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December 2, 2011

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

Re: Chronic Hazard Advisory Panel (CHAP) for Phthalates

Dear Ms. Falvey:

We are writing on behalf of ExxonMobil Chemical Company (ExxonMobil) to express our appreciation for the opportunity to meet with you and Commission staff on Tuesday, November 29, 2011, to discuss issues pertaining to the ongoing deliberations of the Chronic Hazard Advisory Panel (CHAP) on Phthalates. This letter also summarizes key points that we made during the meeting.

As we stated Tuesday, we present our concerns respectfully, with full appreciation for the complexity of the task set before the CHAP, and full appreciation for the considerable efforts already taken by the Commission to support the CHAP deliberations.

For the reasons presented Tuesday and in this letter, we believe additional legal guidance will help the CHAP produce a report that meets the CHAP's legal duties, as set forth in the Consumer Product Safety Improvement Act (CPSIA). We also believe additional guidance will ensure that the final report contains the findings and recommendations that the Commission needs to fulfill its legal responsibilities under Section 108 of the CPSIA.

1. The CHAP Should Make the Recommendations Required by the CPSIA

The CPSIA requires the CHAP to make recommendations regarding any phthalates (or combinations of phthalates) or phthalate alternatives "that the panel determines should be declared banned hazardous substances."¹ This specific element of the CHAP's charge was not discussed during the recent CHAP deliberations. Nor was there any discussion of the legal definition of the term "banned hazardous substance," or of the essential components of the statutorily-mandated analysis.

¹ CPSIA § 108(b)(2)(C).

Instead, the CHAP deliberations focused on whether to recommend that the interim ban set forth in the CPSIA for three phthalates be made permanent, left as interim, or ended, and whether other phthalates should be subject to an interim or permanent ban or if no action should be taken. That is a different inquiry, and not the CHAP's responsibility under the terms of the statute.

The CPSIA expressly reserves *for the Commission* the responsibility to determine whether to extend the interim ban for any phthalates,² and also to determine whether any children's products should be declared "banned hazardous products."³ The CHAP is not charged with those determinations, nor with any other *risk management* functions. The CHAP is charged with considering hazard and exposure information, and reaching *science-based* conclusions about potential risks, that might then inform the Commission's risk management decisions.

We believe the CHAP should be given additional guidance concerning the charge set forth in the statute and how to follow that charge. Specifically, CHAP members need to be aware that the term "banned hazardous substance," as used in the CPSIA, is a legally defined term with specifically delineated criteria.⁴ Absent such additional guidance, we are concerned that the CHAP will fail to undertake the analysis and fail to make the recommendations required by the statute, and will implement an approach that is not consistent with the legal requirements set forth in the CPSIA.

2. The CHAP Should Implement a Risk-Based Approach as Required by the CPSIA

The CHAP deliberations during the recent public meetings initially appeared grounded in risk, as required by the CPSIA. However, during the course of the deliberations, and seemingly after recognizing that standard risk assessment methodologies did not indicate significant risks even for some phthalates subject to the permanent ban, the CHAP appeared to move away from standard risk assessment methodology. Instead, the CHAP appeared to move toward hazard-driven approaches that we believe are not consistent with the legal mandate set forth in the CPSIA.

As we have noted in prior correspondence, the definition of "banned hazardous substance" in the Federal Hazardous Substances Act is risk-based and expressly requires consideration of potential adverse effects from "reasonably foreseeable handling and use."⁵ Similarly, the CPSIA contains numerous references to exposure and unquestionably requires the

² CPSIA § 108(b)(3)(A) ("Not later than 180 days after receiving the report of the [CHAP] ..., the Commission shall ... promulgate a final rule to—(A) determine, based on such report, whether to continue in effect the prohibition under paragraph (1)").

³ CPSIA § 108(b)(3)(B).

⁴ FHSA §§ 2(f), (g) & (q).

⁵ 15 U.S.C. § 1261(f)(1)(A). The full definition of "banned hazardous substance" is found in the FHSA at 15 U.S.C. § 1261(q)(1).

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CHAP to base its recommendations on estimates of risk.⁶ Any dilution of this essential element of the charge, or any attempt to base recommendations primarily on hazard, or some combination of hazard and personal views about chemical risk management or acceptable levels of risk, would be inconsistent with the statute. It also would be an inappropriate role for a *scientific* panel charged with conducting purely *scientific* assessments.

The CHAP's decision to depart from standard risk assessment methodology was based in part on speculation about why phthalate toy bans were enacted in Europe. Those bans are *legislative*, not regulatory, and unlike EU risk assessments, were not based on risk.⁷ They have no relevance to the CHAP's deliberations. There is no need for the CHAP to be concerned about being consistent with EU legislative bans. The legislative bans in Europe also are irrelevant to any regulatory actions the Commission might take. The CHAP's recommendations should be guided by the legal requirements of the CPSIA, not political actions in Europe.

The CHAP also appeared concerned about being consistent with the permanent ban in the CPSIA for three phthalates. However, this legislative ban also should have no bearing on the CHAP's *scientific* assessment of other phthalates and phthalate alternatives. Even if, as the CHAP recently appeared to recognize, some of the permanently banned phthalates do not pose a significant health risk when standard risk assessment methodologies are employed, this would not justify departing from standard risk assessment methodology when evaluating other phthalates or phthalate alternatives. Nor would it justify recommending that any other phthalate be deemed a "banned hazardous substance" in the absence of significant health risks. Again, the CHAP's recommendations should be guided solely by application of science to the legal requirements of the CPSIA, and not by any prior legislative actions that were not based on risk.

Because CHAP members at their last meeting were not focusing on their legal charge to recommend whether any phthalates, or combinations of phthalates, should be declared "banned hazardous substances," they also did not focus on the fact that "banned hazardous substance" is a legally defined term with specifically delineated criteria.⁸ Instead, CHAP members at that meeting expressed the view that they needed to develop their own criteria for making their recommendations, and appeared to do so to a considerable extent based on their own views about risk management and risk policy, rather than on generally accepted scientific criteria for hazard, exposure or risk assessment. CHAP members should be aware of the legal criteria set forth in the FHSA for determining "banned hazardous substances," and should be guided by those statutory criteria, rather than developing their own.

⁶ See especially CPSIA § 108(b)(2)(B)(iii), (iv), (v) & (vii).

⁷ This is in contrast to EU risk assessments, which *are* based on risk. See Commission Communication on the results of the risk evaluation and the risk reduction strategies for [10 substances], O.J. C 90/04, 13.4.2006, pp. 10-15, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:090:0004:0028:EN:PDF> (discussing EU risk assessments which found no concern for exposures to adults or children from current uses of certain individual phthalates).

⁸ FHSA §§ 2(f), (g) & (q).

CHAP members also should be advised that the CPSC has promulgated guidelines for assessing chronic hazards and risks.⁹ These guidelines specify, for example, that: (i) when an ADI is based on a no effect level in animal studies, an uncertainty factor of 100 normally will be applied, and if a low effect level is used, a safety factor of 1000 will be applied;¹⁰ (ii) no additional uncertainty factor normally will be applied for children's products;¹¹ and (iii) "In most cases the best estimate of exposure (average exposure) is acceptable."¹² These guidelines do not preclude application of expert judgment in individual cases, but they do provide valuable guidance for the CHAP. In the interests of transparency, we believe the CHAP should be directed to apply these risk assessment guidelines, and if they then decide to depart from the specific guidelines in individual cases, they should explain the scientific basis for doing so in each case.

In summary, the CHAP should base its recommendations on standard risk assessment principles, consistent with the legal definition of a "banned hazardous substance" set forth in the CPSIA.¹³ The CHAP should document and justify any departures from generally accepted risk assessment methodologies. The CHAP should adhere to the CPSIA mandate, discussed further below, to base estimates of risk on reasonably foreseeable exposures.

3. The CHAP Should Assess Separately Potential Risks from Children's Products, as Required by the CPSIA

The CPSIA directed the Commission to appoint a CHAP "to study the effects on children's health of all phthalates and phthalate alternatives *as used in children's toys and child care articles.*"¹⁴ Moreover, the CPSIA expressly requires the CHAP to "examine the likely levels of children's, pregnant women's, and others' exposure to phthalates, *based on a reasonable estimation of normal and foreseeable use and abuse of such products.*"¹⁵ We understand the CHAP's work is ongoing, but the CHAP deliberations as yet have not included separate discussion of potential exposures and risks from children's products. This separate analysis is essential to meet the legal charge to the CHAP, and equally essential to producing a report that is useful to the Commission.

⁹ See 16 C.F.R. § 1500.135 and 57 Fed. Reg. 46626 (Oct. 9, 1992).

¹⁰ See 16 C.F.R. § 1500.135(d)(4)(ii)(B).

¹¹ See 57 Fed. Reg. at 46631.

¹² *Id.* at 46647.

¹³ For some phthalates or phthalate alternatives, sufficient hazard or exposure information might not be available to support a standard risk assessment. This does not justify failing to conduct a risk assessment where sufficient information is available.

¹⁴ CPSIA § 108(b)(2)(A) (emphasis added).

¹⁵ CPSIA § 108(b)(2)(B)(iii) (emphasis added). "Such products" refers to "products for children." See CPSIA § 108(b)(2)(B).

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The Commission must determine whether to “declare any children's product” containing any phthalates to be a “banned hazardous product.”¹⁶ A “banned hazardous product” is defined as a consumer product that presents an “unreasonable risk of injury.”¹⁷ Accordingly, the Commission’s determinations by law must focus on children’s products and must be based on risk. Further, the Commission is expressly directed to make its determinations concerning children’s products “based on the findings and recommendations of the [CHAP].”¹⁸ The Commission cannot base any such determinations on the CHAP report, if the CHAP report does not adequately address potential exposures and risks from children’s products.

The CHAP’s deliberations during the public meetings thus far have focused on estimates of aggregate exposures from all sources, not just products within the CPSC’s jurisdiction. The CPSIA does direct the CHAP to consider exposure from “children’s products and from other sources, such as personal care products,” when considering “the potential cumulative effect of total exposure to phthalates.”¹⁹ However, when making recommendations about whether any phthalate should be declared a “banned hazardous substance” by the CPSC, the CHAP should base its assessment on reasonably foreseeable exposures from children’s products, as contemplated by other provisions of the CPSIA,²⁰ and as required by the legal definition of a “banned hazardous substance.”²¹ That legal definition is not altered by any other provisions in the CPSIA, and thus applies as stated in the FHSA.

When conducting this separate analysis of exposure from children’s products, the CHAP can take advantage of exposure assessment work conducted by the prior phthalate CHAP²² and the Commission,²³ which focused on exposure to one phthalate from children’s products, including objects mouthed by children, and found “no demonstrated health risk.” Though this CHAP is directed to conduct a *de novo* review, the CPSIA expressly directs the CHAP to review the “findings and conclusions of any previous [CHAP] on this issue and other studies conducted

¹⁶ CPSIA § 108(b)(3)(B).

¹⁷ 15 U.S.C. § 2057.

¹⁸ *Id.*

¹⁹ CPSIA § 108(b)(2)(B)(iv). We note that for the CHAP’s consideration of the “cumulative effect of total exposure to phthalates,” there is as yet no standard methodology for *quantitative* risk assessment and that a *qualitative* cumulative assessment would meet the CHAP’s legal mandate. See Letter from A. Rollins to M. Babich, Oct. 27, 2011, page 6 (available at <http://www.cpsc.gov/about/cpsia/chap/emchap.pdf>); and ExxonMobil Comments to the CPSC CHAP, Mar. 29, 2011, pp. ii, and 1-2 (available at <http://www.cpsc.gov/about/cpsia/chap/exxonmobil.pdf>).

²⁰ See CPSIA § 108(b)(2)(B)(iii).

²¹ See notes 4, 5, and 8, *supra* and associated text.

²² CHAP (2001). Report to the US Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP), June 2001, available at <http://www.cpsc.gov/LIBRARY/FOIA/Foia01/os/dinp.pdf>.

²³ CPSC (2002). Response to Petition Requesting Ban of Use of PVC in Products (HP 99-1). US Consumer Products Safety Commission, Bethesda, MD, available at <http://www.cpsc.gov/library/foia/foia02/brief/briefing.html> (first seven links).

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by the Commission.”²⁴ The exposure assessment work evaluated by the prior CHAP and conducted by the Commission included cutting-edge “chew and spit” migration studies as well as sophisticated child observation studies. This work is a valuable resource for this CHAP.

The CHAP report should include a separate assessment of potential exposures and risks from children’s products for each phthalate and phthalate alternative. Recommendations concerning whether any phthalates should be declared a “banned hazardous substance” should be based on that analysis. The CHAP should review the findings and conclusions of the previous phthalate CHAP and explain any conclusions reached by the current CHAP that are at variance with the work of the prior CHAP.

Conclusion

For the reasons set forth in this letter, we respectfully request that you provide the CHAP with additional guidance concerning its legal charge, as set forth in the CPSIA. We believe additional guidance, addressing the topics discussed in this letter, will help the CHAP produce a report that meets the legal requirements set forth in the CPSIA and is useful to the Commission. Thank you for considering this request.

Sincerely yours,



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²⁴ CPSIA § 108(b)(2)(B).