



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Patricia Semple
Executive Director

February 10, 2009

Ralph J. Cicerone, Ph.D.
President
National Academy of Sciences
500 Fifth Street, NW
Washington, DC 20001

Dear Dr. Cicerone:

On August 14, 2008, President Bush signed the Consumer Product Safety Improvement Act (CPSIA, Public Law 110-314), which, among other things, requires the U.S. Consumer Product Safety Commission (CPSC) to appoint a Chronic Hazard Advisory Panel (CHAP) to examine the potential effects on children's health of phthalates and phthalate alternatives as used in children's toys and child care articles. The CHAP must be appointed not earlier than 180 days after enactment of the CPSIA, that is, after February 10, 2009. According to the requirements for establishing a CHAP in Section 28 of the Consumer Product Safety Act (15 U.S.C. § 2077), the Commission must appoint seven CHAP members from a list of at least 21 scientists nominated by the President of the National Academy of Sciences. Because the nominees must be willing to serve and pass the conflict of interest criteria (see below), we ask that you nominate more than 21 scientists. As this work is to be completed by a Congressionally mandated deadline, we also request that you nominate scientists to serve on this CHAP by March 31, 2009, if possible.

Prospective nominees are ineligible if they "receive compensation from or have substantial financial interest in any manufacturer, distributor, or retailer" of products or chemicals covered by the CHAP or if they are federal employees, excluding those at the National Institutes of Health, the National Toxicology Program, or the National Center for Toxicological Research. Moreover, candidates must "have demonstrated the ability to critically assess chronic hazards and risks to human health presented by the exposure of humans to toxic substances or as demonstrated by the exposure of animals to such substances." 15 U.S.C. § 2077.

The task of the CHAP is to conduct a *de novo* examination of the risks associated with phthalates and phthalate alternatives in children's toys and child care articles. Specifically, Section 108 (b)(2)(B)(i)-(viii) of the CPSIA states that the panel will:

- (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.

We anticipate that the CHAP will need scientists with expertise in the following areas:

- Exposure Assessment
- Reproductive/Developmental Toxicity
- General Toxicology
- Risk Assessment of Mixtures/Cumulative Risk Assessment
- Risk Assessment for Children
- Epidemiology/Biostatistics
- Biomonitoring/Pharmacokinetic Modeling

Dr. Cicerone
Page 3

We appreciate your prompt attention to this matter and look forward to working with you. If you have any questions, please contact Dr. Michael A. Babich, the Commission's project manager for phthalates, at 301-504-7253 or mbabich@cpsc.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Patricia M. Semple". The signature is written in black ink and is positioned above the printed name and title.

Patricia M. Semple
Executive Director

Enclosures:

15 U.S.C. § 2077

CPSIA, Section 108

cc: James J. Reisa, Ph.D., Director
Board on Environmental Studies and Toxicology
National Research Council

CONSUMER PRODUCT SAFETY ACT

from providing robust oversight of the activities of the Commission, and any additional authority or resources that would facilitate more effective oversight.

(2) Reviews of improvements and employee complaints—Beginning for fiscal year 2010, the Inspector General of the Commission shall include in an annual report to the appropriate Congressional committees the Inspector General's findings, conclusions, and recommendations from the reviews and audits under subsections (a) and (b).

REPORT ON CIVIL PENALTIES

Sec. 27a. [15 U.S.C. § 2076a]. {This reporting requirement ceased to be effective with respect to Congress on December 21, 1999 per Pub. L. 104-66, § 3003.}

(1) Beginning 1 year after the date of enactment of this Act [enacted Nov. 16, 1990], and every year thereafter, the Consumer Product Safety Commission shall submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce of the House of Representatives the information specified in paragraph (2) of this subsection. Such information may be included in the annual report to the Congress submitted by the Commission. {This reporting requirement ceased to be effective with respect to Congress on December 21, 1999 per Pub. L. 104-66, § 3003.}

(2) The Commission shall submit information with respect to the imposition of civil penalties under the statutes which it administers. The information shall include the number of civil penalties imposed, an identification of the violations that led to the imposition of such penalties, and the amount of revenue recovered from the imposition of such penalties. {This reporting requirement ceased to be effective with respect to Congress on December 21, 1999 per Pub. L. 104-66, § 3003.}

~~CHRONIC HAZARD ADVISORY PANEL~~

SEC. 28. [15 U.S.C. § 2077a].

(a) The Commission shall appoint Chronic Hazard Advisory Panels (hereinafter referred to as the Panel or Panels) to advise the Commission in accordance with the provisions of section 31(b) [15 U.S.C. § 2080(b)] respecting the chronic hazards of cancer, birth defects, and gene mutations associated with consumer products.

(b) Each Panel shall consist of 7 members appointed by the Commission from a list of nominees who shall be nominated by the President of the National Academy of Sciences from scientists—

(1) who are not officers or employees of the United States (other than employees of the National Institutes of Health, the

CONSUMER PRODUCT SAFETY ACT

National Toxicology Program, or the National Center for Toxicological Research), and who do not receive compensation from or have any substantial financial interest in any manufacturer, distributor, or retailer of a consumer product; and

(2) who have demonstrated the ability to critically assess chronic hazards and risks to human health presented by the exposure of humans to toxic substances or as demonstrated by the exposure of animals to such substances.

The President of the National Academy of Sciences shall nominate for each Panel a number of individuals equal to three times the number of members to be appointed to the Panel.

(c) The Chairman and Vice Chairman of the Panel shall be elected from among the members and shall serve for the duration of the Panel.

(d) Decisions of the Panel shall be made by a majority of the Panel.

(e) The Commission shall provide each Panel with such administrative support services as it may require to carry out its duties under section 31 [15 U.S.C. § 2080].

(f) A member of a Panel appointed under subsection (a) shall be paid at a rate not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule ["General Schedule", appears following 5 U.S.C. 5332] for each day (including travel time) during which the member is engaged in the actual performance of the duties of the Panel.

(g) Each Panel shall request information and disclose information to the public, as provided in subsection (h), only through the Commission.

(h)(1) Notwithstanding any statutory restriction on the authority of agencies and departments of the Federal Government to share information, such agencies and departments shall provide the Panel with such information and data as each Panel, through the Commission, may request to carry out its duties under section 31 [15 U.S.C. § 2080]. Each Panel may request information, through the Commission, from States, industry and other private sources as it may require to carry out its responsibilities.

(2) Section 6 [15 U.S.C. § 2055] shall apply to the disclosure of information by the Panel but shall not apply to the disclosure of information to the Panel.

{See section 31(b) for additional provisions.}

COOPERATION WITH STATES AND WITH OTHER FEDERAL AGENCIES

SEC. 29. [15 U.S.C. § 2078]

(a) The Commission shall establish a program to promote

of minority populations and recommendations for minimizing such risks;

(2) recommendations for public outreach, awareness, and prevention campaigns specifically aimed at racial minority populations; and

(3) recommendations for education initiatives that may reduce statistical disparities.

15 USC 2057c.

~~2057c. PROHIBITION ON THE SALE OF CERTAIN PRODUCTS CONTAINING
SPECIFIED PHTHALATES.~~

Effective date.

(a) **PROHIBITION ON THE SALE OF CERTAIN PRODUCTS CONTAINING PHTHALATES.**—Beginning on the date that is 180 days after the date of enactment of this Act, it shall be unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP).

Effective date.

(b) **PROHIBITION ON THE SALE OF ADDITIONAL PRODUCTS CONTAINING CERTAIN PHTHALATES.**—

(1) **INTERIM PROHIBITION.**—Beginning on the date that is 180 days after the date of enactment of this Act and until a final rule is promulgated under paragraph (3), it shall be unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP).

Deadlines.

(2) **CHRONIC HAZARD ADVISORY PANEL.**—

(A) **APPOINTMENT.**—Not earlier than 180 days after the date of enactment of this Act, the Commission shall begin the process of appointing a Chronic Hazard Advisory Panel pursuant to the procedures of section 28 of the Consumer Product Safety Act (15 U.S.C. 2077) to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles.

(B) **EXAMINATION.**—The panel shall, within 18 months after its appointment under subparagraph (A), complete an examination of the full range of phthalates that are used in products for children and shall—

(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 panel's examinations pursuant to this paragraph shall be conducted *de novo*. The findings and conclusions of any previous Chronic Hazard Advisory Panel on this issue and other studies conducted by the Commission shall be reviewed by the panel but shall not be considered determinative.

(C) REPORT.—Not later than 180 days after completing its examination, the panel appointed under subparagraph (A) shall report to the Commission the results of the examination conducted under this section and shall make recommendations to the Commission regarding any phthalates (or combinations of phthalates) in addition to those identified in subsection (a) or phthalate alternatives that the panel determines should be declared banned hazardous substances.

(3) PERMANENT PROHIBITION BY RULE.—Not later than 180 days after receiving the report of the panel under paragraph (2)(C), the Commission shall, pursuant to section 553 of title 5, United States Code, promulgate a final rule to—

Deadline.

(A) determine, based on such report, whether to continue in effect the prohibition under paragraph (1), in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety; and

(B) evaluate the findings and recommendations of the Chronic Hazard Advisory Panel and declare any children's product containing any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057), as the Commission determines necessary to protect the health of children.

(c) TREATMENT OF VIOLATION.—A violation of subsection (a) or (b)(1) or any rule promulgated by the Commission under subsection (b)(3) shall be treated as a violation of section 19(a)(1) of the Consumer Product Safety Act (15 U.S.C. 2068(a)(1)).

(d) TREATMENT AS CONSUMER PRODUCT SAFETY STANDARDS; EFFECT ON STATE LAWS.—Subsections (a) and (b)(1) and any rule promulgated under subsection (b)(3) shall be considered consumer product safety standards under the Consumer Product Safety Act. Nothing in this section or the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) shall be construed to preempt or otherwise

affect any State requirement with respect to any phthalate alternative not specifically regulated in a consumer product safety standard under the Consumer Product Safety Act.

(e) DEFINITIONS.—

(1) DEFINED TERMS.—As used in this section:

(A) The term “phthalate alternative” means any common substitute to a phthalate, alternative material to a phthalate, or alternative plasticizer.

(B) The term “children’s toy” means a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays.

(C) The term “child care article” means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.

(D) The term “consumer product” has the meaning given such term in section 3(a)(1) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(1)).

(2) DETERMINATION GUIDELINES.—

(A) AGE.—In determining whether products described in paragraph (1) are designed or intended for use by a child of the ages specified, the following factors shall be considered:

(i) A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable.

(ii) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children of the ages specified.

(iii) Whether the product is commonly recognized by consumers as being intended for use by a child of the ages specified.

(iv) The Age Determination guidelines issued by the Commission staff in September 2002 and any successor to such guidelines.

(B) TOY THAT CAN BE PLACED IN A CHILD’S MOUTH.—For purposes of this section a toy can be placed in a child’s mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children’s product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth.

TITLE II—CONSUMER PRODUCT SAFETY COMMISSION REFORM

Subtitle A—Administrative Improvements

SEC. 201. REAUTHORIZATION OF THE COMMISSION.

(a) AUTHORIZATION OF APPROPRIATIONS.—Subsection (a) of section 32 (15 U.S.C. 2081) is amended to read as follows:

“(a) GENERAL AUTHORIZATION OF APPROPRIATIONS.—