Publication 100,'' guidelines published by NTIS and available at *https://dmf.ntis.gov.* Such attestation must be based on the Accredited Certification Body's review or assessment conducted no more than three years prior to the date of submission of the Person's or Certified Person's completed certification statement, and, if an audit of a Certified Person by an Accredited Certification Body is required by NTIS, no more than three years prior to the date upon which NTIS notifies the Certified Person of NTIS's requirement for audit, but such review or assessment or audit need not have been conducted specifically or solely for the purpose of submission under this part.

(c) Where review or assessment or audit by an Accredited Certification Body was not conducted specifically or solely for the purpose of submission under this part, the written attestation or assessment report (if an audit) shall describe the nature of that review or assessment or audit, and the Accredited Certification Body shall attest that on the basis of such review or assessment or audit, the Person or Certified Person has systems, facilities, and procedures in place as required under § 1110.102(a)(2). In so attesting, an Accredited Certification Body may reference ''Limited Access Death Master File (LADMF) Certification Program Publication 100,'' guidelines published by NTIS and available at *https://dmf.ntis.gov.*

(d) Notwithstanding paragraphs (a) through (c) of this section, NTIS may, in its sole discretion, require that review or assessment or audit by an Accredited Certification Body be conducted specifically or solely for the purpose of submission under this part.

§ 1110.503 Acceptance of accredited certification bodies.

(a) NTIS will accept written attestations and assessment reports from an Accredited Certification Body that attests, to the satisfaction of NTIS, as provided in § 1110.502.

(b) NTIS may decline to accept written attestations or assessment reports from an Accredited Certification Body, whether or not it has attested as provided in § 1110.502, for any of the following reasons:

(1) When it is in the public interest under Section 203 of the Bipartisan Budget Act of 2013, and notwithstanding any other provision of this part;

(2) Submission of false or misleading information concerning a material fact(s) in an Accredited Certification Body's attestation under § 1110.502;

(3) Knowing submission of false or misleading information concerning a material fact(s) in an attestation or assessment report by an Accredited Certification Body of a Person or Certified Person;

(4) Failure of an Accredited Certification Body to cooperate in response to a request from NTIS verify the accuracy, veracity, and/or completeness of information received in connection with an attestation under § 1110.502 or an attestation or assessment report by that Body of a Person or Certified Person. An Accredited Certification Body ''fails to cooperate'' when it does not respond to NTIS inquiries or requests, or it responds in a manner that is unresponsive, evasive, deceptive, or substantially incomplete; or

(5) Where NTIS is unable for any reason to verify the accuracy of the Accredited Certification Body's attestation.

[FR Doc. 2014–30199 Filed 12–29–14; 8:45 am]

BILLING CODE 3510–04–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1307

[Docket No. CPSC–2014–0033]

Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to convene a Chronic Hazard Advisory Panel (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 and to provide recommendations to the Commission regarding whether any phthalates or phthalate alternatives other than those already permanently prohibited should be prohibited. The CPSIA requires the Commission to promulgate a final rule after receiving the final CHAP report. The Commission is proposing this rule pursuant to section 108(b) of the CPSIA.

DATES: Submit comments by March 16, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2014–0033, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov*. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *www.regulations.gov*. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: Mail/Hand delivery/Courier, preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov*. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number, CPSC–2014–0033, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Kent R. Carlson, Ph.D., Toxicologist, Division of Toxicology & Risk Assessment, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850–3213; email: *kcarlson@cpsc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Consumer Product Safety Improvement Act

1. Statutory Prohibitions

Section 108 of the CPSIA establishes requirements concerning phthalates. The term ''phthalates'' generally refers to *ortho*-phthalate diesters (phthalate esters, phthalates), which are a class of organic compounds used primarily as plasticizers for polyvinyl chloride (PVC). Phthalates also are used as solvents and stabilizers for fragrances. Phthalates have been used in teethers, plastic toys, home furnishings, air fresheners, automobile interiors, cosmetics, medications, medical devices, and many other products.

Phthalates are also found in food, indoor air, outdoor air, household dust, soil, and other environmental media.

Section 108(a) of the CPSIA permanently prohibits the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of 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 butyl benzyl phthalate (BBP). Section 108(b)(1) of the CPSIA prohibits on an interim basis (*i.e.,* until the Commission promulgates a final rule), the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of ''any children's toy that can be placed in a child's mouth'' or ''child care article'' containing concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-*n*-octyl phthalate (DNOP). The CPSIA defines a ''children's toy'' as ''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.'' *Id.* Section 108(g)(1)(B). A ''child care article'' is defined as ''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.'' *Id.* Section 108(g)(1)(C). 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.'' *Id.* Section 108(g)(2)(B). These statutory prohibitions became effective in February 2009. The interim prohibitions remain in effect until the Commission issues a final rule determining whether to make the interim prohibitions permanent. *Id.* Section 108(b)(1).

2. Chronic Hazard Advisory Panel

Section 108(b)(2) of the CPSIA directs the CPSC 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(g) of the CPSIA defines a ''phthalate alternative'' as ''any common substitute to a phthalate, alternative material to a phthalate, or alternative plasticizer.''

Section 28 of the Consumer Product Safety Act (CPSA), requires a CHAP to consist of seven independent scientists appointed by the Commission from a list of nominees nominated by the president of the National Academy of Sciences (NAS). CHAP members 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(b)(2). Additionally, CHAP members must not receive compensation from, or have any substantial financial interest in, any manufacturer, distributor, or retailer of a consumer product. *Id.* at 15 U.S.C. 2077(b)(1). Members of the CHAP may not be employed by the federal government, except the National Institutes of Health, the National Toxicology Program, or the National Center for Toxicological Research. *Id.*

Section 108(b)(2) directs the CHAP to recommend to the Commission whether any phthalates or phthalate alternatives other than those permanently prohibited should be declared banned hazardous substances. Specifically, section 108(b)(2) directs the CHAP to:

Complete an examination of the full range of phthalates that are used in products for children and shall—

- 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 on 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.

CPSIA section 108(b)(2)(B). The CHAP's examinations must be conducted *de novo,* and the findings and conclusions of any previous CHAP on this issue and other studies conducted by the Commission must be reviewed by the CHAP but are not to be considered determinative. *Id.*

Section 108(b)(2)(C) of the CPSIA requires the CHAP to complete its examination and final report within 2 years of the CHAP's appointment. In the final report, the CHAP is required to recommend to the Commission whether any ''phthalates (or combinations of phthalates)'' in addition to those permanently prohibited, including the phthalates covered by the interim prohibition or phthalate alternatives, should be declared banned hazardous substances.

3. Rulemaking

Section 108(b)(3) of the CPSIA requires the Commission to promulgate a final rule, pursuant to section 553 of the Administrative Procedure Act (APA), not later than 180 days after the Commission receives the final CHAP report. The Commission must ''determine, based on such report, whether to continue in effect the [interim] prohibition . . ., in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety . . .'' CPSIA section 108(b)(3)(A). Additionally, the Commission must ''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.'' *Id.* Section 108(b)(3)(B).

B. CHAP Process

The CHAP held its first meeting on April 14–15, 2010. The CHAP met in public session seven times and met via teleconference (also open to the public) six times.[1] The meetings were held at the CPSC offices in Bethesda, MD, and also aired via webcast. A record of the CHAP's public meetings, including video recordings and information submitted to the CHAP, in addition to

[1] The CHAP met in one closed meeting as part of the peer review process, January 28–29, 2014.

the final CHAP report, are available on the CPSC Web site.[2]

At a July 26–28, 2010 meeting, the CHAP heard testimony from the public, including from federal agency representatives who discussed federal activities on phthalates. The CHAP also invited experts to present their latest research findings at the July 2010 and subsequent meetings. Members of the public who presented testimony to the CHAP at the July 2010 meeting included manufacturers of phthalates and phthalate alternatives, as well as representatives of nongovernmental organizations. In addition to oral testimony, the manufacturers and other interested parties submitted an extensive volume of toxicity and other information to the CHAP and/or the CPSC staff. All submissions given to CPSC staff were provided to the CHAP.

Although the CPSIA did not require peer review of the CHAP's work, at the CHAP's request, four independent scientists peer-reviewed the draft CHAP report. CPSC staff applied the same criteria for selecting the peer reviewers as is required for the CHAP members. Peer reviewers were nominated by the National Academy of Sciences. Peer reviewers did not receive compensation from, nor did they have a substantial financial interest in, any of the manufacturers of the products under consideration. In addition, the peer reviewers were not employed by the federal government, except the National Institutes of Health, the National Toxicology Program, or the National Center for Toxicological Research. The CHAP report was due to the Commission on April 13, 2012 based on the requirement in section 108(b)(2)(C) of the CPSIA. The CHAP submitted the final report to the Commission on July 18, 2014.

C. The Proposed Rule

The Commission proposes this rule in accordance with the CPSIA's direction to follow section 553 of the APA. CPSC staff reviewed the CHAP report and provided the Commission with a briefing package that assessed the CHAP report and made recommendations for a notice of proposed rulemaking (NPR). The staff's briefing package is available on CPSC's Web site at *http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2015/ProposedRule-Phthalates-112514.pdf.* As discussed in this preamble, the Commission agrees with the staff's recommendations.

[2] *http://www.cpsc.gov/chap.*

II. CHAP Report

A. Summary of the CHAP Report

1. Health Effects in Animals

As staff explained in their briefing package, the CHAP reviewed all of the potential health effects of phthalates. Although phthalates are associated with a number of adverse health effects, the CHAP considered effects on male reproductive development to be the most relevant for human risk assessment. This is, in part, because these effects constitute the ''most sensitive and most extensively studied endpoint'' for phthalates. (CHAP 2014; pp. 1–2, 12–13). In support of this decision, the CHAP noted that a 2008 National Research Council (NRC) report also recommended using male reproductive development effects as the basis for a cumulative risk assessment of phthalates. (CHAP, 2014; NRC, 2008). The CHAP explained that exposing pregnant female rodents to certain phthalates causes a suite of effects on the male reproductive tract in male pups, known as the ''phthalate syndrome in rats.'' The syndrome includes: malformations of the testes, prostate, and penis (hypospadias); undescended testes; reduced anogenital distance (AGD); and retention of nipples.[3] Male pups also have reduced fertility as adults. The incidence and severity of these effects increases with dose. In addition, the male fetus is the most sensitive, followed by juveniles and adults. The phthalate syndrome effects are due largely to the suppression of testosterone production (Foster 2006), as well as reduced expression of the insulin-like hormone 3 gene (CHAP 2014; Wilson et al. 2004; p. 16). Thus, the CHAP refers to these effects as ''antiandrogenic'' to reflect their effect on testosterone production. Not all phthalates cause antiandrogenic effects; only phthalates meeting certain structural criteria, termed ''active'' phthalates, are associated with the phthalate syndrome. (CHAP 2014; p. 16; Foster et al. 1980; Gray et al. 2000).

The CHAP, citing published reports, noted (CHAP 2014, p.2) an additional reason for focusing on effects on male reproductive development: is empirical evidence demonstrates that the effects of active phthalates on male reproductive development are additive (Hannas et al. 2011b; 2012; Howdeshell et al. 2007; 2008). That is, exposures to multiple phthalates at lower doses act in concert to produce the same effect as a higher dose of a single phthalate. The additive effects of different phthalates are significant because humans are exposed to multiple phthalates simultaneously. (CHAP 2014; p. 2). The CHAP also noted that, in addition to phthalates, other chemicals, including certain pesticides and preservatives, add to the male reproductive effects of phthalates. (CHAP 2014; pp. 26–27, p. D–26; Rider et al. 2010).

The CHAP also reviewed available toxicity data on six phthalate alternatives. (CHAP 2014; p. 22). The CHAP found none of the alternatives to be antiandrogenic, that is, causing effects consistent with the phthalate syndrome. Therefore, because these phthalate alternatives did not contribute to the cumulative antiandrogenic effect, the CHAP assessed the potential risks of phthalate alternatives, as well as non-antiandrogenic phthalates, in isolation. These assessments were based on the most sensitive health endpoint[4] for each chemical, such as liver toxicity, for assessing risk. (CHAP 2014, pp. 121–142).

2. Health Effects in Humans

The CHAP noted that the phthalate syndrome in rats resembles the ''testicular dysgenesis syndrome'' (TDS) in humans. (CHAP 2014, pp. 2, 28). TDS includes poor semen quality, reduced fertility, testicular cancer, undescended testes, and hypospadias.[5] After reviewing all of the available studies on associations between phthalate exposure and human health (CHAP 2014, pp. 27–33; Appendix C), the CHAP noted that two of three studies found an association between prenatal or neonatal phthalate exposure and reduced anogenital distance[6] in male infants. Several studies also found associations between prenatal or neonatal exposure and neurobehavioral effects in children. These effects included reductions in mental and psychomotor development and increases in attention deficits and behavioral symptoms. The CHAP cited several studies that found associations between phthalate exposure in adult males and reduced sperm quality and infertility. (Reviewed in CHAP 2014, p. C–8).

Based on this information, the CHAP concluded that there is a growing body of studies reporting associations between phthalate exposure and human health. (CHAP 2014, p. 27). Many of the reported health effects are consistent with testicular dysgenesis syndrome in

[3] Nipple retention does not normally occur in rodents, as it does in humans.

[4] That is, the effect occurring at the lowest dose.

[5] A malformation of the penis.

[6] Distance between the anus and genitals, which is greater in males than in females.

humans. (CHAP 2014, p. 28). However, the CHAP acknowledged the limitations of these studies, noting that the epidemiological studies were not designed specifically to provide information on sources of exposure or the relative contributions of different phthalates. Furthermore, the studies were limited by simultaneous human exposure to multiple phthalates and other environmental chemicals and by the study design. (CHAP 2014, pp. 2–3).

3. Human Phthalate Exposure

The CHAP assessed human exposure to phthalates by two different, but complementary, methods: human biomonitoring (HBM) and exposure scenario analysis. HBM relies on measurements of phthalate metabolites in human urine to estimate phthalate exposure. (CHAP 2014, pp. 34–48; Appendix D). The HBM method provides good estimates of total exposure based on empirical measurements (CHAP 2014, p. 6, 75, E1–38; Clark et al. 2011), but the method does not provide information on sources of exposure. The CHAP used two data sources for HBM—each will be described in turn. The National Human Health and Nutrition Survey (NHANES), which is conducted by the U.S. Department of Health and Human Services, periodically measures phthalates and other chemicals in human urine and blood in a statistically representative sample of thousands of U.S. residents. The CHAP used data from NHANES to estimate daily exposures to various phthalates in pregnant women and women of reproductive age. (CDC 2012). NHANES does not measure phthalate metabolites in children younger than 6 years old. Therefore, the CHAP used measurements from an NIH- and EPA-funded study of mother-child pairs, the Study for Future Families (SFF), to obtain exposure estimates for infants. (Sathyanarayana et al. 2008a; 2008b). The SFF study also provided additional data for the mothers, both before and after they gave birth.

The CHAP also found, based on the HBM studies, that ''exposure to phthalates in the United States (as worldwide) is omnipresent.'' (CHAP 2014, p. 37). Virtually all Americans are exposed simultaneously to multiple phthalates. (CHAP 2014, p. 37). Based on NHANES data, pregnant women have median exposures that are roughly similar to those of women of reproductive age. (CHAP 2014, Table 2.7, page 45). Based on the SFF data, infants have threefold to fourfold greater median exposures than their mothers. (CHAP 2014, Table 2.7, p. 45).

The second method that the CHAP used to assess human exposure was through analyzing numerous exposure scenarios. The CHAP used the scenario-based method because that method provides information on sources of exposure. (CHAP 2014, pp. 49–60, Appendix E1). Thus, the scenario-based method complements the information obtained from the HBM method, which provides estimates of total exposure. The CHAP estimated exposure from individual sources using data on phthalate levels in products and environmental media, migration rates, and product use information. (CHAP 2014, pp. 49–60; Appendices, E1, E3).

For most phthalates, the CHAP found that food, rather than children's toys or child care articles, provides the primary source of exposure to both women and children. (CHAP 2014, pp. 52–53, Table 2.1). For example, DINP exposure to infants and children is primarily from diet, although mouthing of DINP-containing toys or contact with DINP-containing toys and child care articles may contribute to the overall exposure. (CHAP 2014, Figure 2.1, page 59; Table E1–23, page E1–32; and Table E1–24, page E1–36). The CHAP also found that personal care products (cosmetics) are a major source of exposure to diethyl phthalate (DEP) and dibutyl phthalate (DBP) (*id.*). Indoor air and household dust are also major sources of diethyl phthalate (DEP), dibutyl phthalate (DBP), and butyl benzyl phthalate (BBP) (*id.*).

4. Risk

a. Cumulative Risk Assessment Generally

Section 108(b)(2)(B)(iv) of the CPSIA directed the CHAP specifically to ''consider the cumulative effect of total exposure to phthalates, both from children's products and from other sources.''

Cumulative risk assessment (CRA) generally refers to the combined effects of multiple environmental stressors. (Sexton and Hattis, 2007). CRA may combine different types of hazards, such as air pollution combined with psychological stress. More commonly, CRA includes mixtures of different chemicals. Chemical mixtures may be complex mixtures, such as air pollution or combustion emissions. Mixtures may include unrelated chemicals or, in the case of phthalates, a family of closely related chemicals. Human exposure to phthalates is a ''coincidental'' exposure, meaning that different individuals are exposed to phthalates in different proportions.

Section 108(b)(2)(B)(ii) of the CPSIA also directed the CHAP to ''consider the potential health effects of each of [the specified] phthalates both in isolation and in combination with other phthalates.'' Components of a mixture may interact in different ways regarding health risks. For example, suppose two chemicals produce the same health effect in animals. Furthermore, assume that 1 mg of *A* affects 10 percent of animals tested, and 1 mg of *B* affects 15 percent of animals. If the effects of the mixture are ''dose additive,'' then 25 percent of animals would be affected. In the case of phthalates, there is evidence in animal studies that the effects are ''dose additive.'' (Howdeshell *et al.,* 2007; Howdeshell *et al.,* 2008; Hannas *et al.,* 2011b; Hannas *et al.,* 2012). In other words, the whole equals the sum of its parts. Dose additivity does not necessarily apply in all cases. With other mixtures, the effects could be less than, or more than, dose additive. The process of performing a CRA differs in several respects from that of single-chemical risk assessment. One key difference is the choice of health endpoint. Risk assessments for chemicals in isolation are usually based on the most sensitive health effect. The most sensitive endpoint is the one that is observed at the lowest dose or has the greatest risk at a given dose. CRAs are generally based on a health effect that is common to the components of the mixture. The common health endpoint is not necessarily the most sensitive health endpoint for each of the mixture components.

b. Cumulative Risk and Risk in Isolation—Hazard Index

As required by section 108(b)(2)(B)(ii) of the CPSIA, the CHAP assessed the potential risks from phthalates in isolation and in combination with other phthalates, that is, cumulative risk. The CHAP chose antiandrogenic effects on male reproductive development as the focus of the CHAP's cumulative risk assessment. Only antiandrogenic (*i.e.,* active) phthalates cause male reproductive developmental effects and, therefore, only active phthalates contribute to the cumulative risk of male developmental reproductive effects. (CHAP 2014, pp. 61–70). The CHAP applied the hazard index (HI) approach to assess the cumulative risk for antiandrogenic effects in males. The HI approach is widely used for chemical mixtures and other cumulative risk assessments. (Kortenkamp and Faust 2010; NRC 2008; Teuschler and Hertzberg 1995). Calculating the HI is a two-step process:

1. Calculate the ''hazard quotient'' (HQ) for each phthalate. The HQ is the exposure divided by the ''potency estimate for antiandrogenicity'' (PEAA).[7] The PEAA is an estimate of the level of exposure at which the risk of antiandrogenic effects is considered negligible. If the HQ is greater than one for a given phthalate, there may be a concern for antiandrogenic effects in the exposed population due to the effect of an individual phthalate.

$$HQ = \frac{Exposure}{PEAA} \quad (1)$$

2. The hazard index (HI) is the sum of the hazard quotients (HQs) for the phthalates of interest. If the HI is greater than one, there may be a concern for antiandrogenic effects in the exposed population due to the cumulative effects of phthalates.[8]

$$HI = HQ_1 + HQ_2 \cdots + HQ_n \quad (2)$$

The CHAP calculated the HI for each individual in two populations of interest: (1) Pregnant women, and (2) children up to 36 months old. Pregnant women represent exposure to the fetus, which is considered more sensitive than newborns, children, and adults.

The CHAP used three sets of PEAAs that were derived by different approaches. (CHAP 2014, p. 62, 64; Table 2.15). This was done to assess the effect of using different PEAAs on the overall conclusions. The CHAP report refers to these as cases 1, 2, and 3:

- Case 1: Published values used from a cumulative risk assessment for phthalates (Kortenkamp and Faust 2010);
- Case 2: Values derived by the CHAP based on relative potency comparisons across chemicals from the same study (Hannas et al. 2011b); and
- Case 3: Values from the CHAP's *de novo* literature review of reproductive and developmental endpoints based on the no observed adverse effect levels (NOAEL) in Table 2.1 of the CHAP report.

Results for the three sets of PEAAs were roughly similar; HIs were within 2-fold, although HIs were slightly lower for Case 3. (CHAP 2014, p. 65).

Using NHANES data, the CHAP found that pregnant women had median HIs of about 0.1 (0.09 to 0.14), while the 95th percentile HIs were about 5, depending on which set of PEAAs was used. Roughly 10 percent of pregnant women had HIs greater than one. (CHAP 2014, Table 2.16).

Using SFF data, the CHAP found that the mothers had median HIs about 0.1 (0.06 to 0.11), while the 95th percentiles were less than one (0.33 to 0.73). (CHAP 2014, Table 2.16). There was little difference between pre- and post-natal exposures. The CHAP report shows that up to 5 percent of women had HIs greater than one. For infants, HIs were about twofold greater than their mothers. Infants had median HIs about 0.2, while the 95th percentiles were between 0.5 and 1.0. About 5 percent of infants had HIs greater than one.

Based on these results, the CHAP concluded that there may be a concern for adverse effects from the cumulative effects of phthalates in individuals with a hazard index greater than one, representing up to 10 percent of pregnant women and up to 5 percent of infants. (CHAP 2014, p. 65).

Looking at the HQs for individual phthalates, the CHAP concluded: ''Clearly, the hazard quotient for DEHP dominates the calculation of the HI, as expected, with high exposure levels and one of the lowest PEAAs.'' (CHAP 2014, p. 65). Thus, DEHP (which the CPSIA permanently prohibits from use in children's toys and child care articles) contributes the most to the cumulative risk. (CHAP 2014, Table 2.16). This is due to a combination of exposure and potency. (CHAP 2014, p. 65). The CHAP found that the median HQs for DEHP range from 0.1 to 0.2, with 95th percentiles up to 12. DEHP contributed between 50 (case 2) and 90 percent (case 1) of the median HI in pregnant women (summarized in Table 1). For comparison, DBP, BBP, and DINP each contributed up to 8 percent of the HI in pregnant women (Table 1).

TABLE 1—PERCENT CONTRIBUTION OF INDIVIDUAL PHTHALATES TO THE CUMULATIVE RISK [a]

	Case 1	Case 2	Case 3
NHANES Pregnant Women:			
Diisobutyl phthalate, DIBP	0.7	2.3	<1.1
Dibutyl phthalate, DBP	7.1	7.7	1.1
Butyl benzyl phthalate, BBP	0.7	7.7	1.1
Di(2-ethylhexyl) phthalate, DEHP	85.7	53.8	77.8
Diisononyl phthalate, DINP	0.7	7.7	2.2
SFF Infants:			
Diisobutyl phthalate, DIBP	0.9	5.0	<0.8
Dibutyl phthalate, DBP	9.1	15.0	2.5
Butyl benzyl phthalate, BBP	18.2	10.0	2.5
Di(2-ethylhexyl) phthalate, DEHP	81.8	55.0	91.7
Diisononyl phthalate, DINP	0.9	15.0	8.3

[a] Calculated from data in CHAP, 2014, Table 2.16. Based on median exposures.

[7] The PEAA is essentially similar to a ''reference dose'' (RfD) or ''acceptable daily intake'' (ADI), which are commonly used terms, except that the PEAA applies only to antiandrogenic effects. The RfD and ADI generally apply to the most sensitive health effect of a given chemical. RfD and ADI are estimates of a dose at which one could be exposed to for up a lifetime with a negligible risk of adverse effects.

[8] Having a HI greater than one does not necessarily mean that adverse effects will occur; however, this possibility cannot be ruled out.

In infants, DEHP also contributed the most to the cumulative risk. DEHP contributed between 50 and 90 percent of the median HI (Table 1). However, the relative contributions of other phthalates were somewhat greater in infants than in pregnant women. DINP contributed between 1 percent (case 1) and 15 percent (case 2) of the median HI. DBP and BBP contributed between 2 percent and 18 percent of the HI. (Table 1).

According to the CHAP, these results indicate that DEHP contributed between 50 and 90 percent of the cumulative risk from exposure to antiandrogenic phthalates. The HQs of DBP, BBP, and DINP were similar. (CHAP 2014, p. 65). DINP contributed between 1 percent and 15 percent of the cumulative risk. (Table 1).

Furthermore, the CHAP noted that consumers are exposed to other types of chemicals, such as parabens [9] and certain pesticides that also add to the total risk of antiandrogenic effects. (CHAP 2014, p. D–26). These additional chemicals may increase the risk slightly or, as a worst case, double the percentage of pregnant women with an HI greater than one. (*Id.*). The CHAP did not have data to estimate the effects of the additional chemicals in infants. (*Id.*).

c. Risks in Isolation—Margin of Exposure

As required by section 108(b)(2)(B)(ii) of the CPSIA, the CHAP also considered the risks of phthalates and phthalate alternatives in isolation. Risks in isolation are of particular importance for the phthalate alternatives and the non-antiandrogenic phthalates. The CHAP did not include these compounds in the cumulative risk assessment because they are not antiandrogenic, and therefore, do not contribute to the cumulative risk for male reproductive developmental effects. The CHAP used a margin of exposure (MoE) approach to assess the risks in isolation. (CHAP 2014, p. 4). The MoE is the ''no observed adverse effect level'' (NOAEL) of the most sensitive endpoint in animal studies divided by the estimated exposure in humans. Higher MoEs indicate lower risks. Generally, MoEs greater than 100 to 1,000 are adequate to protect public health. (CHAP 2014, p. 20).

DIDP and DNOP are subject to the interim prohibition on phthalates under section 108 of the CPSIA. The CHAP concluded that they are not antiandrogenic; their most sensitive health effect is liver toxicity. (CHAP 2014, pp. 94, 104). MoEs for DIDP range from 300 (modeling using conservative assumptions) to 10,000 (biomonitoring). (CHAP 2014, pp. 24, 104). DNOP was largely not detectable in biomonitoring studies; MoEs based on modeling (with conservative assumptions) are 1,800 or more. (CHAP 2014, pp. 24, 95). Because the MoEs in humans are likely to be very high, and thus adequate to protect public health, the CHAP did not find compelling data to justify maintaining the current interim bans on the use of DNOP and DIDP in children's toys and child care articles. The CHAP recommended that the interim prohibitions on DNOP and DIDP be lifted. (CHAP 2014, pp. 95, 104).

In addition to noting DINP's antiandrogenic characteristics, the CHAP also stated that DINP is associated with liver toxicity. (CHAP 2014, pp. 95–99). Furthermore, liver toxicity is the most sensitive health effect for DINP. Thus, to assess the adverse effects of DINP in isolation, the CHAP considered liver toxicity to calculate MoEs. The CHAP stated: ''Using the NOAEL of 15 mg/kg-d for systemic toxicity [liver toxicity], the MoE for infants ranged from 830 to 4,200. The MoE for women ranged from 1,600 to 15,000. MoEs exceeding 100–1000 are considered adequate for public health.'' (CHAP 2014, p. 99). Despite high MoEs associated with DINP, the CHAP nevertheless recommended a permanent ban on DINP in children's toys and child care articles, concluding that: ''DINP does induce antiandrogenic effects in animals, although at levels below that for other active phthalates, and therefore can contribute to the cumulative risk from other antiandrogenic phthalates.''

Exposure data on many of the nonregulated phthalates are limited. Considered in isolation, MoEs for DIBP were 40,000 or more. (CHAP 2014, p. 111). However, DIBP contributes to the cumulative risk, due to its antiandrogencity.

The CHAP noted that exposure data on phthalate alternatives are also limited. Estimates of mouthing exposure to children up to 3 years old are available for TPIB, DEHT, ATBC, and DINX. MoEs for mouthing exposure for TPIB, DEHT, ATBC, and DINX are greater than 5,000. (CHAP 2014, pp. 121–142). However, DEHT, ATBC, TOTM, and DEHA are high production volume chemicals. (*Id.*). TPIB, DEHA, DEHT, ATBC, and TOTM are used in many types of products found in the home. Thus, as the CHAP noted, human exposure may occur from other sources, in addition to mouthing by children. (*Id.*).

The CHAP found that, among the permanently banned phthalates, DBP and BBP had MoEs of 5,000 or more. (CHAP 2014, pp. 82–88). For DEHP, MoEs ranged from 30 to 3,000. (CHAP 2014, p. 91). The 95th percentile exposure to pregnant women had a MoE of 30, which is less than the minimum value of 100, based on biomonitoring. The 95th percentile exposure in infants had a MoE of 100, based on modeling and 170 for biomonitoring. (*Id.*). Thus, the CHAP found that some highly exposed pregnant women, more than 5 percent of the population, had DEHP exposures that may present a concern for adverse health effects. (*Id.,* p. 65). Furthermore, the CHAP noted that DEHP contributes more than half of the cumulative risk from phthalates. (Table 1; CHAP 2014, p. 65).

B. The CHAP's Recommendations to the Commission

1. Recommendations on Phthalates Permanently Prohibited by the CPSIA

The CHAP did not recommend any Commission action on DBP, BBP, or DEHP because these phthalates are already permanently prohibited by the CPSIA. (CHAP 2014, pp. 83–91). However, the CHAP recommended that U.S. agencies responsible for DBP, BBP, and DEHP exposures from all sources conduct the necessary risk assessments with a view to supporting risk management steps. (CHAP 2014, pp. 83–91).

2. Recommendations on Phthalates Prohibited by the CPSIA on an Interim Basis

a. Diisononyl Phthalate (DINP)

The CHAP recommended that DINP at levels greater than 0.1 percent should be permanently prohibited from use in children's toys and child care articles. (CHAP 2014, pp. 95–99). Although DINP is less potent than DEHP, or other active phthalates, the CHAP reasoned that DINP is antiandrogenic and contributes to the cumulative risk from phthalates. (*Id.*).

b. Di-n-octyl Phthalate (DNOP)

The CHAP concluded: ''DNOP does not appear to possess antiandrogenic potential; nonetheless, the CHAP is aware that DNOP is a potential developmental toxicant, causing supernumerary ribs, and a potential systemic toxicant, causing adverse effects on the liver, thyroid, immune system, and kidney. However, because the MoE in humans is likely to be very high, the CHAP does not find

[9] Parabens are antimicrobials commonly used in cosmetics.

compelling data to justify maintaining the current interim ban on the use of DNOP in children's toys and child care articles. Therefore, the CHAP recommends that the current ban on DNOP be lifted.'' (CHAP 2014, p. 95).

c. Diisodecyl Phthalate (DIDP)

The CHAP concluded: ''DIDP does not appear to possess antiandrogenic potential; nonetheless, the CHAP is aware that DIDP is a potential developmental toxicant, causing supernumerary ribs, and a potential systemic toxicant, causing adverse effects on the liver and kidney. However, because DIDP is not considered in a cumulative risk with other antiandrogens, its MoE in humans is considered likely to be relatively high. The CHAP did not find compelling data to justify maintaining the current interim ban on the use of DIDP in children's toys and child care articles. Therefore, the CHAP recommends that the current ban on DIDP be lifted . . .'' (CHAP 2014, pp. 100–105).

3. Recommendations on Phthalates Not Currently Prohibited by the CPSIA

The CHAP recommended that the Commission permanently prohibit the use of the following phthalates at levels greater than 0.1 percent in children's toys and child care articles: diisobutyl phthalate (DIBP) (CHAP 2014, pp. 110–112), di-*n*-pentyl phthalate (DPENP) (*id.,* pp. 112–113), di-*n*-hexyl phthalate (DHEXP) (*id.,* pp. 114–116), and dicyclohexyl phthalate (DCHP) (*id.,* pp. 116–118). These are antiandrogenic phthalates that adversely affect male reproduction development. The CHAP noted that current exposures to DIBP, DPENP, DHEXP, and DCHP are low and, therefore, ''. . . do not indicate a high level of concern.'' (CHAP 2014, p. 8). However, because they are active phthalates, they contribute to the cumulative risk from other antiandrogenic phthalates. Allowing their use in toys and child care articles would increase the cumulative risk to children. The CHAP also noted that DPENP is the most potent antiandrogenic phthalate. (CHAP 2014, pp. 112–113).

In addition, the CHAP recommended that the Commission prohibit the use of diisooctyl phthalate (DIOP) on an interim basis at levels greater than 0.1 percent until sufficient data are available. (CHAP 2014, pp. 118–119). DIOP has been detected, although rarely, in child care products. (Chen 1998). Although toxicity data on DIOP are limited, the CHAP concluded, ''. . . the isomeric structure of DIOP suggests that DIOP is within the range of the structure-activity characteristics associated with antiandrogenic activity.'' (CHAP 2014, pp. 118–119).

The CHAP did not recommend to CPSC any action on the use of di(2-propyl) heptyl phthalate (DPHP) in toys and child care articles, at this time. (CHAP 2014, pp. 120–121). However, the CHAP recommended that appropriate federal agencies obtain toxicity and exposure data for DPHP. The CHAP noted that most of the toxicity data are unpublished and were not available to the CHAP. DPHP does not appear to be antiandrogenic, based on limited information. However, the CHAP noted: ''Currently, there is an undetermined frequency and duration of exposures; however, analytical methods cannot differentiate DPHP metabolites from DIDP metabolites because they are closely related.'' The CHAP noted further that production levels of DPHP have increased in recent years, suggesting that human exposure may also be increasing. (*Id.,* p. 120).

The CHAP did not recommend Commission action on dimethyl phthalate (DMP) (CHAP 2014, pp. 105–107) or diethyl phthalate (DEP). (*Id.,* pp. 107–109). However, the CHAP recommended that the U.S. federal agencies responsible for DEP exposures from food, pharmaceuticals, and personal care products perform the necessary risk assessments with a view to supporting risk management steps. (*Id.,* p. 109).

4. Recommendations on Phthalate Alternatives

The CHAP found that data on the six phthalate alternatives reviewed by the CHAP are generally limited. (CHAP 2014, pp. 121–142). The CHAP noted that CPSC staff has found four of the alternatives—acetyl tributyl citrate (ATBC); di(2-ethylhexyl) terephthalate (DEHT); 1,2-cyclohexanedicarboxylic acid, diisononyl ester (DINX); and 2,2,4-trimethyl-1,3 pentanediol diisobutyrate (TPIB)—in many children's toys and child-care articles. (Dreyfus 2010). Two of the alternatives—di(2-ethylhexyl) adipate (DEHA) and tris(2-ethylhexyl) trimellitate (TOTM)—have not been identified by CPSC staff in toys or child care articles, thus far. (Dreyfus, 2010). For all of the phthalate alternatives, the CHAP recommended obtaining additional data on exposure from all sources because many of the alternatives have multiple uses. The CHAP also recommended obtaining additional toxicity data on TPIB, ATBC, DINX, and TOTM.

III. CPSC Staff's Assessment of the CHAP Report

CPSC staff assessed the CHAP report, examining whether the CHAP met the requirements of the CHAP's charge and whether the CHAP report was otherwise scientifically sound in its methodology, findings and recommendations.

A. Charge to the CHAP

Section 108(b)(2)(B) of the CPSIA required the CHAP to ''. . . complete an examination of the full range of phthalates that are used in products for children. . . .'' To meet its charge, the CHAP reviewed all of the available toxicity data on 14 phthalates. The 14 phthalates included the six phthalates set forth in the CPSIA and eight additional phthalates selected on the basis of toxicity (*i.e.,* male developmental reproductive effects) and exposure potential (*e.g.,* availability of human biomonitoring data). The CPSIA also required the CHAP to consider the following:

- ''Examine all of the potential health effects (including endocrine disrupting effects) of the full range of phthalates.'' The CHAP examined all of the health effects associated with phthalates, including carcinogenicity, liver toxicity, and reproductive/developmental toxicity. (CHAP 2014, pp. 13–29; Appendices A–C). As discussed in detail below, the CHAP conducted its cumulative risk assessment based on male developmental reproductive effects. The phthalate syndrome is due largely to the inhibition of testosterone production in the male fetus, which is a type of endocrine disruption. The CHAP's cumulative risk assessment focused on male developmental reproductive effects. (CHAP 2014, pp. 69–70).
- ''Consider the potential health effects of each of these phthalates both in isolation and in combination with other phthalates.'' To assess the potential health effects of phthalates in isolation, the CHAP used the MoE based on the most sensitive endpoint for each phthalate. (CHAP 2014, pp. 69–70). To assess the potential health effects of phthalates in combination, the CHAP conducted a cumulative risk assessment, based on male developmental reproductive effects. (*Id.*).
- ''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.'' The CHAP assessed exposure by two complementary methods. Biomonitoring studies provide good

estimates of total exposure to phthalates but do not provide information on the sources of exposure. (CHAP 2014, pp. 34–48). The scenario-based approach estimates exposure to specific products and sources of exposure, including toys, child care articles, and personal care products. (CHAP 2014, pp. 49–60; Appendices E1–E3).

• ''Consider the cumulative effect of total exposure to phthalates, both from children's products and from other sources, such as personal care products.'' The CHAP conducted a cumulative risk assessment, based on total phthalate exposure, as estimated from biomonitoring studies. (CHAP 2014; pp. 61–68; Appendix D).

• ''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.'' The CHAP reviewed all of the available data on phthalates, including publications in peer-reviewed scientific journals; reports submitted by manufacturers to the U.S. EPA; [10] and authoritative reviews from agencies such as the Agency for Toxic Substances and Disease Registry (ATSDR), the European Chemical Agency (ECHA), the International Agency for Research on Cancer (IARC), Center for the Evaluation of Research on Human Reproduction (CERHR), National Toxicology Program (NTP); and the National Research Council (NRC). (CHAP, 2014, p. 12). In addition, the CHAP invited scientific experts to present their latest research in areas such as biomonitoring, epidemiology, phthalate syndrome, toxicology of phthalates mixtures, phthalates mode of action, and species differences. The CHAP also invited a co-author of an NRC report (NRC, 2009) to present the NRC panel's perspective on risk assessment methodology, especially as applied to phthalates risk assessment. Furthermore, the CHAP heard testimony from federal agency scientists, as well as scientists representing manufacturers of phthalates alternatives.

• ''Consider the health effects of phthalates not only from ingestion but also as a result of dermal, hand-to-mouth, or other exposures.'' The CHAP estimated phthalate exposure by two methods. Biomonitoring studies estimated total exposure, regardless of source or route of exposure. (CHAP 2014, pp. 34–48). The scenario-based approach estimated exposure to specific products and sources of exposure by all routes of exposure, including oral, dermal, inhalation, and hand-to-mouth. (CHAP 2014, pp. 49–60; Appendices E1–E3).

• ''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.'' For antiandrogenic phthalates, the CHAP derived reference doses (PEAAs) that were specific for male developmental reproductive effects. (CHAP 2014, Table 2.15). For non-antiandrogenic phthalates and phthalate alternatives, the CHAP selected appropriate NOAELs that were based on the most sensitive endpoint. (*Id.,* pp. 79–142, Appendices A–B). The CHAP also recommended the use of additional uncertainty factors (safety factors) for selected compounds where the database was limited (ATBC and DEHA).

• ''Consider possible similar health effects of phthalate alternatives used in children's toys and child care articles.'' The CHAP considered all health effects associated with six phthalate alternatives and, where sufficient data were available, estimated the potential health risks based on the most sensitive health endpoint. (CHAP, 2014, pp. 121–142, Appendices A–B).

Furthermore, section 108(b)(2)(B) required the CHAP to perform its examination *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.'' Although the CHAP considered previous CHAP reports and CPSC staff reports, the CHAP also conducted its own review of the scientific literature (including studies conducted by phthalate manufacturers) and invited experts to present their most recent research. (CHAP, 2014, p. 12).

Finally, section 108(b)(2)(C) required the CHAP to ''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.'' The CHAP completed its charge by making recommendations to prohibit additional phthalates (*id.,* pp. 110–117), make the interim prohibition of DINP permanent (*id.,* pp. 95–99), lift the interim prohibitions of DNOP (*id.,* pp. 91–94) and DIDP (*id.,* pp. 100–104), and prohibit DIOP on an interim basis (*id.,* pp. 118–119).

The staff concluded that the CHAP fully met the charge in section 108 of the CPSIA.

B. Selection of Phthalates and Phthalates Alternatives

The CHAP selected phthalates for inclusion in its examination based on the following non-exclusive criteria: inclusion in the CPSIA, availability of human biomonitoring data, potential for exposure, and evidence of male developmental reproductive toxicity. (CHAP, 2014, pp. 22–23):

• Six phthalates subject to the CPSIA—DBP, BBP, DEHP, DNOP, DINP, and DIDP;

• Availability of biomonitoring data—DMP, DEP, DIBP, in addition to the six phthalates subject to the CPSIA;

• Increasing production, which suggests increasing exposure—DPHP; and

• Ability to induce male developmental reproductive effects—DIBP, DPENP, DHEXP, and DCHP. (*Id.,* p. 16).

The CPSC staff concurs with the CHAP's selection of phthalates because the 14 phthalates that the CHAP reviewed include phthalates with high exposure potential and phthalates that contribute to the cumulative risk for male developmental reproductive effects.

The CHAP selected six phthalate alternatives for study, either because they were known to be used in children's toys and child care articles (ATBC, DEHT, DINX, TPIB) (Dreyfus 2010) or because they were considered likely to be used (DEHA, TOTM) (CHAP, 2014; p. 23; Versar/SRC, 2010a). CPSC staff recognizes that there is a broad range of potential phthalate alternatives (Versar/SRC, 2010a), including phthalates that are not prohibited by the CPSIA. Nonetheless, CPSC staff agrees with the CHAP's choice of phthalate alternatives because it includes all of the non-phthalate plasticizers known to be used in toys and child care articles (Dreyfus 2010; TAB B), as well as other commonly used plasticizers. After the CHAP completed its report, CPSC staff identified DPHP in children's toys; DPHP is an emerging phthalate that was included in the CHAP report.

C. Selection of Health Endpoint

After reviewing all of the available toxicity data on 14 phthalates, the CHAP selected male developmental reproductive toxicity as the critical endpoint for its cumulative risk assessment. (CHAP 2014, pp. 13). CPSC

[10] For example, toxicity data submitted under § 8(e) of the Toxic Substances Control Act.

staff supports the selection of male developmental reproductive toxicity for several reasons. Male developmental reproductive effects in animals are associated with many of the most common phthalates. For most of the active phthalates, these effects are the most sensitive health effect; that is, these effects are observed at lower doses than other adverse health effects (*see* CPSC staff and contractor reports at *http://www.cpsc.gov/chap*). Male developmental reproductive effects (phthalate syndrome) are of particular concern because they may adversely affect human reproduction. Furthermore, the phthalate syndrome in animals bears a striking resemblance to the testicular dysgenesis syndrome in humans. (Skakkebaek et al., 2001).

The availability of empirical evidence also supports the choice to base the cumulative risk assessment on male developmental reproductive effects because such evidence eliminates the need to make critical assumptions that might not be borne out. Specifically, empirical evidence demonstrates that mixtures of active phthalates interact in a dose-additive fashion with respect to developmental male reproductive effects. (Howdeshell et al., 2007, 2008; Hannas et al., 2011b, 2012). Thus, it was not necessary for the CHAP to make any assumptions regarding the effects of phthalate mixtures. Most other health effects of phthalates have not been studied with mixtures; performing a cumulative risk assessment on any other endpoint would require assumptions regarding the mode of action and possible mixture effects.

Furthermore, the male developmental reproductive effects of phthalates are well-studied. (Reviewed in Foster, 2006). These effects, which were first reported in 1980 (Foster et al., 1980), persist into adulthood, even in the absence of further exposure (Barlow and Foster, 2003; Barlow et al., 2004; McIntyre et al., 2001). Similar effects have been reported in multiple mammalian species, including guinea pigs (Gray et al., 1982), mice, (Gray et al., 1982; Moody et al., 2013; Ward et al., 1998), rabbits (Higuchi et al., 2003), and ferrets (Lake et al., 1976). Hamsters were resistant due to slow metabolism of the phthalate ester to the monoester, which is believed to be the active metabolite. Hamsters responded to the monoester, however. (Gray et al., 1982). The observation of similar effects in multiple species demonstrates that these effects are not unique to rats. Based on the CPSC chronic hazard guidelines, the CPSC staff regards active phthalates as ''probably toxic to humans,'' based on ''sufficient evidence'' in animal studies. (CPSC, 1992).

Other authors also have selected male developmental reproductive effects as the basis of cumulative risk assessments of phthalates. The U.S. Environmental Protection Agency (EPA) convened a National Research Council (NRC) committee to consider approaches to assessing the cumulative risk of phthalates; the committee recommended using male developmental reproductive effects as the basis for a cumulative risk assessment. (NRC, 2008). Additionally, two subsequent publications conducted cumulative risk assessments based on male developmental reproductive effects. (Benson, 2009; Christensen et al., 2014).

CPSC staff recognizes that a number of other health effects are associated with phthalates. (Reviewed in Babich, 2010). Although some phthalates are associated with cancer, cancer is only associated with a relatively small number of phthalates, and many of the cancers induced by phthalates are of uncertain relevance to humans. (CHAP, 2001; CPSC, 2002; Klaunig et al., 2003). Other effects, such as liver toxicity, are common to most phthalates; but there are little or no data available on mode of action or the effects of mixtures. Thus, there is less scientific basis for performing a cumulative risk assessment with liver toxicity as the critical endpoint.

Finally, a growing number of epidemiological studies have reported associations of phthalate exposure with adverse health effects in humans. (As cited in CHAP 2014, pp. 27–33, Appendix C). Many of these adverse health effects are consistent with the effects in animal studies. The staff concludes that the epidemiological studies, though not conclusive on their own, provide supporting evidence that the animal studies are relevant to humans.

Therefore, CPSC staff supports using male developmental reproductive effects as the basis for the CHAP's cumulative risk assessment due to the importance of the endpoint; the abundance of data, the known additive nature of phthalate mixtures regarding male developmental reproductive effects, and NRC's recommendation.

D. Methodology

1. Hazard Index

The CHAP chose the hazard index (HI) approach for its cumulative risk assessment because that index is widely accepted for this purpose. (Teuschler and Hertzberg, 1995). The National Research Council (NRC, 2008) recommended this approach for phthalates cumulative risk assessment. Two other publications on phthalates' cumulative risk also used the HI approach. (Benson, 2009; Christensen et al., 2014). ExxonMobil scientists [11] also recommended the HI approach to CPSC in 2010, before the CHAP met for the first time.

The CHAP found that up to 10 percent of pregnant women and up to 5 percent of infants, those with the highest exposure, have a HI greater than one. The portion of the population with a HI greater than one may be at risk for the adverse effects of phthalates. (EPA, 1993). This does not necessarily mean that anyone will suffer adverse effects; however, one cannot rule out the possibility of adverse effects. The greater the HI, the greater the risk.

Although the HI approach is widely accepted, the CHAP introduced a novel process to calculate the HI. The CHAP calculated hazard quotients (HQ) and a HI for each individual in the population of interest (*i.e.,* pregnant women or infants), and then derived distributions of the HI. This was necessary because each individual is exposed to phthalates in differing proportions. For example, some individuals may be exposed almost exclusively to a single phthalate, while others may be exposed to several phthalates in roughly equal proportion. After calculating the HQs and HIs for all individuals, the CHAP then generated frequency distributions for the HI. This process allowed the CHAP to estimate the average and 95th percentile of the HI, as well as the portion of the population with a HI greater than one.

The alternative to the CHAP's approach would be to calculate hazard quotients using summary data on metabolite levels, that is, median and 95th percentile levels (*e.g.,* Benson, 2009). This would have allowed the CHAP to estimate median and 95th percentile hazard quotients for each phthalate. Under this approach, the median hazard quotients are summed to calculate the average HI, which would be roughly similar to the median hazard quotient calculated as above. However, summing the 95th percentile values would overestimate the 95th percentile HI. Therefore, the CHAP introduced this novel process to calculate the hazard quotients and HI more accurately, especially at the upper-bound (*e.g.,* 95th percentile) exposures. Had the CHAP not applied this novel approach, the result would have been an overestimate

[11] ''Approach to Cumulative Risk,'' presented to the CPSC staff, March 2010. *http://www.cpsc.gov/PageFiles/125812/CummRiskExxon03232010.pdf.*

of the 95th percentile exposures and the percentage of pregnant women and infants with HI greater than one.

2. Margin of Exposure

The CHAP chose the margin of exposure (MoE) approach to assess potential health risks for phthalates and phthalate alternatives in isolation. The CHAP chose this approach, in part, due to the recommendation of a NRC report on risk assessment methodology (NRC, 2009). Like the HI approach, the MoE is also widely accepted. (*Id.*).

The MoE is the ratio of the no observed adverse effect level (NOAEL) to the estimated exposure. Generally, a MoE of 100 to 1,000 is needed to protect public health (EPA, 1993). The minimum value of the MoE depends on the compound. If a NOAEL has been established in animal (rather than human) studies, a MoE of 100 or greater is sufficient to protect public health (CPSC, 1992). If a NOAEL has not been established, and a LOAEL (lowest observed adverse effect level) is used instead, or if the available toxicity data for the chemical of interest is inadequate, then a MoE of 1,000 may be required. Based on the knowledge that adequate animal data are available and NOAELS have been established for most of the phthalates, staff believes, consistent with the CHAP report, that a MoE of 100 is sufficient for most of the compounds in the CHAP report. The CHAP recommended an additional uncertainty factor for the phthalate alternatives ATBC and DEHA. Staff concurs that an additional uncertainty factor for ATBC and DEHA is appropriate because of limitations in the available toxicity data.

The MoE approach is conceptually similar to the CPSC staff's default approach for assessing non-cancer risks (CPSC, 1992) and would lead to similar conclusions about risk. CPSC staff approves of the CHAP's selection of the MoE approach to assess the risks of phthalates and phthalate alternatives in isolation because the MoE approach leads to the same conclusion as the staff's default methodology.

3. Exposure Assessment

The CHAP assessed exposure by two complementary methods. Biomonitoring studies provide good estimates of total exposure to phthalates but do not provide information on the sources of exposure. (CHAP 2014, pp. 34–48). The scenario-based approach estimates exposure to specific products and sources of exposure, including toys, child care articles, and personal care products. (CHAP 2014, pp. 49–60; Appendices E1–E3). Staff concurs with the CHAP's use of these approaches to assess exposure for the reasons explained below.

The CHAP used exposure estimates from biomonitoring data as the basis for its cumulative risk assessment. CPSC staff considers biomonitoring to provide the best available estimates of total exposure because biomonitoring is based on empirical measurements in individuals. Furthermore, the NHANES study is a large statistically representative sample. In contrast, the alternative approach, scenario-based estimates, are subject to a number of assumptions and uncertainties. (CHAP, 2014, Appendix E). The method for estimating exposure from biomonitoring data has been in use since 2000 and was developed by an industry scientist. (David, 2000). The CHAP devoted considerable effort to discussing potential errors and bias in this methodology, having invited two experts (Stahlhut and Lorber) to address this issue at the December 2010 meeting. As discussed in the CHAP report, any errors in this methodology are relatively small and are unbiased (CHAP 2014, pp. 73–75). ''Unbiased'' means that any errors are equally likely to lead to overestimation or underestimation of risk.

The staff notes that the CHAP used the latest data available at the time the CHAP performed its analysis. Phthalate exposures in the U.S. population, as measured by biomonitoring, have remained essentially constant for about a 10-year period. (CDC, 2012; EPA, 2013). However, the most recent report from CDC shows that phthalate exposures are beginning to change as one might expect, as products are reformulated in light of concerns about phthalate toxicity. (CDC, 2013). The CDC report shows that exposure to DBP, BBP, and DEHP is declining, while exposures to DINP and DIBP are increasing. The decline in DEHP exposure may be due, in part, to concerns about its toxicity and replacement with other plasticizers. Exposure to DEP and DBP has declined somewhat, possibly due to reformulation of cosmetics and other products. (Zota et al., 2014). Staff has not assessed the effect of changing phthalate exposures on the HI.

4. Human Relevance of Animal Data

One source of uncertainty in any risk assessment is the use of animal data as the basis for estimating the risk to humans. Male developmental reproductive effects have been well-studied in rats. In addition, similar effects have been reported in multiple mammalian species, including guinea pigs (Gray et al., 1982), mice, (Gray et al., 1982; Moody et al., 2013; Ward et al., 1998), rabbits (Higuchi et al., 2003), and ferrets (Lake et al., 1976) (Lake et al. 1976). Hamsters were resistant to male developmental reproductive effects due to slow metabolism of the phthalate ester to the monoester, which is believed to be the active metabolite. Hamsters responded to the monoester, however. (Gray et al. 1982). The observation of similar effects in multiple species demonstrates that these effects are not unique to rats. This is not surprising because male reproductive development is essentially similar in all mammalian species (NRC, 2008).

In contrast to these findings, a single study in marmosets that exposed pregnant females to DBP did not lead to any adverse effects in male offspring (McKinnell et al., 2009). However, as with most primate studies, this study was limited by small numbers.

Similarly, in two recent studies in which fetal rat and mouse testes, or fetal human testicular tissue, were transplanted into laboratory animals and exposed to phthalates (Heger et al., 2012; Mitchell et al., 2012), only the rat testes responded to the phthalates. However, the human fetal tissue was generally past 14 weeks of gestation, which is outside the window of maximum sensitivity. Nevertheless, given the potential significance of these studies, the CHAP invited the principal investigators of both studies (Boekelheide and Sharpe) to present their findings at the November 2011 CHAP meeting. Both of these scientists stated that their studies were very preliminary and that it would be premature to use their results to support public health decisions.

Finally, a growing number of epidemiological studies have reported associations of phthalate exposure with adverse health effects in humans. (CHAP 2014, pp. 27–33). Many of these effects are consistent with male developmental effects observed in animal studies. The human studies, although not conclusive on their own, provide supporting evidence that the animal studies are relevant to humans. (CPSC, 1992). The consistency of the results of the epidemiological studies with the animal studies provides additional support for the relevance of the animal studies to humans.

To summarize, active phthalates cause testicular effects in multiple animal species. The animal studies are further supported by the results of epidemiological studies. CPSC staff concludes that the weight of the evidence overwhelmingly supports the conclusion that male developmental

reproductive effects in animals are appropriate for estimating risks to humans.

IV. Commission Assessment of the CHAP Report's Recommendations for the Proposed Rule

As discussed in the staff's briefing package, staff assessed the recommendations of the CHAP. The Commission agrees with the staff's assessment and provides the following explanation.

A. Interim Prohibited Phthalates: DINP, DIDP, and DNOP

Section 108(b)(3)(A) of the CPSIA requires the Commission to determine, based on the CHAP report, whether to continue in effect the interim prohibitions on children's toys that can be placed in a child's mouth and child care articles containing DINP, DIDP, and DNOP ''to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.'' For each phthalate, the Commission must decide whether to make the interim prohibitions permanent.

Consistent with the CHAP and the statutory framework, the Commission considered both cumulative risk and risk in isolation. For active phthalates, that is, phthalates causing male developmental reproductive effects, the Commission considered the cumulative risk, which was based on the HI. Consistent with the CHAP report and the CPSC chronic hazard guidelines (CPSC, 1992), the Commission considers that the acceptable risk is exceeded when the HI is greater than one (CPSC, 1992). Thus, the Commission considers that an HI <1 is necessary ''to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.''

For non-antiandrogenic phthalates and phthalate alternatives, the Commission considered the MoE, as estimated by the CHAP. MoEs greater than 100–1,000 are generally considered adequate to protect human health (EPA, 1993). As discussed above, the staff considers a MoE of 100 or more to be adequate if a NOAEL has been identified in animal studies (CPSC, 1992), which is the case for most of the compounds discussed by the CHAP. Thus, for the phthalates discussed in this section, the Commission considers a MoE of 100 or greater to be necessary ''to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.''

1. Di-n-octyl Phthalate (DNOP)

The CHAP recommended that the interim prohibition on DNOP not be continued (CHAP 2014, pp. 91–95). The CHAP concluded: ''DNOP does not appear to possess antiandrogenic potential'' (CHAP, 2014, pp. 24, 95), and therefore, DNOP does not contribute to the cumulative risk from other phthalates. Thus, the CHAP considered DNOP risks in isolation because DNOP is not antiandrogenic. As with virtually all chemicals, DNOP is associated with toxicological effects, including liver toxicity and developmental effects. The CHAP did not use biomonitoring data to estimate DNOP exposure because DNOP metabolites were undetectable in most individuals. Using the scenario-based approach, the CHAP estimated exposures to infants and toddlers ranging from 4.5 to16 μg/kg-d. The margins of exposure (MoEs) [12] ranged from 2,300 to 8,300. The CHAP considered an MoE of at least 100 to be adequate to protect human health from the potential effects of DNOP. The CHAP concluded that the MoE for DNOP was sufficiently high and that continuing the interim prohibition was unnecessary. Therefore, the CHAP recommended removing the interim prohibition on children's toys and child care articles containing DNOP.

The Commission considers that a MoE of 100 or greater is sufficient to protect human health with respect to DNOP. The Commission agrees with the CHAP's assessment of the potential health risks from DNOP because the MoEs are greater than 100. DNOP levels are so low that they are not detectable in about 90 percent of humans. (CHAP 2014, Table 2.6). Furthermore, DNOP is not antiandrogenic, and therefore, DNOP does not contribute to the cumulative risk from antiandrogenic phthalates. The Commission concludes that continuing the prohibition of DNOP is not necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety. Accordingly, under the proposed rule, children's toys that can be placed in a child's mouth and child care articles containing DNOP would no longer be prohibited.

2. Diisononyl Phthalate (DINP)

DINP is currently subject to an interim prohibition. The CHAP recommended that ''the interim prohibition on the use of DINP in children's toys and child care articles at levels greater than 0.1 percent be made permanent.'' (CHAP, 2014, pp. 95–99). DINP is associated with adverse effects on male development (antiandrogenicity). In addition, DINP acts in concert with other antiandrogenic phthalates, including the permanently banned phthalates, thereby contributing to the cumulative risk.

Multiple published studies confirm the antiandrogenicity of DINP (Adamsson et al., 2009; Boberg et al., 2011; Borch et al., 2004; Clewell et al., 2013; Gray et al., 2000; Hannas et al., 2011b; Hass et al., 2003; Masutomi et al., 2003; reviewed in NRC, 2008). Even though DINP is less potent, by perhaps twofold to tenfold, than DEHP (Gray et al., 2000; Hannas et al., 2011b), DINP contributes to the cumulative risk from all antiandrogenic phthalates. The CHAP estimated that DINP contributes 1 percent to 8 percent of the cumulative risk to pregnant women and 1 percent to 15 percent in infants (Table 1). The CHAP found that 10 percent of pregnant women and up to 5 percent of infants have a HI greater than one. The CHAP also estimated that allowing the use of DINP in children's toys and child care articles would increase DINP exposure to infants by about 13 percent. (CHAP 2014, Table E1–21).

The Commission notes that the CHAP assessed the risks of DINP both in isolation and in combination with other phthalates. Considered in isolation, staff concluded that DINP would not present a hazard to consumers because the MoE (830 to 15,000) is well in excess of 100. (CHAP, 2014, p. 99). This is consistent with previous work. (CHAP, 2001; CPSC, 2002). However, the Commission agrees with the CHAP that DINP is antiandrogenic and contributes to the cumulative risk. Specifically, the CHAP found that 10 percent of pregnant women and up to 5 percent of infants have a HI greater than one. Therefore, as discussed previously, the Commission concludes that the cumulative risk of male developmental reproductive effects should be considered ''to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.''

The Commission agrees with the CHAP's recommendation to make permanent the prohibition on DINP because the Commission concludes that allowing the use of DINP in children's toys and child care articles would further increase the cumulative risk to male developmental reproductive development. Multiple studies indicate that DINP is antiandrogenic and contributes to the cumulative risk from phthalates. As discussed previously, the Commission considers that a HI <1 is

[12] The margin of exposure (MoE) is the ratio of the NOAEL to the estimated exposure.

necessary ''to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.'' Therefore, to ensure a reasonable certainty of no harm with an adequate margin of safety to children, pregnant women, or other susceptible individuals (*i.e.,* male fetuses), the proposed rule would permanently prohibit children's toys and child care articles containing more than 0.1 percent of DINP.

The statute's interim prohibition on DINP applies only to children's toys that can be placed in a child's mouth,[13] which is narrower in scope than the permanent prohibitions on DEHP, DBP, and BBP in all children's toys.[14] The CHAP recommended that DINP be permanently prohibited in all children's toys but did not explain why the CHAP recommended expanding the prohibition on DINP to include all children's toys. However, the CHAP's recommendation is consistent with the scope of the permanently prohibited phthalates.

The proposed rule would permanently prohibit DINP in all children's toys and child care articles, rather than only children's toys that can be mouthed. The Commission believes that the expansion in scope is appropriate because exposure occurs from handling children's toys, as well as from mouthing. (CHAP, 2014, Appendix E1). The additional exposure from handling toys would add to the cumulative risk. Therefore, the Commission concludes that expanding the scope of the DINP prohibition to include all children's toys is necessary to ensure a reasonable certainty of no harm to children with an adequate margin of safety.

The European Commission (EC) directive on phthalates in toys and child care articles also distinguished between all children's toys and toys that can be mouthed, prohibiting DBP, BBP, and DEHP in all children's toys, and prohibiting DINP, DNOP, and DIDP in toys that can be mouthed. (EC, 2005). The directive cited greater uncertainty about hazards presented by DINP, DNOP, and DIDP as the reason for this distinction. (EC, 2005, paragraph 11). As discussed in the CHAP report, there are multiple studies related to the male developmental reproductive effects of DINP, many of which were published after 2005, the date of the ECdirective. Thus, the Commission concludes that because the CHAP report addresses uncertainties regarding the potential hazard associated with DINP, an expansion of the prohibition on DINP to all children's toys is appropriate.

Additionally, we expect that expanding the scope to all children's toys would have a minimal effect on manufacturers because few products would need to be reformulated to comply with the broader scope. (*See* Tab A of the staff's briefing package.) In practice, children's toys and toys that can be placed in a child's mouth all require testing for phthalates. The testing costs are the same in either case. The only change caused by expanding the scope to all children's toys is that toys too large to be mouthed could not be made with DINP.

3. Diisodecyl Phthalate (DIDP)

The CHAP recommended that the interim prohibition on DIDP not be continued. (CHAP, 2014, pp. 100–105). DIDP is not associated with antiandrogenicity. Thus, DIDP does not contribute to the cumulative risk from the antiandrogenic phthalates. As with virtually all chemicals, DIDP is associated with toxicological effects, including liver toxicity and developmental effects. The CHAP assessed the potential risks from DIDP in isolation. The CHAP concluded that the MoE for DIDP is relatively high (>100) and that there is no compelling reason to continue the interim prohibition.

The CHAP concluded: ''DIDP does not appear to possess antiandrogenic potential'' (CHAP, 2014, pp. 24, 104); therefore, DIDP does not contribute to the cumulative risk (CHAP 2014, p. 104). However, the CHAP stated that it is aware that DIDP is associated with other health effects in animal studies, including chronic liver and kidney toxicity and developmental effects (*e.g.,* supernumerary ribs). (CHAP 2014, pp. 100–105). The CHAP considered DIDP risks in isolation because DIDP is not antiandrogenic. The lowest NOAEL for DIDP was 15 mg/kg-d, based on liver effects. Using biomonitoring data, the CHAP estimated that human exposures range from 1.5 to 26 μg/kg-d. The MoEs range from 2,500 to 10,000 for median DIDP exposures and 586 to 3,300 for upper-bound exposures. Therefore, the CHAP recommended that the interim prohibition on children's toys and child care articles containing DIDP be lifted.

As discussed previously, the Commission considers that a MoE of 100 or greater is sufficient to protect human health with respect to DIDP. The Commission agrees with the CHAP's assessment of the potential health risks from DIDP because the MoEs are much greater than 100. DIDP exposure would need to increase by more than 250 times to exceed the acceptable level. Furthermore, DIDP is not antiandrogenic; and therefore, DIDP does not contribute to the cumulative risk from antiandrogenic phthalates. The Commission concludes that continuing the prohibition of DIDP is not necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety. Accordingly, under the proposed rule, children's toys and child care articles containing DIDP would no longer be prohibited.

B. Phthalates Not Prohibited by the CPSIA

The CPSIA requires the Commission to ''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.'' CPSIA section 108(b)(3)(B). The CHAP reviewed the potential health risks associated with eight phthalates that were not prohibited by the CPSIA. The CHAP recommended permanent prohibitions on four additional phthalates: DIBP, DPENP, DHEXP, and DCHP. The CHAP recommended an interim prohibition of DIOP. The CHAP did not recommend prohibitions on DMP, DEP, or DPHP; although the CHAP recommended additional study on DEP and DPHP.

Consistent with the CHAP report, the Commission considered both cumulative risk and risk in isolation. For active phthalates, that is, phthalates causing male developmental reproductive effects, the Commission considered the cumulative risk, which was based on the HI. Consistent with the CHAP report and the CPSC chronic hazard guidelines (CPSC 1992), the Commission considers that the acceptable risk is exceeded when the HI is greater than one (CPSC 1992). Thus, the Commission considers that a HI <1 is necessary ''to protect the health of children.''

For non-antiandrogenic phthalates and phthalate alternatives, the Commission considered the MoE, as estimated by the CHAP. MoEs greater than 100 to 1,000 are generally considered adequate to protect human health (EPA 1993). As discussed previously, staff considers a MoE of 100 or more to be adequate if a NOAEL has been identified in animal studies (CPSC 1992), which is the case for most of the

[13] CPSIA § 108(b)(1).

[14] CPSIA § 108(a).

compounds discussed by the CHAP. Thus, for the phthalates discussed in this section, the Commission considers a MoE of 100 or greater to be necessary ''to protect the health of children.''

1. Diisobutyl Phthalate (DIBP)

The CHAP recommended that diisobutyl phthalate (DIBP) should be permanently banned from use in children's toys and child care articles at levels greater than 0.1 percent. (CHAP 2014, pp. 110–112). DIBP is associated with adverse effects on male reproductive development and contributes to the cumulative risk from antiandrogenic phthalates. Furthermore, DIBP has been found in some toys and child care articles during compliance testing by CPSC. (*See* TAB B of staff's briefing package).

DIBP is similar in toxicity to DBP (CHAP 2014, pp. 24, 110–111), which is one of the phthalates subject to the CPSIA's permanent prohibition. DIBP was shown to be antiandrogenic in numerous studies and it acts in concert with other antiandrogenic phthalates (Howdeshell et al., 2008). The CHAP found that current exposures to DIBP are low. When considered in isolation, DIBP has a MoE of 3,600 or more (CHAP 2014, p. 111). DIBP contributes roughly 1 percent to 2 percent of the cumulative risk from phthalate exposure to pregnant women and 1 percent to 5 percent in infants (Table 7). However, the CHAP based its recommendation on cumulative risk.

The Commission agrees with the CHAP's recommendation for DIBP. Based on previous CPSC staff and contractor toxicity reviews (Versar/SRC, 2010c) and the CHAP's review, the Commission finds that there is sufficient evidence to conclude that DIBP is antiandrogenic and is able to contribute to the cumulative risk. The Commission also concludes that, applying the CPSC chronic hazard guidelines (CPSC, 1992), this phthalate is considered ''probably toxic'' to humans based on sufficient evidence in animal studies. Five percent to 10 percent of the population exceeds the negligible risk level (HI >1). Allowing the use of DIBP in children's toys and child care articles would further increase the cumulative risk. As discussed previously, the Commission considers that a HI <1 is necessary ''to protect the health of children.'' In addition, CPSC staff has identified DIBP in a small portion of toys and child care articles during routine compliance testing. Therefore, the proposed rule would permanently prohibit children's toys and child care articles containing more than 0.1 percent of DIBP. The Commission concludes that this action is necessary to protect the health of children because it would prevent current and future use of this antiandrogenic phthalate in toys and child care articles.

2. Di-n-pentyl Phthalate (DPENP)

The CHAP recommended that di-*n*-pentyl phthalate (DPENP) should be permanently banned from use in children's toys and child care articles at levels greater than 0.1 percent (CHAP pp. 112–113). DPENP is associated with adverse effects on male reproductive development and contributes to the cumulative risk from antiandrogenic phthalates. Furthermore, DPENP is the most potent of the antiandrogenic phthalates. The Commission agrees with the CHAP's recommendation for DPENP. Based on previous CPSC staff and contractor toxicity reviews (Patton, 2010) and the CHAP's review, the Commission concludes that there is sufficient evidence to conclude that DPENP is antiandrogenic and is able to contribute to the cumulative risk. The Commission also concludes that, applying the CPSC chronic hazard guidelines (CPSC, 1992), this phthalate is considered ''probably toxic'' to humans, based on sufficient evidence in animal studies. Furthermore, DPENP is roughly twofold to threefold more potent than DEHP. (Hannas et al., 2011a). Although CPSC staff has not detected DPENP in children's toys or child care articles, metabolites of DPENP have been detected in humans (Silva et al., 2010), indicating that some exposure to DPENP does occur. Moreover, prohibiting the use of DPENP would prevent its use as a substitute for other banned phthalates. Up to five percent of infants and up to 10 percent of pregnant women exceed the negligible risk level (HI >1). Allowing the use of DPENP in children's toys and child care articles would further increase the cumulative risk. As discussed previously, the Commission considers that a HI <1 is necessary ''to protect the health of children.'' Therefore, the proposed rule would permanently prohibit children's toys and child care articles containing more than 0.1 percent of DPENP. The Commission concludes that this action is necessary to protect the health of children because it would prevent current and future use of this antiandrogenic phthalate in toys and child care articles.

Recently, the EPA proposed a significant new use rule (SNUR) for DPENP (EPA, 2012). If finalized, the rule would require any company planning to manufacture or import DPENP to notify EPA before beginning this activity. EPA would review the potential health risks of DPENP and could impose restrictions. If EPA issues a final rule, the likelihood that manufacturers would produce DPENP may be reduced. However, a SNUR would not prevent the importation of products containing DPENP into the United States. Therefore, the Commission believes that the proposed prohibition of children's toys and child care articles containing concentrations of more than 0.1 percent of DPENP is still necessary to protect the health of children.

3. Di-n-hexyl Phthalate (DHEXP)

The CHAP recommended that di-*n*-hexyl phthalate (DHEXP) should be permanently banned from use in children's toys and child care articles at levels greater than 0.1 percent (CHAP pp. 114–116). DHEXP is associated with adverse effects on male reproductive development and may contribute to the cumulative risk from antiandrogenic phthalates.

The Commission agrees with the CHAP's recommendation for DHEXP. Based on previous CPSC staff and contractor toxicity reviews (Patton, 2010) and the CHAP's review, the Commission concludes that there is sufficient evidence to conclude that DHEXP is antiandrogenic and is able to contribute to the cumulative risk (*e.g.,* Foster et al., 1980). The Commission also concludes that, by applying the CPSC chronic hazard guidelines (CPSC, 1992), this phthalate may be considered ''probably toxic'' to humans based on sufficient evidence in animal studies. Up to five percent of infants and up to 10 percent of pregnant women exceed the negligible risk level (HI >1). Allowing the use of DHEXP in children's toys and child care articles would further increase the cumulative risk. As discussed previously, the Commission considers that a HI <1 is necessary ''to protect the health of children.'' Although CPSC staff has not detected DHEXP in toys and child care articles during routine compliance testing thus far, prohibiting children's toys and child care articles containing DHEXP would prevent its use in these products as a substitute for other banned phthalates. Therefore, the proposed rule would permanently prohibit children's toys and child care articles containing more than 0.1 percent of DHEXP. The Commission concludes that this action is necessary to protect the health of children because it would prevent future use of this antiandrogenic phthalate in toys and child care articles.

4. Dicyclohexyl Phthalate (DCHP)

The CHAP recommended that dicyclohexyl phthalate (DCHP) should be permanently banned from use in children's toys and child care articles at levels greater than 0.1 percent. (CHAP pp. 116–118). DCHP is associated with adverse effects on male reproductive development and contributes to the cumulative risk from antiandrogenic phthalates.

The Commission agrees with the CHAP's recommendation for DCHP. Based on previous CPSC staff and contractor reviews (Versar/SRC, 2010b) and the CHAP's review, the Commission concludes that there is sufficient evidence to conclude that DCHP is antiandrogenic and is able to contribute to the cumulative risk (*e.g.,* Foster et al., 1980). The Commission also concludes that, by applying the CPSC chronic hazard guidelines (CPSC, 1992), this phthalate is considered ''probably toxic'' to humans, based on sufficient evidence in animal studies. Up to five percent of infants and up to 10 percent of pregnant women exceed the negligible risk level (HI >1). Allowing the use of DCHP in children's toys and child care articles would further increase the cumulative risk. As discussed previously, the Commission considers that a HI <1 is necessary ''to protect the health of children.'' Although the CPSC staff has not detected DCHP in toys and child care articles during routine compliance testing thus far, prohibiting the use of DCHP would prevent its use as a substitute for other banned phthalates. The Commission concludes that this action is necessary to protect the health of children because it would prevent future use of this antiandrogenic phthalate in toys and child care articles.

5. Diisooctyl Phthalate (DIOP)

The CHAP recommended an interim prohibition for diisooctyl phthalate (DIOP). (CHAP 2014, pp. 118–119). DIOP has a chemical structure consistent with other antiandrogenic phthalates.

DIOP is a high production volume chemical (EPA 2006), that is, over a million pounds are produced or imported each year (Versar/SRC, 2010d). DIOP is approved for use in food contact applications. (CHAP 2014, pp. 118–119). DIOP was identified in a small number of child care articles in the past (Chen, 2002); although it has not been detected by CPSC in children's toys and child care articles since the CPSIA was enacted in 2008.

The possible antiandrogenicity of DIOP is a potential concern (CHAP 2014, pp. 118–119). However, the CHAP concluded that there is not sufficient evidence to support a permanent prohibition. The only developmental study on DIOP is an older study in which DIOP was administered by intraperitoneal injection, which is not relevant to consumer exposures. The study's authors reported the presence of soft tissue abnormalities, a type of birth defect; but there were insufficient details to assess whether the abnormalities could be related to the phthalate syndrome. (Versar/SRC, 2010d). The primary reason for suspecting antiandrogenic activity is DIOP's structural similarity to other active phthalates (CHAP 2014, p. 119).

The CHAP did not recommend a permanent prohibition because the CHAP concluded that existing data are insufficient to support a permanent ban. Although the CHAP recommended an interim prohibition, the CPSIA did not provide for an interim prohibition as an option for the Commission's rule under section 108. CPSIA section 108(b)(3). As discussed above, insufficient data exists to determine that a permanent prohibition of DIOP is necessary to protect the health of children. Thus, the Commission is not proposing any prohibition of products containing DIOP.

C. Scope of Phthalate Prohibitions

Currently, under section 108(a) of the CPSIA, the permanent phthalate prohibitions apply to ''any children's toy or child care article that contains concentrations of more than 0.1 percent'' of the permanently prohibited phthalates. In addition, under section 108(b)(1) of the CPSIA, the interim phthalate prohibitions apply to ''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.'' Section 108(g)(1)(B) of the CPSIA defines a ''children's toy'' as ''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.'' Section 108(g)(1)(C) of the CPSIA defines a ''child care article'' as ''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.'' Finally, section 108(g)(2)(B) states that 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.''

Section 108(b)(3)(B) of the CPSIA requires the Commission to ''evaluate the findings and recommendations'' of the CHAP and consider whether to prohibit ''any children's product containing any phthalates'' if the Commission determines that this is ''necessary to protect the health of children.'' Action by the Commission under this subsection could result in extending the phthalates prohibition beyond children's toys and child care articles and could be taken for any or all of the phthalates the proposed rule would prohibit, including those that are permanently prohibited, were subject to the interim prohibition, or that would be prohibited by the proposed rule. A ''children's product'' is defined as a ''a consumer product designed or intended primarily for children 12 years of age or younger.'' 15 U.S.C. 2052(a)(2). Children's products that are not children's toys or child care articles that might contain phthalates, for example, include rainwear, footwear, backpacks, some school supplies, apparel containing elastic waistbands, and printed T-shirts and sweatshirts.

The CHAP report did not specifically discuss the possibility of expanding the scope of the phthalates prohibitions to children's products. That inquiry was not part of the CHAP's charge. CPSIA section 108(b)(2). However, all of the CHAP's recommendations to prohibit certain phthalates apply to ''children's toys and child care articles.''

In the CHAP's scenario-based exposure assessment, the CHAP initially considered assessing exposures to phthalates for some children's products that were not toys or child care articles.[15] The CHAP ultimately decided, however, to limit its analysis to exposure activity scenarios that were thought to contribute significantly to human exposure. Specifically, these exposure activity scenarios included mouthing of teethers and toys, and dermal exposure to play pens and changing pads (CHAP 2014, Table 2.1). The CHAP found that most phthalate exposure comes from food and beverages (CHAP, 2014, pp. 50–52). Mouthing teethers and toys may also contribute to total exposure (*See also,* CHAP 2014, Table E1–24).

The Commission is not proposing to expand the scope of the phthalates prohibitions to include all children's products. The Commission does not

[15] CPSC staff meeting with Dr. Lioy. May 3, 2011. *http://www.cpsc.gov//PageFiles/157051/Meeting%20Log%20050311.pdf.*

have sufficient information to assess the impact on the health of children from expanding the phthalates prohibition from children's toys and child care articles to include other children's products. In addition, the limited information available suggests that increased exposure to phthalates from most children's products outside children's toys and child care articles would be negligible. The Commission believes this for two reasons. First, the broader category of all children's products is likely to contain proportionately fewer products that contain phthalates. (Laursen et al., 2003). Second, the exposure activity patterns, in combination with the primary exposure route (dermal), would generally lead to lower exposures than with children's toys (CHAP, 2001, 2014; CPSC, 2002).

Based on the limited available data, the Commission notes that most children's products are not made of PVC and are not expected to contain phthalates. For example, most textiles contain less than 0.01 percent phthalates (Laursen et al., 2003). Thus, with a few possible exceptions, such as PVC sandals (CHAP, 2001; Tønning et al., 2009), the Commission does not expect other children's products to contribute significantly to phthalate exposure.

Determining the relative importance of various exposure activity pathways (*e.g.,* playing with plastic toys, sitting on a vinyl couch) can be challenging. For example, much more data are available on exposure from mouthing teethers and toys than dermal exposure (CHAP 2014, Appendix E1; (CHAP, 2001). Thus, regarding DINP, the CHAP concluded: ''Although dermal uptake of DINP may occur through prolonged contact of DINP-containing products with skin or mouth, data on the prevalence of DINP in consumer products are not available and there is a fundamental uncertainty concerning the magnitude of dermal DINP uptake. Therefore, estimation of potential dermal exposure to humans remains speculative.'' (CHAP, 2001, p. 3).

The Commission agrees that oral exposure to phthalates is generally considered more important than dermal exposure. (CHAP, 2001; Wormuth et al., 2006). Studies of children's mouthing activity demonstrate that children age 3 or younger primarily mouth their fingers, pacifiers, teethers, and toys. (EPA, 2011; Greene, 2002; Juberg et al., 2001). Mouthing of other articles is infrequent. (*Id.*). Mouthing times for pacifiers, teethers, and plastic toys are 12–15-fold and 20–64-fold higher than all other objects, including other children's products. (EPA, 2011). Mouthing activity declines rapidly after age 3 years. (Greene, 2002).

Because the Commission believes that increased exposure to phthalates from most children's products would be negligible, the Commission concludes that expanding the phthalate prohibition beyond children's toys and child care articles is not warranted.

D. Concentration Limit

Section 108(a) and (b)(1) of the CPSIA sets a concentration limit of 0.1 percent for the permanently and interim-prohibited phthalates in children's toys and child care articles. This is a statutory limit. However, if the Commission chooses to prohibit additional phthalates, the agency could choose to set a different limit for the additional phthalates, as well as for any interim-prohibited phthalates that are being permanently prohibited under this rulemaking. As discussed in the CHAP report:

> The CPSIA prohibits the use of certain phthalates at levels greater than 0.1%, which is the same level used by the European Commission. When used as plasticizers for polyvinyl chloride (PVC), phthalates are typically used at levels greater than 10%. Thus, the 0.1% limit prohibits the intentional use of phthalates as plasticizers in children's toys and child care articles but allows trace amounts of phthalates that might be present unintentionally. There is no compelling reason to apply a different limit to other phthalates that might be added to the current list of phthalates permanently prohibited from use in children's toys and child care articles.

(CHAP, 2014, p. 79). The CHAP found no compelling reason to support lowering or raising the concentration limit. The Commission agrees with the CHAP that the 0.1 percent limit is not risk-based; rather, the limit is based on practical considerations, that is, the desire to prohibit intentional phthalate use while allowing trace levels.

Therefore, the Commission concludes that there is no risk-based justification to change the limit from the 0.1 percent level specified in the CPSIA. In the absence of any information to support a different limit, the proposed rule would maintain the limit at 0.1 percent for the proposed prohibitions on DINP, DIBP, DPENP, DHEXP, and DCHP.

Deriving a risk-based limit would require additional analysis beyond the CHAP's scenario-based exposure assessment. This would be difficult because exposure by a given scenario is not necessarily proportional to the phthalate concentration in the product. The sources of uncertainty and data gaps in the CHAP's scenario-based assessment (CHAP 2014, Appendix E1) would still apply. Thus, it would be difficult to derive a risk-based level.

The Commission considers that the 0.1 percent limit is practical. A lower limit would make it more difficult to perform the testing required of third party laboratories, which may lead to increased testing costs. Compliance testing would also be more difficult.

V. Description of the Proposed Rule

Section 1307.1—Scope and Application

Proposed § 1307.1 describes the actions that the proposed rule would prohibit. This provision tracks the language in section 108(a) of the CPSIA regarding the permanent prohibition and prohibits the same activities: manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of a children's toy or child care article that contains any of the prohibited phthalates.

Section 1307.2—Definitions

Proposed § 1307.2 provides the same definitions of ''children's toy'' and ''child care article'' found in section 108(g) of the CPSIA. ''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. ''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. Although these definitions are stated in the CPSIA, the proposed rule text would restate them for convenience.

Section 1307.3—Prohibition on Children's Toys and Child Care Articles Containing Specified Phthalates

Proposed § 1307.3(a) states which products would be prohibited. For convenience, the proposed section would provide both the items that are subject to the CPSIA's existing permanent prohibition and the items that would be subject to prohibition under the proposed rule. Stating all prohibitions in this section will allow a reader of the CFR to be aware of all the CPSC's restrictions concerning phthalates.

Proposed paragraph (a) sets out the CPSIA's existing permanent prohibition that makes it unlawful 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 DEHP, DBP, or BBP. The restriction on these products

is currently in place as a result of section 108(a) of the CPSIA. This statutory prohibition is not affected by the proposed rule but is merely restated in the proposed regulatory text.

Proposed paragraph (b) would prohibit the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any children's toy or child care article that contains concentrations of more than 0.1 percent of DINP, DIBP, DPENP, DHEXP, or DCHP. As explained above, in accordance with section 108(b)(2) of the CPSIA, the Commission appointed a CHAP that considered the effects on children's health of phthalates and phthalate alternatives as used in children's toys and child care articles. After completing its work, the CHAP presented the Commission with a report of its findings and recommendations. After reviewing the CHAP's report and making the appropriate determinations and evaluations, the Commission is proposing a rule in accordance with section 108(b)(3) of the CPSIA.

For the reasons explained in Section IV of this preamble, the Commission concludes that prohibiting children's toys and child care articles that contain more than 0.1 percent of DINP would ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety. DINP is currently subject to the CPSIA's interim prohibition. CPSIA section 108(b)(1). Proposed § 1307.3(b) would change the scope of regulation of DINP from the current interim scope of ''children's toys that can placed into a child's mouth'' [16] (and child care articles) to also include all children's toys. Based on the recommendations in the CHAP report, the Commission is not proposing to continue the interim prohibitions on DIDP and DnOP.

Additionally, proposed § 1307.3(b) would prohibit children's toys and child care articles containing four phthalates that are not currently subject to restrictions under the CPSIA: DIBP, DPENP, DHEXP, and DCHP. For the reasons stated in section IV of this preamble, the Commission concludes that prohibiting children's toys and child care articles containing more than 0.1 percent of DIBP, DPENP, DHEXP, or DCHP is necessary to protect the health of children.

[16] Section 108(g)(2)(B) of the CPSIA states that ''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.''

VI. Effective Date

The APA generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The Commission is proposing an effective date of 180 days after publication of the final rule in the **Federal Register**.

As discussed in Tab A of the staff's briefing package, the proposed rule is expected to have a minimal impact on manufacturers. The proposed rule would prohibit four additional phthalates—DIBP, DPENP, DHEXP, and DCHP—which currently are not widely used in children's toys and child care articles. Only DIBP has been detected in a small portion of toys tested by the staff. The proposed rule would also make the interim prohibition on DINP permanent and expand the scope from children's toys that can be place in a child's mouth to all children's toys (along with child care articles). Based on staff's testing results, to meet the proposed rule, a relatively small percentage of non-mouthable toys would need to be reformulated to remove DINP. To meet the statutory testing and certification requirements if the proposed rule were in place, testing laboratories would need to expand their procedures to include the four additional prohibited phthalates, which the staff believes would require minimal effort by testing laboratories. Therefore, none of the prohibitions in the proposed rule is likely to require more than 180 days for manufacturers and testing laboratories to become compliant. For these reasons, the Commission proposes an effective date of 180 days after publication of the final rule in the **Federal Register**.

VII. Notice of Requirements

The CPSA establishes certain requirements for product certification and testing. Children's products subject to a children's product safety rule under the CPSA must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* 2063(a)(2). The Commission must publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. *Id* 2063(a)(3). Thus, the proposed rule for 16 CFR part 1307, ''*Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates,*'' when issued as a final rule, would be a children's product safety rule that requires the issuance of an NOR. The Commission previously published in the **Federal Register** an NOR for the phthalate-containing products prohibited by section 108 on August 10, 2011. (76 FR 49286). The codified listing for the NOR can be found at 16 CFR 1112.15(b)(31). If the Commission finalizes the proposed rule with prohibitions restricting phthalates that are not covered by the current NOR, the Commission would issue a new NOR that would include the additional phthalates. The NOR would notify manufacturers and testing laboratories of the additional requirements and would include a revised test method. Any revisions to the existing NOR will be done in a separate future rulemaking.

VIII. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the APA or any other statute, unless the agency certifies that the rulemaking will not have a significant economic impact on a substantial number of small entities. U.S.C. 603 and 605. Small entities include small businesses, small organizations, and small governmental jurisdictions. After considering the economic impacts of this proposed rule on small entities, the Commission certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

A. Background

As discussed above, the proposed rule would fulfill a requirement in section 108 of the CPSIA that the Commission issue a rule to determine whether the interim prohibitions established in section 108(b)(1) of the CPSIA should be made permanent and whether any children's product containing any phthalates that were not prohibited by the CPSIA should be declared a banned hazardous product. The proposed rule would lift the interim prohibitions for two of the three phthalates (DIDB and DNOP) and would permanently prohibit children's toys and child care articles containing more than 0.1 percent of the third phthalate (DINP). The proposed rule would also prohibit children's toys and child care articles containing more than 0.1 percent of any of four specified phthalates that were not prohibited by

the CPSIA (DIBP, DPENP, DHEXP, and DCHP).

B. Small Entities To Which the Rule Would Apply

Small entities would be subject to the proposed rule if they manufacture or import children's toys or child care articles that contain phthalates. These companies are already subject to the restrictions imposed by the CPSIA on children's toys and child care articles containing certain phthalates. The draft proposed rule would neither increase, nor decrease, the number of small entities to which the phthalate restrictions apply. More detailed information about the entities that likely manufacture or import children's toys and child care articles and would be considered small businesses under the criteria established by the Small Business Administration (SBA) is provided at Tab A of the staff's briefing package.

C. Potential Impact on Small Businesses

1. Impact From Meeting Substantive Requirements of the Proposed Rule

The proposed rule would impact which plasticizers are available to manufacturers for use in children's toys and child care articles. We discuss the anticipated impact from each aspect of the Commission's proposed action.

Lifting restriction on DNOP and DIDP. The proposed rule would end the CPSIA's interim restrictions on the use of DNOP and DIDP in children's toys and child care articles. Manufacturers would be free to use these two phthalates. Ending restrictions for these phthalates would benefit manufacturers if DNOP and DIDP are less costly than the alternatives or they impart other desirable attributes to the final product.

Altering restriction on DINP. The proposed rule would broaden the restrictions on DINP. The interim ban prohibits children's toys that can be placed in a child's mouth and child care articles that contain more than 0.1 percent of DINP. The proposed rule would extend the prohibition to all children's toys and child care articles regardless of whether the toy can be placed in a child's mouth. Manufacturers who were using DINP in toy components that could not be placed in a child's mouth would have to find an alternative for DINP in these applications. The Commission expects the impact of changing the prohibition on the use DINP to include children's toys that cannot be placed in a child's mouth would be limited to a small number of firms. A review of samples tested by CPSC staff indicated that of 725 samples that were found to contain phthalates through infrared screening techniques, fewer than 5 samples (or less than 1 percent) contained DINP but were probably too large to be placed in a child's mouth. (*See* Tab B of staff's briefing package). The percentage of all children's toys that could be impacted by broadening the restrictions on the use of DINP to all children's toys would be substantially less than 1 percent because the only samples reviewed in this analysis were those that were already found to contain phthalates using infrared screening techniques. This would be a small subset of all children's toys.

Restricting four additional phthalates. The proposed rule would also prohibit children's toys and childcare articles containing four additional phthalates: DIBP, DPENP, DHEXP, and DCHP. The prohibition on the use of these additional phthalates is not expected to have a significant impact on a substantial number of manufacturers because the CHAP found that three of these phthalates (DPENP, DHEXP, and DCHP) are not currently used in children's products and that although the fourth (DIBP) has been found in some toys, it ''is not widely used in toys and child care articles.'' (CHAP 2014, pp. 111,113,116, and 117). This aspect of the proposed rule is intended to prevent these phthalates from being used in children's toys and child care articles in the future.

Summary of impact from meeting substantive requirements of proposal. For the reasons described above, the Commission expects that few, if any, manufacturers would need to alter their formulations to comply with the proposed rule.

2. Impact From Third Party Testing to the Proposed Rule

The CPSIA requires manufacturers of children's products subject to a children's product safety rule to certify that their children's products comply with all applicable children's product safety rules based on the results of third party tests. 15 U.S.C. 2063(a)(2). Third party testing is only required for those components of children's toys and child care articles that are accessible and that could contain one or more of the prohibited phthalates. These third party testing requirements are set forth in the CPSIA and are unaffected by the proposed rule.

The CPSIA permanently prohibits children's toys and child care articles that contain concentrations of more than 0.1 percent of DEHP, DBP or BBP. This restriction is unaffected by the proposed rule. Thus, manufacturers of children's toys and child care articles currently must comply with the third party testing requirements to certify that their products do not contain more than 0.1 percent of DEHP, DBP, or BBP. Manufacturers of children's toys and child care articles currently must also certify, based on the results of third party tests, that their products do not contain more than 0.1 percent of the phthalates subject to the interim prohibitions (DINP, DIDP, and DNOP), unless the product is a children's toy that cannot be placed in a child's mouth. (The prohibitions on DEHP, DBP, and BBP apply regardless of whether a toy can be placed in a child's mouth).

a. Scope of Products That Must Be Tested

The proposed rule would not affect the scope of products subject to the third party testing requirement because even in the absence of the proposed rule, manufacturers of children's toys and child care articles that may contain accessible phthalates are required to certify those products based on third party testing.

Lifting restriction on DNOP and DIDP. Because the proposed rule would remove the interim prohibitions for DIDP and DNOP, manufacturers of children's toys and child care articles would no longer be required to certify that their products do not contain these phthalates. However, third party testing of children's toys and child care articles would still be required to ensure that these products do not contain concentrations of more than 0.1 percent for DEHP, DBP, and BBP.

Altering restriction on DINP. Under the proposed rule, manufacturers of children's toys that can be placed in a child's mouth and child care articles would need to continue to test to ensure that their products do not exceed concentrations of more than 0.1 percent for DINP. Additionally, under the proposed rule, manufacturers would have to certify, based on third party tests, that toys that cannot be placed in a child's mouth do not contain DINP. However, as noted above, these manufacturers are already required to test their products for DEHP, DBP, and BBP. The extension of the DINP prohibition would not require testing of additional products; the extension simply adds another phthalate for which certification is required when testing children's toys and child care articles that cannot be placed in the mouth.

Restricting four additional phthalates. Under the proposed rule, manufacturers of children's toys and child care articles

would have to certify that their products do not contain DIBP, DPENP, DHEXB, and DCHP in concentrations of greater than 0.1 percent based on third party tests. However, as noted above, these manufacturers are already subject to third party testing for DEHP, DBP, and BBP.

Summary of impact of proposal on scope of testing. Because children's toys and child care articles that may contain phthalates are already subject to the CPSIA's testing requirement to determine the presence of any of the phthalates that are prohibited by section 108(a) of the CPSIA, the proposed rule would not affect the scope of products that are subject to third party testing.

b. Proposed Rules's Impact on Cost of Testing

Under the proposed rule, manufacturers would need to test for the presence of four phthalates that they currently do not have to test for under the CPSIA's permanent and interim prohibitions. According to the Directorate for Laboratory Sciences, including the additional phthalates that would be prohibited by the proposed rule, DIBP, DPENP, DHEXP, and DCHP is not expected to increase significantly the cost to manufacturers for having a products third party test their products for phthalates. The same equipment and procedures for sample preparation and extraction could be used. Although the data analysis procedure would need to be modified to include the new phthalates, each of the additional phthalates can be isolated at unique elution times by gas chromatography and should not be difficult for qualified conformity assessment bodies to identify and quantify. (*See* Tab B of the staff's briefing package.)

Third party conformity assessment bodies will have to obtain eight phthalate analytic standard materials for calibration purposes for use during phthalate testing. This is a net increase of two over the six that are currently required. These additional analytic standards are expected to cost very little, especially on a per-test basis. The analytic standards cost about $3.50 per gram (based on prices by some suppliers on the Internet), but less than 50 milligrams of a standard is required per test batch. Therefore, the additional two standards that would be required by the proposed rule would increase the cost per test batch by about $0.35.[17] Multiple samples can be tested in one test batch. Therefore, the per-test cost of the additional phthalate standards would be less than $0.35 per test.

D. Conclusion

The CPSIA established prohibitions on children's toys and child care articles containing phthalates. The CPSIA also put in place requirements for third party testing and certification of children's products. As discussed above, because these requirements area already in place by statute and will continue regardless of the proposed rule, the Commission expects that the proposed rule's impact on small business would not be significant. Therefore, the Commission certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

IX. Paperwork Reduction Act

The proposed rule does not include any information-collection requirements. Accordingly, this rule is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501–3520.

X. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a ''consumer product safety standard under [the Consumer Product Safety Act (CPSA)]'' is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. (Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances.) Section 108(f) of the CPSIA is entitled, ''Treatment as Consumer Product Safety Standards; Effect on State Laws.'' That provision states that the permanent and interim prohibitions and any rule promulgated under section 108(b)(3) ''shall be considered consumer product safety standards under the Consumer Product Safety Act.'' That section further states: ''Nothing in this section of 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.'' CPSIA section 108(f). This provision indicates that the preemptive effect of section 26(a) of the CPSA would apply to the proposed rule which does not include any requirements regarding phthalate alternatives.

XI. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(2). Because this rule falls within the categorical exclusion, no environmental assessment or environmental impact statement is required.

XII. List of References

This section provides a list of the documents referenced in this preamble.

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List of Subjects in 16 CFR Part 1307

Consumer protection, Imports, Infants and children, Law enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations by adding part 1307 to read as follows:

■ 1. Add Part 1307 to read as follows

PART 1307—PROHIBITION OF CHILDREN'S TOYS AND CHILD CARE ARTICLES CONTAINING SPECIFIED PHTHALATES

Sec.

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, Sec. 108, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

§ 1307.1 Scope and application.

This part prohibits the manufacture for sale, offer for sale, distribution in commerce or importation into the United States of any children's toy or child care article containing any of the phthalates specified in § 1307.3.

§ 1307.2 Definitions.

The definitions of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2052)(a)) and the Consumer Product Safety Improvement Act of 2008 (CPSIA) (Pub. L. 110–314, 108)(g)) apply to this part. Specifically, as defined in the CPSIA:

(a) *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.

(b) *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.

§ 1307.3 Prohibition of children's toys and child care articles containing specified phthalates.

(a) As provided in section 108(a) of the CPSIA, the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethyhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP) is prohibited.

(b) In accordance with section 108(b)(3) of the CPSIA, the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any children's toy or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisobutyl phthalate (DIBP), di-*n*-pentyl phthalate (DPENP), di-*n*-hexyl phthalate (DHEXP), or dicyclohexyl phthalate (DCHP) is prohibited.

Dated: December 17, 2014.

Alberta E. Mills,

Acting Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2014–29967 Filed 12–29–14; 8:45 am]

BILLING CODE 6355–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230 and 240

[Release No. 33–9693; 34–73876; File No. S7–12–14]

RIN 3235–AL40

Changes to Exchange Act Registration Requirements To Implement Title V and Title VI of the Jobs Act

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: We are proposing amendments to our rules to implement Title V and Title VI of the Jumpstart Our Business Startups Act (the ''JOBS Act''). The proposed amendments would