

September 24, 2010

Ms. Cheryl Falvey General Counsel U.S. Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814

Re: Charge to the Chronic Hazard Advisory Panel on Phthalates under Section 108 of the Consumer Product Safety Improvement Act of 2008

Dear Ms. Falvey:

The Phthalate Esters Panel (PE Panel) of the American Chemistry Council would like to take this opportunity to comment on the explanation of the charge to the Chronic Hazard Advisory Panel (CHAP), as set forth in the Consumer Product Safety Improvement Act of 2008 (CPSIA), that you provided at the outset of the CHAP's meeting on July 26, 2010. In particular, this letter discusses the extent to which potential health endpoints affecting adults should be considered in the CHAP's deliberations, and the level of scrutiny that phthalates found in sources other than children's products should receive. We also wish to comment on the questions raised during the July meeting about the CHAP's approach to assessing risk.

The PE Panel understands fully the importance of appropriately limiting the scope of the CHAP's inquiry so that it may timely complete the tasks assigned to it by Section 108 of the CPSIA. We believe that our interpretation of CPSIA, as set forth below, will assist the CHAP in both meeting its statutory obligations and in improving the utility of the CHAP's report to the CPSC.

The Commission's central message to the CHAP should be that its charge relates solely to potential exposures of children to phthalates and phthalate alternatives, the potential health effects in children resulting from such exposures, and recommendations arising from those considerations. Accordingly, while in the course of examining those issues the CHAP may hear of adult exposures or adult health effects, these are not within its scope except to the extent that they may impact on children (e.g., exposures of pregnant women and resulting health effects, if any, on the child born following such exposures, or exposure of children to phthalates in adult products).

This singular focus arises directly from the language of Section 108(b)(2). Paragraph (A) thereof directs the 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.*" (Emphasis added.) Paragraph (B)



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directs the CHAP to examine phthalates "that are used in products for children." All subparagraphs under Paragraph (B) necessarily relate back to the statements in Paragraphs (A) and (B) for their scope.

During your presentation, CHAP members voiced concern about the lack of guidance on the appropriate health endpoints to consider, including whether the CHAP should limit its review to children. We agree with your assessment that the CHAP members should use their "scientific judgment" in determining which endpoints are relevant, but we encourage you to provide further guidance that Section 108(b) is "uniquely" focused on children. Importantly, this section makes no mention of studying the health risks associated with phthalate exposure to adults. Moreover, the reference to "pregnant women" and "susceptible individuals," is in the context of protecting the developing fetus and child. We, therefore, recommend that you provide the CHAP with an unambiguous statement removing adult-specific endpoints from the scope of its task.¹

The Commission also should provide the Panel with guidance on the age range of children that should be considered. Subsequent to your presentation, the CHAP members discussed considering exposures in individuals up to 18 years of age. We encourage you to instruct the CHAP that it should only consider health effects in children 12 years of age or younger. This age limit is clear from Section 108(e). Section 108(b)(2)(A) refers to phthalates and their alternatives "as used in children's toys and child care articles." Section 108(e) defines "children's toy" as a toy designed or intended "for a child 12 years of age or younger," and it defines "child care article" as a certain kind of product for "children age 3 and younger." Thus, Congress clearly intended to limit the CHAP's inquiry to exposures and effects in children 12 years of age or younger.

The CPSIA provides clear guidance on children's exposure to phthalates from sources other than children's products. During the July meeting, Dr. Michael Babich expressed concern about the CHAP's ability to examine the "full range of phthalates" given the large number of various phthalates that exist. Dr. Babich went on to state that the task would be more manageable if the CHAP were to limit its review to phthalates found in children's products. In response, you cited the language of Section 108(b)(2)(B) and indicated that "the statute expects the Commission to be looking at the exposures to the full range of phthalates in the home generally." Section 108(b)(2)(B) references "other sources, such as personal care products," but does so only in the context of a cumulative assessment. Accordingly, we encourage you to instruct the CHAP that, in light of Paragraphs (A) and (B), it should focus on exposures to children from phthalates in "children's toys and child care articles," and any other "products for



According to multiple reviews both here and in Europe, adult exposures are generally well below levels of concern.

Dr. Babich suggested that there are 29 commercial phthalates other than the six addressed by the CPSIA. The PE Panel, which represents the North American manufacturers of phthalates, does not believe that all of these 29 substances remain in production. We will provide information to support this belief in the near future.

³ Section 108(b)(2)(B) is the only reference to sources other than toys and child care articles.

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children." It may consider incidental exposures of children to phthalates from adult products to which they might have exposure, but the CHAP should not spend its time assessing the exposures of adults to phthalates in adult products.

We also strongly encourage the CHAP to utilize biomonitoring data from the Centers for Disease Control and Prevention (CDC) for assessing children's exposure. The CDC's latest report provides biomonitoring results for 13 phthalate metabolites from eight common phthalates, broken down by age range, including children ages 6-11. The CDC data provide reasonable confidence that exposures to the most widely used phthalates within the general population, including children as young as age 6, are very low. The CHAP need not spend time identifying the sources of these exposures; instead, the CHAP can direct its attention to the potential exposures of children less than 6 years of age, for which CDC biomonitoring data are not available.

One final area that we would like to address is the interpretation of Section 108(b)(2)(B)(vii) instructing the CHAP to consider, as part of its examination, "the level at which there is a reasonable certainty of no harm." In his questions to you, Dr. Andreas Kortenkamp suggested that recent recommendations of a National Academy of Sciences (NAS) committee regarding a unified approach to risk assessment may require a shift in the CHAP's approach to evaluating "no harm" levels. In fact, the NAS report to which Dr. Kortenkamp refers suggests a radical departure from basic tenets of toxicology and risk analysis that has not been widely accepted by the scientific community. Moreover, it is unclear whether, or how, the NAS committee's recommended approach can be practically incorporated into the regulatory decision-making process.

Section 108(b)(2)(B)(vii) does not require that the CHAP establish no harm or safe levels of exposure, only that it "consider the level at which there is a reasonable certainty of no harm" in conducting its evaluation of plasticizers used in children's products. In this regard, the CHAP can rely on existing safety levels established by the U.S. Environmental Protection Agency, the 2001 CHAP, and other entities as a basis for its recommendations to the CPSC, rather than attempt to calculate safe levels, or critique existing levels. Contrary to the suggestion by Dr. Kortenkamp during the July meeting, consideration of such "no harm" levels necessarily entails assessing *both* the potential hazards and exposures associated with phthalates in children's products.

In sum, the PE Panel encourages you to provide additional guidance to the CHAP as outlined above to ensure that the CHAP completes its statutory obligations in a manner wholly consistent with the CPSIA.

NAS. Science and Decisions: Advancing Risk Assessment. National Academies Press, Washington DC (2008).



⁴ CDC. Fourth National Report on Human Exposure to Environmental Chemicals. pages 258-294 (2009).

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Please do not hesitate to contact me at david_fischer@americanchemistry.com or 202-249-6717, or Steve Risotto, ACC's Senior Director for Phthalate Esters, at steve_risotto@americanchemistry.com or 202-249-6727, if you have any questions. I further request that this correspondence be included in the record for the CHAP proceedings.

Sincerely,

David B. Fischer

David B. Fischer Assistant General Counsel

cc: Chairman Inez TenenbaumCPSC CommissionersDr. M. Babich, Directorate for Health Sciences

