



MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

July 15, 2013

Ms. Wendy Cleland-Hamnett
Director Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
Ariel Rios Building
Mail Code: 7401M
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Cleland-Hamnett:

I am writing to express significant concerns with the Environmental Protection Agency's (EPA) apparent approach to the peer review process for the TSCA Work Plan Chemicals in the Existing Chemicals Program. In particular, EPA's approach suggests that despite EPA statements to the contrary, the Work Plan chemical assessments will in fact be used as the basis for regulation. I request that you take action to address these concerns and ensure that the peer review process is open, transparent, and responsive, in line with other peer review processes.

My concerns arise from the first public webinar meeting of the peer review panel convened on EPA's risk assessment of trichloroethylene (TCE, held on July 9, 2013. The panel was moderated by EPA's consultant, Scientific Consulting Group, Inc. (SCG), and was dedicated primarily to an overview of the assessment and reviewing the charge questions, with an opportunity for public comment for those who registered in advance to speak.

Representatives of the American Chemistry Council (ACC) participated in the meeting and provided oral comment on the charge questions consistent with our written comments on the charge questions submitted to the docket in March 2013. In the five minutes allotted, ACC responded to EPA's specific request and identified five key changes to the charge that would significantly enhance the technical and scientific quality of the peer review. Neither the meeting moderator nor the panel chair provided any opportunity for engagement between the public commenters and the panel members following the public comments. Indeed, there was no discussion by the panel whether the suggestions of the public should be considered, accepted, rejected, or whether any changes should be made to the peer review charge. It is unclear whether the panelists have any obligation to consider public input at all, and when and in what form the input will be considered.



The second public webinar meeting of the panel is scheduled for July 16, 2013. At that meeting, reviewers will discuss each panel member's draft written comments on the assessment. The meeting is open to the public, but the public will not have access to the peer reviewers' comments in advance of or during that meeting. It is not clear how the public will follow the reviewers' conversation without access to the peer review material. The peer review moderator stated on July 9 that the peer reviewers' comments on the assessment will not be made available to the public until they are finalized by each reviewer *after* the third peer review meeting at the end of the peer review process. This process is not transparent, and affords the public no real opportunity to provide input.

Statements made by Dr. Barone during the July 9, 2013, webinar implied that EPA is not treating the TCE assessment as a screening-level assessment. If this is the case, and as we noted in our September 27, 2012, letter to EPA, the Work Plan assessments should be treated as Highly Influential Scientific Assessments (HISAs) consistent with the 2004 OMB Information Quality Bulletin for Peer Review (OMB Bulletin). The OMB Bulletin mandates that federal Agencies improve the rigor of the peer review process. Consistent with the OMB Bulletin, peer review must be more rigorous than simple journal peer review. It is not clear to ACC that the peer reviewers are aware of their responsibility to review the document at this level, that they have been provided access to the underlying data and models as required by the OMB Bulletin, or even if they have been informed of the applicable access, objectivity, reproducibility and other quality standards under the federal information quality requirements.

ACC recognizes that the Work Plan peer review is not an EPA Science Advisory Board (SAB) review. Nevertheless, it would be very useful to have more consistent practices across the agency concerning scientific assessments. ACC has recommended that all the practices developed by the SAB Staff Office (2011) should be incorporated into OPPT's risk assessment peer review of TCE and all other Work Plan chemical risk assessments:

- ❖ *Federal Register* notices published by the Staff Office will clarify that public comments are welcome on all technical materials prepared for or by an advisory committee, including the charge to the committee.
- ❖ The Staff Office and advisory committees will not accept a charge from the agency that unduly narrows the scope of an advisory activity.
- ❖ Time will be reserved on meeting agendas for committee members to discuss the charge.
- ❖ Following public comments at advisory committee meetings, chairs will ask committee or panel members if they have clarifying or follow-up questions for public presenters.
- ❖ Chairs will offer a second brief opportunity for additional clarifying remarks from agency representatives or members of the public later in the meeting, as the committee or panel deliberates on responses to the charge questions.
- ❖ Advisory committee reports will acknowledge scientific information from the public that was helpful in forming the committee's conclusions and recommendations.
- ❖ Advisory committee reports will continue to focus on scientific and technical – rather than policy – issues, although reports may discuss the policy context and may note policy implications of technical findings.¹

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ACC has supported EPA's efforts to conduct targeted risk assessments of the Work Plan priority chemicals. Unfortunately, the lack of transparency and apparent disinterest in (if not indifference to) public input and engagement, threatens to undermine the integrity of EPA's efforts and the credibility of the peer review of the Agency's risk assessments under the program. ACC strongly encourages you to make a rapid course correction to the peer review process, which is essential in order for these "highly influential scientific assessments" to be credible and accorded scientific, stakeholder, and public confidence.

Sincerely,

A handwritten signature in black ink that reads "Michael P. Walls". The signature is written in a cursive style and is positioned above the typed name and title.

Michael P. Walls

Vice President

Regulatory & Technical Affairs

cc: Jim Jones
Glenn Paulson