U.S. Consumer Product Safety Commission

LOG OF MEETING

SUBJECT: Chronic Hazard Advisory Panel (CHAP) on Phthalates and Phthalate Substitutes

DATE: July 26-28, 2010

TIME: 8:30 a.m. to 5:00 p.m. on July 26 and 27; 8:00 a.m. to 2:00 p.m. on July 28

PLACE: CPSC Headquarters

ENTRY SOURCE: Michael A. Babich, HSHS

COMMISSION REPRESENTATIVE: Michael Babich

CHAP Members: Philip Mirkes (Chair), Bernard Schwetz (Vice-Chair), Chris Gennings, Russ Hauser, Holger Koch, Andreas Kortenkamp.

NON FEDERAL REPRESENTATIVES: See attendee list.

SUMMARY:

This was the second meeting of the 2010 Chronic Hazard Advisory Panel (CHAP) on Phthalates and Phthalate Substitutes. Following introductions, Cheryl Falvey, CPSC General Counsel, addressed the CHAP regarding the responsibilities of the CHAP, as outlined in section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). Regarding requirement *vii* of the CHAP's examination [§108 (b)(2)(B)(vii)], Dr. Kortenkamp asked whether it is necessary for the CHAP to derive levels "at which there is a reasonable certainty of no harm" per se, or whether other methods such as risk estimates could be applied. Ms. Falvey replied that she would consider the question and respond to the CHAP.

The remainder of the first day (Monday July 26) was devoted to public testimony. A complete list of speakers is in the attached agenda. Their slides and/or written submissions are available on the CPSC web page (see below). Presenters included non-governmental organizations and manufacturers of phthalates and phthalate substitutes. Some manufacturers also submitted extensive written comments and background information, which is available on the CPSC web page (see below).

One significant point of discussion during the public testimony was the availability of proprietary toxicity data on phthalate substitutes. BASF manufactures DINCH, a phthalate substitute that is commonly used in children's products. BASF has extensive toxicological data on DINCH, but will not release the studies to CPSC or the CHAP unless the data remain confidential. Dr. Otter, BASF explained that the European REACH legislation maintains the confidentiality of data submitted by manufacturers to the European Commission. However, the CHAP has stated that, in the interest of transparency, it would not use data in its risk assessment if the data are not available to the public.

On the second day (Tuesday July 27), invited scientists presented their research on the toxicity of phthalates. Paul Foster, NIEHS, and Earl Gray, EPA, spoke about the developmental effects of phthalates and phthalate mixtures. Shanna Swan, University of Rochester School of Medicine and Dentistry, reviewed published epidemiological studies. Jeffrey Peters spoke about the role of PPAR nuclear receptors in the toxicity of phthalates, including the induction of liver tumors in rodents. A general discussion followed the presentations.

Also on the third day, representatives of other federal agencies and programs, including EPA and FDA, gave summaries of ongoing regulatory and research activities relating to phthalates. EPA's National Center for Environmental Assessment (NCEA) described its ongoing cumulative risk assessment of selected phthalates for the Integrated Risk Information System (IRIS) program. The EPA Office of Toxics and Pollution Prevention (OPPT) described its phthalates action plan. Representatives from various FDA programs discussed the use of phthalates in medical devices, cosmetics, and pharmaceuticals. FDA declined the CHAP's invitation to discuss the contribution of diet to total phthalate exposure.

On the third day (Wednesday July 28) the CHAP discussed the next steps in their risk assessment. The next meeting will be on December 2-3, at CPSC headquarters. The CPSC staff will invite Thomas Burke, Johns Hopkins University, to speak on the recent National Research Council (NRC) report on risk assessment at the December meeting. Dr. Burke was unable to attend the July meeting as planned. The staff will also invite Richard Stahlhut, University of Rochester School of Medicine and Dentistry, and Matthew Lorber, EPA to speak about the analysis of biomonitoring data. The staff will draft a "framework" for the cumulative risk assessment of phthalates and phthalate substitutes. Using the framework as an aid, the CHAP members will draft proposals for how to complete the CHAP's risk assessment and answer the charge questions. These will be shared among the CHAP prior to the December meeting. In addition, the CPSC staff will prepare toxicity reviews of 29 additional phthalates.

Attachments:

- Agenda
- List of meeting attendees

Supplemental Information is available at:
http://www.cpsc.gov/about/cpsia/chap0710.html

- Video recording of the meeting
- Speakers' slides, written testimony, and data submissions
- Other written comments submitted by the public