



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 4330 EAST WEST HIGHWAY
 BETHESDA, MD 20814

BALLOT VOTE SHEET

MAY 19 2010

TO: The Commission
 Todd A. Stevenson, Secretary

THROUGH: Maruta Budetti, Executive Director
 Cheryl A. Falvey, General Counsel
 Philip L. Chao, Assistant General Counsel

MZ/S
CAF
[Signature]

FROM: Harleigh Ewell, Attorney, GCRA *HE*

SUBJECT: Federal Register Notice: Notice of Meeting of Chronic Hazard Advisory Panel on Phthalates and Phthalate Substitutes and Opportunity for Public Comment

MAY 28 2010

Ballot Vote Due: _____

Attached for the Commission's consideration is a draft *Federal Register* notice announcing the second meeting of the Chronic Hazard Advisory Panel on Phthalates on July 26-28, 2010, including an opportunity for the public to present oral comments on July 26, 2010. Written comments may be submitted until July 12, 2010.

Please indicate your vote on the attached draft notice.

- I. Approve publication of the draft notice in the *Federal Register* without change.

 (Signature)

 (Date)

RH 5/19/2010
 CLEARED FOR PUBLIC RELEASE
 UNDER CPSA 6(b)(1)

THIS DOCUMENT HAS NOT BEEN
 REVIEWED OR ACCEPTED BY THE
 COMMISSION.

II. Do not approve publication of the draft notice in the *Federal Register*.

(Signature)

(Date)

III. Publish the draft notice in the *Federal Register* with changes.

(Please specify.)

(Signature)

(Date)

IV. Other.

(Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Notice of Meeting of Chronic Hazard Advisory Panel on Phthalates and Phthalate Substitutes and Opportunity for Public Comment

CONSUMER PRODUCT SAFETY COMMISSION

**Notice of Meeting of Chronic Hazard Advisory Panel on Phthalates and Phthalate
Substitutes and Opportunity for Public Comment**

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of meeting.

SUMMARY: The Consumer Product Safety Commission (“CPSC” or “Commission”) announces the second meeting of the Chronic Hazard Advisory Panel (CHAP) on phthalates and phthalate substitutes. The Commission appointed this 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, pursuant to section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) (Public Law 110-314). The public may submit written or oral comments on the issues to be considered by the CHAP.

DATES: The opportunity to present oral comments will be on July 26, 2010, from 10:00 a.m. to 5:00 p.m. The remainder of the meeting will be from 8:30 a.m. to 5:00 p.m. on July 27 and from 8:30 a.m. to 4 p.m. on July 28, 2010. Requests to present oral comments must be filed with the Office of the Secretary no later than July 1, 2010.

Written comments, and a written copy of the text of the oral comments, must be received no later than July 12, 2010. Commenters should limit their presentations to approximately 15 minutes, exclusive of any periods of questioning by the members of the CHAP or the Consumer Product Safety Commission (CPSC) staff. The CHAP may

further limit the time for any presentation and to impose restrictions to avoid excessive duplication of presentations.

ADDRESSES: The meeting will be in the fourth floor hearing room on July 26 and 27 and in room 410 on July 28, 2010, in the Commission's offices at 4330 East West Highway, Bethesda, Maryland. Written comments, or requests to present oral comments and the written text of such comments, should be captioned "CHAP on Phthalates" and sent by electronic mail ("email") to cpsc-os@cpsc.gov, or mailed or delivered to the Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814.

ONLINE REGISTRATION AND WEBCAST: Members of the public who wish to attend the meeting are requested to preregister online at <http://www.cpsc.gov/cgibin/chap.aspx>. This meeting will also be available live via webcast on July 26 and July 27, and by prerecorded webcast on July 28, 2010, at <http://www.cpsc.gov/> webcast. Registration is not necessary to view the webcast.

FOR FURTHER INFORMATION CONTACT: Concerning requests and procedures for oral presentations of comments: Rockelle Hammond, Consumer Product Safety Commission, Bethesda, MD 20814; telephone: (301) 504-6833; email cpscos@cpsc.gov. For all other matters: Michael Babich, Directorate for Health Sciences, Consumer Product Safety Commission, Bethesda, MD 20814; telephone (301) 504-07253; email mbabich@cpsc.gov.

SUPPLEMENTARY INFORMATION: The Commission has previously investigated potential risks posed to children from phthalate plasticizers, especially di(2-ethylhexyl) phthalate (DEHP) and diisononyl phthalate (DINP), which were used to soften some

children's teething rings, rattles, and toys made from polyvinyl chloride (PVC). Phthalates can leach from such products when they are mouthed by children, causing some phthalates to be ingested. In addition, children and adults can be exposed to phthalates from many sources, including consumer products, food, cosmetics, medical devices, and the environment. Certain phthalates have been shown to cause adverse health effects, including birth defects, in laboratory animals. Section 108 of the CPSIA permanently prohibits the sale of any "children's toy or child care article" containing more than 0.1 percent of each of three specified phthalates—di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP). Section 108 of the CPSIA also prohibits on an interim basis the sale of any "children's toy that can be placed in a child's mouth" or "child care articles" containing more than 0.1 percent of each of three additional phthalates—diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-*n*-octyl phthalate (DnOP). Moreover, section 108 of the CPSIA requires the Commission to convene 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."

Section 108 of the CPSIA requires the Commission to convene 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." The CPSIA requires the CHAP to complete an examination of the full range of phthalates that are used in products for children and to: (i) examine all of the potential health effects (including endocrine disrupting effects) of the full range of phthalates; (ii) consider the potential health effects of each of these phthalates both in isolation and in combination with other phthalates; (iii) 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; (iv) consider the cumulative effect of total exposure to phthalates, both from children's products and from other sources, such as personal care products; (v) 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; (vi) consider the health effects of phthalates not only from ingestion but also as a result of dermal, hand-to-mouth, or other exposure; (vii) 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 (viii) consider possible similar health effects of phthalate alternatives used in children's toys and child care articles.

The CHAP's examination must be conducted *de novo*, and the statute specifies completion of its examination within 18 months of appointment of the CHAP. The CHAP must review prior work on phthalates by the Commission, but the Commission's prior work is not to be considered determinative. Within 180 days after completing its examination, the CHAP shall report to the Commission the results of the examination and shall make recommendations to the Commission regarding any phthalates (or combinations of phthalates or alternatives to phthalates) in addition to those permanently banned by the CPSIA that the CHAP determines should be declared hazardous substances.

The first meeting of the CHAP was on April 14-15, 2010. The second meeting of the CHAP will be on July 26-28, 2010, in the fourth floor hearing room at the Commission's offices in Bethesda, MD (see address above). The CHAP is seeking public comment on issues relating to the hazard, exposure, and risk posed by phthalates and phthalate substitutes from all sources of exposure, and especially in children's products. The CHAP is especially interested in comments and data pertaining to:

1. Information on current and anticipated future uses of phthalates and phthalate substitutes in products, including market data, production levels, and the range of uses of specific phthalates and phthalate substitutes in different product types.
2. Data on the types and levels of phthalates and phthalate substitutes found in consumer products, cosmetics, pharmaceutical drugs, medical devices, food, food supplements, food packaging, and pesticides.
3. Information on the relative importance of different sources, routes, and pathways of exposure to phthalates in the general population, expectant mothers, and children. For example, what are the relative contributions of exposure from diet, consumer products, ambient air, and other sources, which may differ depending on the particular phthalate and the exposed population?
4. Data on consumer use patterns including the use of cosmetics and consumer products that may contain phthalates.
5. Data on children's activity patterns, including mouthing activity, exposure to household dust, dermal exposure to toys, and other potential child-specific exposure pathways.

6. Information relating to human exposure to phthalates and phthalate substitutes, including migration data, levels in environmental media (ambient and indoor air, water, soil, household dust), dermal exposure, oral exposure, and bioavailability.
7. New, unpublished, or soon-to-be published data on the types and levels of phthalates, phthalate substitutes, or their metabolites in human urine, blood, milk, or other biological media.
8. Information relating to metabolism or pharmacokinetic modeling that could be used to estimate human exposure from biomonitoring studies.
9. Toxicity data on the full range of phthalates and phthalate substitutes in commercial use, especially unpublished or soon-to-be-published studies.
10. Human data on the toxicity of phthalates, including epidemiological and clinical studies, especially unpublished or soon-to-be published studies.
11. Information on the relative sensitivity of potentially vulnerable populations, including the fetus, young children, and expectant mothers, and whether there are any other vulnerable populations that should be considered.
12. Information relating to assessing the cumulative (combined) risk from multiple phthalates, including dose response data, methodology, which health endpoint (or endpoints) is the most relevant to human risk assessment, and which phthalate substitutes or other compounds may contribute to the combined risk.

Any information submitted to CPSC in response to this request will become part of the public record. The CHAP is especially interested in unpublished studies relating to toxicity or exposure. However, the CHAP will not consider summaries of toxicological studies prepared by chemical manufacturers as substitutes for the complete studies.

There will be an opportunity for oral comments on July 26, 2010, from 10:00 a.m. to 5:00 p.m. Persons wishing to present oral comments should file a request with the Commission's Office of the Secretary no later than July 1, 2010, and submit the text of their comments not later than July 12, 2010. Commenters should limit their presentations to approximately 15 minutes, exclusive of any periods of questioning by the members of the CHAP or the CPSC staff. The CHAP may further limit the time for any presentation and to impose restrictions to avoid excessive duplication of presentations. Interested persons may also file written comments with the CHAP. Written comments must be filed with the Office of the Secretary no later than July 12, 2010. The remainder of the CHAP meeting will be from 8:30 a.m. to 5:00 p.m. on July 27 and from 8:30 a.m. to 4:00 p.m. on July 28, 2010. During this part of the meeting, the CHAP will discuss issues and the report it will write.

Dated: _____

Todd A. Stevenson, *Secretary,*

Consumer Product Safety Commission.