are discussed below.¹

I. Summary

After the completion of an external peer review of PBDE, EPA received allegations of a lack of impartiality and objectivity by the peer review panel chair, Dr. Rice. EPA examined the allegations, removed her comments from the PBDE peer review report, and published an explanatory message in the report and on the associated Website. We conclude that EPA did not violate existing federal law, regulations, guidance or other relevant requirements in its actions. We suggest that EPA consider establishing a process for reviewing allegations of conflict of interest or lack of impartiality raised after a peer review panel has convened. We also suggest that EPA consider documenting the basis for the decision when resolving allegations of conflict of interest or bias against a peer review panelist.

¹ The OIG is addressing the two other issues referenced in your letter in a related evaluation report, namely, whether (1) current laws, regulations, guidance, and other relevant requirements for EPA expert peer review panels are adequate to produce objective scientific reviews; and (2) the current system of populating and managing such expert panels could be improved.

II. Background

A. The PBDE Peer Review

In June 2008, EPA completed a series of Integrated Risk Information System (IRIS)² toxicological reviews of PBDEs. One external peer review was held as part of that process. The PBDE peer review was conducted for EPA by the Department of Energy's Oak Ridge Institute for Science and Education (ORISE) under an interagency agreement. [See 72 FR 72716 (December 21, 2007); ORISE IAG, No. DW89939822-01-0.] In February 2006, ORISE selected a pool of 10 potential reviewers. After EPA reviewed and approved nine candidates, ORISE selected five final panelists, including Dr. Rice, who was designated the panel chair.

ORISE required each prospective panel member to complete a form disclosing any potential conflicts of interest or lack of impartiality and certifying that full disclosure was made. Dr. Rice completed and signed the form on October 5, 2006. One question on the form asked: "Have you made any public statements or taken positions on or closely related to the subject chemical or topic under review?" Dr. Rice responded by checking "No." Dr. Rice indicated on the form that as a toxicologist for the Maine Center for Disease Control and Prevention, she had written a review of health effects of PBDEs for the Maine legislature during 2004 and 2005. [See U.S. EPA Conflict of Interest Disclosure Form, External Peer Review, Polybrominated Diphenyl Ethers, dated October 5, 2006.] The certification also required Dr. Rice to update the disclosure form "promptly . . . if relevant circumstances change." ORISE received Dr. Rice's form and certified to EPA that there "are no relevant facts or circumstances which could give rise to a conflict of interest" [See ORISE Certification (date illegible).]

In December 2006, EPA announced that the panel would convene on February 22, 2007. On February 16, 2007, ORISE contacted the panelists by e-mail to ". . . double check with each of you that there have been no changes, particularly financial changes, that would now constitute a conflict of interest with regard to the EPA PBDE review being held February 22, 2007." [See e-mail from ORISE Project Manager, to the five panel members, including Dr. Rice, subject: Reconfirming Conflict of Interest, dated February 16, 2007.] ORISE asked each reviewer to "confirm that there are no new changes in a reply to this e-mail." [Id.] Dr. Rice responded that day: "No Changes." [See e-mail from Dr. Rice to ORISE Project Manager, dated February 16, 2007.]

However, on the previous day (February 15, 2007), Dr. Rice had testified before the Maine legislature, in her capacity as an employee for the Maine Center for Disease Control and Prevention, in support of a State ban of decabromodiphenyl ether (deca-BDE), a PBDE. Her testimony was reported in the Bangor Daily News on February 16, 2007:

. . . Deborah Rice with the Maine CDC's Environmental and Occupational Health Program told lawmakers there is no question in her mind that deca should be eliminated because it is a persistent toxin that accumulates in the food chain. . .

² IRIS is a compilation of electronic reports on specific substances found in the environment and their potential to cause human health effects. (<http://cfpub.epa.gov/ncea/iris/index.cfm>)

Rice said scientists now understand that deca rapidly degrades into compounds known to be dangerous. While expressing concern about replacing deca with an equally toxic compound, Rice said that, if given the choice between a television containing deca and one used with an alternative flame retardant, she would choose the alternative. 'The reason we are in this bind is because the industry doesn't have to collect any data about the compounds they are putting into commerce,' Rice said. [See Kevin Miller, DEP Urges Legislative Ban on Fire Retardant, Bangor Daily News, February 16, 2007.]

At the time of the workshop and peer review report preparation, neither EPA nor ORISE was made aware that Dr. Rice had testified before the Maine legislature or of the news account of her testimony. The final comments of each panelist, including those of Dr. Rice, were posted in the external peer review report on EPA's Website in March 2007. [See External Peer Review: Toxicological Review for Polybrominated Diphenyl Ethers (PBDEs) Human Health Assessment, FINAL REPORT.]

B. National Center for Environmental Assessment's Review of Concerns Raised by the American Chemistry Council

In May 2007, the American Chemistry Council (ACC) raised concerns regarding Dr. Rice's participation on the panel in light of her testimony before the Maine legislature. In a letter to Dr. George Gray, Assistant Administrator for the EPA Office of Research and Development (ORD), ACC attached the Bangor Daily News article and raised concerns about Dr. Rice's participation on the panel given her reported statements, as well as her involvement in several other reports on PBDEs. ACC recommended that EPA should base its final assessment on "data, opinions, and conclusions other than (Dr. Rice's)," and requested a meeting with Dr. Gray. [See ACC letter to Dr. George Gray, Assistant Administrator, EPA ORD, re: IRIS Peer Review of Polybrominated Diphenyl Ethers (PBDEs), Docket ID No. EPA-HQ-ORD 2006-0838, dated May 3, 2007 (underline in original).]

Dr. Gray forwarded the letter from ACC to EPA's National Center for Environmental Assessment (NCEA), including specifically both Dr. Peter Preuss, the Director of NCEA, and the Director of the IRIS program.

On May 9, 2007, Dr. Gray notified NCEA that he was arranging a meeting with ACC in June and asked NCEA for a "concrete plan for dealing with the questions about the PBDE peer review," in advance of the meeting. [See e-mail from George Gray to Peter Preuss and NCEA staff, dated May 9, 2007, subj: ACC PBDE Letter.]

Within NCEA, Dr. Preuss; the NCEA Associate Director for Health; the Director of the IRIS program; the IRIS Deputy Director; and the PBDE review project manager, worked on NCEA's review of the ACC allegations and developed an initial position. They considered the Bangor Daily News article and other attachments to ACC's letter, and ascertained with ORISE the facts related to its conflicts review of Dr. Rice. [See Letter from ORISE Peer Review

Manager, to NCEA Project Officer, dated June 1, 2007.³] They did not obtain Dr. Rice's actual testimony before the Maine legislature. However, Dr. Preuss recalled that, in a phone conversation with Dr. Rice during this time period, Dr. Rice confirmed that the substance of the newspaper article was true.

Over the course of a number of meetings and informal discussions, the NCEA staff reached a consensus that Dr. Rice's statements did constitute a problem. A few staff members recalled that the issue was that Dr. Rice's statements created a perception of bias. To others, the problem was not her statement per se, but that she had not disclosed it to EPA or ORISE.

Ultimately, NCEA staff agreed that Dr. Rice's comments should be removed from the peer review report. It appears that the NCEA team considered two options for its final action: taking no action or removing Dr. Rice's comments from the peer review report. The NCEA team consulted EPA's Peer Review Handbook, but it did not provide explicit guidance. [See U.S. Environmental Protection Agency, Peer Review Handbook, 3rd Edition (the "Handbook").]

In support of its recommendation, NCEA also examined whether there was evidence that Dr. Rice had influenced the other panel members. After reviewing comments submitted before and after the workshop by the panelists, NCEA concluded that there was no evidence that Dr. Rice had influenced the other panelists. NCEA also noted that Dr. Rice's comments did not change the substantive conclusions of the report, in part, because her comments were echoed by the other panelists.

The NCEA team briefed Dr. Gray on the matter in early June 2007. This briefing took place prior to June 15, 2007, when Dr. Gray held a meeting with ACC, following up on ACC's letter.

C. EPA's Decision Regarding Dr. Rice's Participation in the Peer Review Panel

Subsequent to the meeting with ACC, Dr. Preuss and Dr. Gray both agreed that Dr. Rice's comments should be removed from the peer review report so as to address the nondisclosure of public statements, as required by the conflict of interest form. The decision making followed no formal process and was not formally documented. Dr. Preuss recalled that he discussed the matter with Dr. Gray and they both agreed that removing Dr. Rice's comments was appropriate. Dr. Gray's recollection was slightly different; he recalled that Dr. Preuss informed him of the decision.

On August 14, 2007, NCEA removed Dr. Rice's comments from the report and issued a revised report. The IRIS Deputy Director notified Dr. Rice by phone about the decision on August 15, 2007.⁴ Initially, NCEA simply removed Dr. Rice's comments from the peer review

³ ORISE was unaware of Dr. Rice's legislative testimony. According to this e-mail from ORISE, "[i]f Dr. Rice had replied that she had taken a position on whether deca should be eliminated, ORISE would have contacted EPA immediately."

⁴ NCEA attempted to contact Dr. Rice by phone the week of August 6 as well as on August 9 and 13.

report without explanation. [See External Peer Review, Toxicological Review for Polybrominated Diphenyl Ethers (PBDEs) Human Health Assessment FINAL REPORT [second version].] However, in response to a September 21, 2007, letter from ACC, NCEA in November 2007 added explanatory language to the report and Website that “[o]ne reviewer’s comments were excluded from the report and were not considered by EPA due to the perception of a potential conflict of interest.” [See ACC letter to Dr. Gray, September 21, 2007; External Peer Review, Toxicological Review for Polybrominated Diphenyl Ethers (PBDEs) Human Health Assessment FINAL REPORT [final].]

In a letter to ACC dated January 8, 2008, Dr. Gray summarized the actions that EPA took in removing Dr. Rice’s comments. [See Letter from Dr. Gray to Nancy Sandrof, ACC, dated January 8, 2007.⁵] Dr. Preuss followed up with a similar letter to ACC on January 11, 2008. [See Letter from Dr. Pruess to Nancy Sandrof, ACC, dated January 11, 2008.] Both letters cite the reason for EPA’s action in removing Dr. Rice’s comments as “the perception that one of the panel members had a potential conflict of interest.”

III. Discussion

Peer reviews are tools used to support Agency decision-making, and, except where provided otherwise by law, are not a formal part of, nor a substitute for, rule-making or adjudicatory procedures. [See Section 2.7 of the Handbook.] Unless carried out by formal and established (chartered) federal advisory committees, which was not the case here, the peer review process is not subject to specific statutory or regulatory requirements. [See Section 2.8 of the Handbook.]

In 2004, the Office of Management and Budget (OMB) issued government-wide guidance on peer reviews of government science documents, including the selection of peer reviewers. [See OMB Memorandum for Heads of Departments and Agencies, Issuance of OMB’s “Final Information Quality Bulletin for Peer Review,” dated December 16, 2004.] EPA’s Handbook sets forth specific Agency-level policy and guidance for the conduct of peer reviews, including ethical standards. [See Memorandum from Administrator Stephen L. Johnson, Peer Review Program, dated January 31, 2006.] A disclaimer in the Handbook notes that “[t]his Handbook is intended to improve the internal management of EPA by providing recommended procedures and approaches for EPA staff and managers. This Handbook is a guidance manual and not a rule or regulation.” [See Handbook, p. iii.]

While the Handbook generally addresses ethical standards and issues, particularly “conflict of interest” and “appearance of lack of impartiality,” the information only focuses on the panel member selection phase of the peer review process.⁶ The Handbook does not

⁵ The letter shows an incorrect date of January 8, 2007.

⁶ For example, with respect to potential bias concerns, the Handbook provides that “[a]s a general rule, experts who have made public pronouncements or have had a predominant influence on the position of a given organization on an issue, those who have clearly ‘taken sides,’ may have an appearance of a lack of impartiality (see Ethical standards below) and should be avoided.” [Handbook at 63.] However, an appearance of impartiality on the part of a potential panelist does not necessarily preclude their participation. Indeed, the Handbook notes that “[f]inding a totally independent peer reviewer is a difficult and daunting task.” [Id. at 68.] The Handbook provides that one way

specifically address the resolution of conflict of interest or bias allegations or issues that arise after a peer review panel has convened. Given the lack of direct guidance concerning the circumstances in this case, we conclude that EPA did not violate federal law, regulations, or guidance when it removed Dr. Rice's comments from the peer review report. However, as described in more detail in a forthcoming OIG report recommendation, we suggest that NCEA consider establishing a procedure by which allegations of conflict of interest or lack of impartiality, raised after peer review panel has convened, can be addressed. A procedure would provide guidance to Agency staff as well as help to reduce the possibility of any appearance of a lack of transparency by the Agency should a similar matter arise in the future.

Although nothing in the Handbook expressly required that EPA document its decision and rationale in this matter; the lack of such documentation may have contributed to inconsistency in EPA's explanations about the reasons for removing Dr. Rice's comments. Dr. Preuss and Dr. Gray explained to us that the action was taken to address the nondisclosure of Dr. Rice's statements before the Maine legislature. In contrast, the language added to the final peer review report, as well as ORD's subsequent correspondence with ACC, characterized the problem as a "potential conflict of interest." In another instance, EPA characterized the issue as "a potential appearance or actual lack of impartiality." [See Letter from Christopher Bliley, the Associate Administrator for the Office of Congressional and Intergovernmental Relations to Senator Dingell, dated June 13, 2008.] When resolving any future allegations of conflict of interest or bias against a peer review panelist, we suggest that NCEA consider including a memorandum that explains the decision in the peer review record.

IV. Conclusion

We conclude that EPA did not violate existing federal law, regulations, guidance or other relevant requirements when it removed Dr. Rice's comments from the PBDE peer review report and published an explanatory message in the report and on the associated Website. While we are not making formal recommendations, we believe that the suggestions noted above should be considered by NCEA for possible improvements to the peer review process.

The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time – is \$48,398.

If you should have any questions on this or any other matter, please contact me at (202) 566-0861.

to negate such an appearance of a lack of impartiality issue is to have the panelist "[d]isclos[e] publicly at the beginning of meetings any previous involvement with the issue." [Id. at 69.]

Appendix A

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