

**From:** Falvey, Cheryl  
**Sent:** Tuesday, December 20, 2011 5:02 PM  
**To:** Babich, Michael; DiMatteo, David; Patton, Leslie; Carlson, Kent; Danello, Mary Ann; Saltzman, Lori; Andreas Kortenkamp; Bernard Schwetz ; Chris Gennings; Holger Koch (koch@ipa-dguv.de); Paul Lioy; Philip Mirkes ; Russ Hauser  
**Subject:** Yesterday's CHAP teleconference  
**Date:** Tuesday, December 20, 2011 5:01:00 PM

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I thought it might be helpful to send you in writing a summary of my comments yesterday about how your report relates to the future policy and regulatory work to be done by the Commission. I explained that the CHAP's report needs to contain a sufficiently detailed description of the scientific analysis to allow the Commission policy makers to conduct the rulemaking activity called for by the statute. I commented that the CHAP report is described in section 108(b)(2)(C) and that the report needs to satisfy two statutory requirements. First, it should report to the Commission the results of your examination as required in CPSIA Section 108(b)(2)(B)(i) through (viii) and should include discussion of each issue as follows:

- Examine all of the potential health effects (including endocrine-disrupting effects) of the full range of phthalates;
- Consider the potential health effects of each of these phthalates, both in isolation and in combination with other phthalates;
- Examine the likely levels of children's, pregnant women's, and others' exposure to phthalates, based upon a reasonable estimation of normal and foreseeable use and abuse of such products;
- Consider the cumulative effect of total exposure to phthalates, both from children's products and from other sources, such as personal care products;
- Review all relevant data, including the most recent, best-available, peer-reviewed, scientific studies of these phthalates and phthalate alternatives that employ objective data-collection practices or employ other objective methods;
- Consider the health effects of phthalates not only from ingestion, but also as a result of dermal, hand-to-mouth, or other exposure;
- Consider the level at which there is a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals and their offspring, considering the best available science, and using sufficient safety factors to account for uncertainties regarding exposure and susceptibility of children, pregnant women, and other potentially susceptible individuals; and
- Consider possible similar health effects of phthalate alternatives used in children's toys and child care articles.

We have always emphasized to you to use your best scientific judgment as to how to evaluate the appropriate scope and depth of the analysis called for by Congress. So, for example, with regard to words like "examine" and "consider" and "review," you should use your best scientific judgment as to what those verbs mean in the context of this scientific review. I also mentioned

that with regard to Section 108(b)(2)(B)(ii), the report needs to consider the phthalates both in isolation and in combination and provide the scientific judgment for both. I also mentioned that in considering the cumulative effect of total exposure to phthalates with regard to Section 108(b)(2)(B)(iv) it would be best to “show your work” so to speak and provide the Commission with a breakdown on the exposures both from children’s products and other sources. The Commission needs to understand what contribution to the total cumulative exposure comes from children’s products and what comes from other sources.

Finally, we discussed Section 108(b)(2)(B)(vii) and your consideration of the level at which there is a “reasonable certainty of no harm to children, pregnant women and other susceptible individuals.” The statute instructs you to use “sufficient safety factors to account for uncertainties regarding exposure and susceptibility of children pregnant women and other potentially susceptible individuals.” I emphasized how important it will be for the Commission to have your scientific justification of your choice of safety factor and that we need to have a scientific and not a policy basis for that choice. While the CPSC has guidance with regard to this that you may find helpful (*see, e.g.*, 16 C.F.R. §1500.135) and the FDA has interpreted a similar “no harm” standard, we need you to explain your choice of safety factor with reference to your own evaluation of the science on phthalates and phthalate alternatives. This final point became important in answering your questions. If the CHAP justifies its choice on policy grounds, whether that is harmonization with the permanent ban of other phthalates in the CPSIA or harmonization with the standards in Europe, that would leave the Commission without the scientific basis for its rulemaking. You should feel free to allow the science to drive your selection of whatever safety factor you think is appropriate to ensure there is a reasonable certainty of no harm to children, pregnant women and other susceptible individuals and explain why scientifically.

The second statutory requirement for your report is that it provide your recommendations regarding any phthalates in addition to those identified in subsection (a) or phthalate alternatives that the panel determines should be banned hazardous substances. I explained that the term “banned hazardous substance” is a term of art under the Federal Hazardous Substances Act (“FHSA”). It is not entirely clear why Congress used FHSA language for your report recommendation when the Commission’s rulemaking activity will be conducted under the Consumer Product Safety Act. The good news for you is that regardless of which statute applies, the Commission needs the recommendation to be based on an assessment of both exposure and risk, not just the presence of the chemical. In considering exposure, the CPSC considers several factors: total amount of the chemical in the product; bioavailability of the chemical; accessibility of the chemical to children; age and foreseeable behavior of the children exposed to the product; foreseeable duration of the exposure; marketing, patterns of use, and life cycle of the product. The CPSC also assesses the toxicological data by evaluating available data from animal studies; human exposure data, if available, with specific attention to issues such as the routes of exposure; length of exposure (*i.e.*, acute or chronic time frames); specific form of chemical; dose-response relationships. CPSC staff estimates doses that correspond to substantial personal injury or substantial illness, for assessment under the FHSA. Staff evaluates all of the information and data collected in the product, toxicological, and

exposure assessments to make conclusions about whether a product may be a hazardous substance. I mentioned that our team had met and come up with the following questions that may help focus your work on the recommendations section of the report.

- Are the phthalates you have studied, either individually or in combination, capable of producing personal injury or illness to humans based on ingestion, inhalation or absorption?
- If so, in your examination of these phthalates, have you concluded that children could be exposed to hazardous levels of those phthalates in reasonably foreseeable conditions of handling, use and abuse, and what are those levels?

Finally, I emphasized to you that the CPSIA contains language that allows the Commission to determine what is “necessary to protect the health of children.” Our team agreed that it would be helpful for the CHAP to consider in making its recommendations whether, in order to protect the health and safety of children, any of the phthalates that you have studied, either individually or in combination, should be restricted from use in children’s products (toys, child care articles or otherwise) because they present an unreasonable risk of injury to children and, if so, at what level and why. As I explained yesterday, your report provides the Commission with the scientific basis it will need to answer that question.