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March 14, 2012

Cheryl Falvey, General Counsel  
US Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

RE: CHAP Report Peer Review; Request for Meeting

Dear Ms. Falvey:

We are submitting this letter on behalf of ExxonMobil Chemical Company to address concerns pertaining to peer review of the report of the Chronic Hazard Advisory Panel (CHAP) on phthalates and to request a meeting to discuss this subject. For reasons presented below, we believe a closed, supplemental review of the CHAP's *draft* report prior to submission to the CPSC would be contrary to Administration policy and CPSC regulations and is not required, but a peer review of the CHAP's *final* report is legally required and should be conducted with the full transparency and public participation as required by Office of Management and Budget (OMB) peer review guidelines.

### An External Review of the CHAP Draft Report Should Not Be Conducted

The CHAP has expressed interest in providing a copy of its draft report to an unspecified number of scientists for supplemental review. The scope of the supplemental review has not been explained in the public meetings. We understand that the supplemental review would be conducted in private, with no opportunity for submission of public comments, but later made a part of the administrative record. We think this supplemental review is inadvisable and unnecessary for several reasons.

CPSC regulations require that CPSC activities be conducted openly and involve the public to the fullest extent possible.<sup>1</sup> This requirement applies to the activities of the CHAP, as all CHAP communications go through the CPSC and the CHAP's deliberations are a part of the administrative record for any rulemaking based on the CHAP's findings.<sup>2</sup> Similarly, this

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<sup>1</sup> 16 C.F.R. §1011.1 (“(a) In order for the [CPSC] to properly carry out its mandate to protect the public from unreasonable risks of injury associated with consumer products, the Commission has determined that it must involve the public in its activities to the fullest possible extent. (b) To ensure public confidence in the integrity of Commission decisionmaking, the Agency, to the fullest possible extent, will conduct its business in an open manner free from any actual or apparent impropriety.”)

<sup>2</sup> 15 U.S.C. §2077(g) and §2080(b).

Administration has stressed the importance of transparency to ensure public trust and analytic rigor in agency activities and decision-making.<sup>3</sup> The CHAP has heard from numerous scientists during the course of its deliberation, always and appropriately in a public forum. By the same token, the CHAP should not conduct any expert consultation on its draft report behind closed doors, even if the outcome might be made publicly available at some later date. Rather, any external consultation should be considered an extension of the CHAP deliberations and should be conducted with the same openness and public involvement.

The closed process currently contemplated for conducting any supplemental review of the draft report would not constitute a proper peer review. First, the process being contemplated would shield the outside scientists from any contrary views and scientific data of interested parties. This would undermine the rigor and integrity of the consultation, rendering the external consultation of doubtful utility and validity. Further, the time currently allotted for the external consultation of the draft report—30 days—is not sufficient for a highly technical scientific document that will exceed well over 100 pages and has taken years to develop. The external reviewers could not conceivably consult original papers and all scientific analysis, and, because they will be shielded from the views of interested parties, they may not know where to direct their closest attention, and might overlook important issues.

Moreover, given the statutory deadline for action by the CPSC, we are concerned that there might not be sufficient time to conduct two proper peer reviews.<sup>4</sup> Unlike the contemplated supplemental review of the draft, a public peer review of the final report is legally *required*, as explained further below. Any review of the report should be conducted primarily for the benefit of the CPSC, not the CHAP, and thus the focus should be on conducting a proper, transparent peer review of the final CHAP report. Further still, it is important that the CPSC get a fast start on that peer review, so that the results are available to support the CPSC's evaluation of the CHAP report and consequent decision-making.

In short, the method and manner of conducting this proposed supplemental review of the draft report is contrary to the transparency demanded by CPSC regulations and Administration policy, and would defeat any useful purpose that it otherwise might serve. Because there is not time to conduct the review in a more rigorous and useful manner, and because a full and rigorous

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<sup>3</sup> E.g., B. Obama, Memorandum of January 21, 2009, Transparency and Open Government, 74 Fed. Reg. 4685 (Jan. 26, 2009) (“My Administration is committed to creating an unprecedented level of openness in Government. We will work together to ensure the public trust and establish a system of transparency, public participation, and collaboration. Openness will strengthen our democracy and promote efficiency and effectiveness in Government.”); C. Sunstein, Open Government is Analytic Government (and Vice-Versa), Remarks on the Occasion of the 30th Anniversary of the Regulatory Flexibility Act (Sept. 21, 2010). (“There is a close connection, even an inextricable relationship, between analytic government and open government.”).

<sup>4</sup> The CPSC is required by the Consumer Product Safety Improvement Act (CPSIA) to complete its assessment and promulgate any final rules necessary to safeguard public health within six months—a very compressed timeframe for regulatory action. CPSIA §108(b)(3).

public peer review is required for the final report, the CPSC should direct the CHAP to simply complete its own review process and report as soon as possible.<sup>5</sup>

### The CPSC Should Conduct a Proper Peer Review of the CHAP Final Report

The purpose of the CHAP report is to provide scientific support to the CPSC. The CPSC is required to determine, based on the findings and recommendations of the CHAP report, whether certain regulatory actions are necessary to protect the health of children.<sup>6</sup> Accordingly, before it may rely on the final CHAP report, the CPSC is legally required to conduct a peer review that meets OMB Guidelines for peer review of “highly influential scientific information.”<sup>7</sup>

A critical element of a proper peer review for “highly influential scientific information,” as reflected in the OMB Peer Review Bulletin, is making the document available for public comment and providing those public comments to the peer reviewers prior to their deliberations.<sup>8</sup> This step is essential to ensuring the rigor and objectivity of the peer review, and thus was followed, for example, in the CPSC’s Peer Review Plan for its scientific assessment of flame retardants.<sup>9</sup> This step also is mandated by the CPSC regulations, cited above, which require public involvement “to the fullest extent possible” to “ensure public confidence in the integrity of Commission decisionmaking.”

A proper peer review for a highly influential scientific assessment requires considerable time and effort. In addition to the solicitation of public comment on the CHAP report, it obviously is necessary to select the peer reviewers and develop a proper charge. These steps can take many weeks. The peer reviewers need adequate time to conduct their review, which should encompass not only the CHAP report but should evaluate the full weight of the evidence including all the data relied upon by the CHAP,<sup>10</sup> as well as all scientific data submitted by interested parties for the benefit of the CHAP. Importantly, the CPSC also must allow adequate time to consider the comments of the peer reviewers and incorporate those comments into its assessment of the need for any regulatory action. Given the tight time constraints set forth in the

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<sup>5</sup> If the CHAP nevertheless proceeds with a supplemental external review of any portion of its report, that review should not be considered or called a “peer review.” The term “peer-reviewed” report implies a process more rigorous and in-depth than that contemplated.

<sup>6</sup> CPSIA §108(b)(3).

<sup>7</sup> OMB Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2667 and 2675-2676 (Jan. 14, 2005).

<sup>8</sup> *Id.*

<sup>9</sup> Available at <http://www.cpsc.gov/library/peerufasses.pdf>.

<sup>10</sup> This data should include, for example, the Versar Report and exposure calculations and analyses performed by CPSC staff. Additionally, while we do not believe it is appropriate for the CHAP to consider scientific information or data that has not been made publicly available, where this has occurred, such as apparently is the case with certain Swan study exposure data, we believe it is imperative that such non-public information be provided to the peer reviewers.

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CPSIA for the Commission to make its determinations and promulgate any rules, the Commission should be preparing for the peer review of the final CHAP report now, with the intention of initiating the public peer review process as soon as the CHAP report is presented to the Commission.

For the reasons set forth in this letter, we respectfully urge the CPSC not to conduct a closed, supplemental review of the draft CHAP report, and instead initiate planning promptly for a proper, transparent, peer review of the final CHAP report that would meet the requirements of OMB Guidelines. We also request an opportunity to meet with you to discuss these issues.

Thank you for your consideration of these issues. Bill Rawson will call within the next few days to arrange a meeting. Because time is short, we request that the meeting occur as soon as reasonably possible.

Sincerely yours,



William K. Rawson  
Ann Claassen  
of LATHAM & WATKINS LLP

cc (email only):

Phillip Chao  
David DiMatteo  
Jay Howell  
DeWane Ray  
Mary Ann Danello  
Lori Saltzman  
Michael Babich

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