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: Final rule.

SUMMARY: The United States Consumer Product Safety Commission (Commission or CPSC) issues this final rule prohibiting children's toys and child care articles that contain concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisobutyl phthalate (DIBP), di-*n-pentyl phthalate (DPENP), di-n-hexyl phthalate* (DHEXP), and dicyclohexyl phthalate (DCHP). Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) established permanent and interim prohibitions on the sale of certain consumer products containing specific phthalates. That provision also directed the 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. This rule fulfills that requirement.

DATES: The rule will become effective on April 25, 2018.

FOR FURTHER INFORMATION CONTACT: For information related to the phthalates prohibitions, contact: Carol L. Afflerbach, Compliance Officer, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814–4408; telephone: 301–504–7529; email: *cafflerbach@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

Outline. The information in this preamble is organized as follows:

I. Background

A. Consumer Product Safety Improvement Act

In accordance with the Consumer Product Safety Improvement Act of 2008 (CPSIA), the Commission issues this final rule prohibiting children's toys and child care articles containing concentrations of more than 0.1 percent of certain phthalates.[1]

[1] The Commission voted 3–2 to publish this final rule in the **Federal Register**. Commissioners Robert S. Adler, Marietta S. Robinson, and Elliot F. Kaye voted to publish this final rule. Acting Chairman Anne Marie Buerkle and Commissioner Joseph Mohorovic voted against publication of this final rule.

1. Statutory Prohibitions

Section 108 of the CPSIA establishes requirements concerning phthalates. 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). 15 U.S.C. 2057c(a). In addition, section 108(b)(1) 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). *Id.* 2057c(b)(1). The CPSIA provides the following definitions:

- ''Children's toy'' is ''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'' is ''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.''
- A ''toy can be place 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. 2057c(g). 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.* 2057c(b)(1).

2. Chronic Hazard Advisory Panel

The CPSIA directs the 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.'' *Id.* 2057c(b)(2). A ''phthalate alternative'' is ''any common substitute to a phthalate, alternative material to a phthalate, or alternative plasticizer.'' *Id.* 2057c(g). The CHAP is to recommend to

the Commission whether any phthalates or phthalate alternatives other than those permanently prohibited should be declared banned hazardous substances. *Id.* 2057c(b)(2)(C).

3. Rulemaking

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. . . .'' 15 U.S.C. 2057c(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.* (b)(3)(B).

B. The Proposed Rule

On December 30, 2014, the Commission published a notice of proposed rulemaking (NPR) in the **Federal Register**. 79 FR 78324. The preamble to the NPR summarized the CHAP report, explaining the CHAP's review of potential health effects of phthalates in animals and humans, the CHAP's assessment of human exposure to phthalates, the CHAP's assessment of risk (both cumulative and in isolation) of various phthalates, and the CHAP's recommendations to the Commission. The preamble to the NPR then provided CPSC staff's assessment of the CHAP report and stated the Commission's description of the proposed rule and its explanation of the rationale for the proposal.

The NPR generally followed the recommendations of the CHAP report. As explained further in section III of this preamble, the CHAP focused on certain phthalates' effect on male reproductive development. After reviewing relevant studies, the CHAP found that certain phthalates (which the CHAP called active or antiandrogenic) cause adverse effects on the developing male reproductive tract. The CHAP determined that these phthalates act in a cumulative fashion. The CHAP concluded that DINP is an active (antiandrogenic) phthalate. Based on the cumulative risk assessment conducted by the CHAP, the Commission determined that ''to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety,'' the Commission proposed to permanently prohibit children's toys and child care articles containing concentrations of more than 0.1 percent of DINP. The Commission proposed making the interim prohibition concerning DINP permanent because the Commission concluded that allowing the use of DINP in children's toys and child care articles would further increase the cumulative risk to male reproductive development. Although the interim prohibition applies to children's toys that can be placed in a child's mouth and child care articles, the NPR proposed permanently prohibiting DINP in all children's toys and child care articles. 79 FR at 78334–35.

The Commission proposed lifting the interim prohibitions regarding DIDP and DNOP. The Commission agreed with the CHAP that DIDP and DNOP are not antiandrogenic, and therefore, they do not contribute to the cumulative risk from antiandrogenic phthalates. The CHAP determined that neither phthalate poses a risk in isolation. Therefore, the Commission concluded that continuing the prohibitions regarding DIDP and 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. *Id.* at 78334–78336.

In addition, the Commission determined that DIBP, DPENP, DHEXP, and DCHP are associated with adverse effects on male reproductive development and contribute to the cumulative risk from antiandrogenic phthalates. The Commission agreed with the CHAP's recommendation and proposed to prohibit children's toys and child care articles containing concentrations of more than 0.1 percent of DIBP, DPENP, DHEXP, and DCHP. 79 FR at 78326–38. The Commission proposed that the rule would take effect 180 days after publication of a final rule in the **Federal Register**. *Id.* at 78339.

C. Additional NHANES Analysis

As explained further in section III.C.2 of this preamble, the CHAP based its analysis, in part, on human biomonitoring data from the Centers for Disease Control and Prevention's (CDC) National Health and Nutrition Examination Survey (NHANES). The CHAP analyzed data from NHANES' 2005/2006 data cycle. That data set had a larger number of pregnant women than is usual for NHANES data sets. Since publication of the NPR, CPSC staff has reviewed and analyzed the NHANES data cycles released by the CDC after the 2005/2006 data cycle. CPSC staff issued a report in June 2015 concerning the NHANES data sets that had been released up to that point: ''Estimated Phthalate Exposure and Risk to Pregnant Women and Women of Reproductive Age as Assessed Using Four NHANES Biomonitoring Data Sets (2005/2006, 2007/2008, 2009/2010, 2011/2012).'' *See https://www.cpsc.gov/s3fs-public/NHANES-Biomonitoring-analysis-for-Commission.pdf* . The June 2015 staff analysis reviewed the 2005/2006 NHANES data set to replicate the CHAP's methodology and reviewed the subsequent NHANES data sets through 2011/2012. Staff's analysis used women of reproductive age (WORA; 15–45 year of age) as the population of interest, because NHANES data sets after 2005/2006 did not have sufficient numbers of pregnant women to be statistically relevant. The Commission published a notice of availability in the **Federal Register** seeking comment on the CPSC staff document. 80 FR 35939 (June 23, 2015).

In December 2016, the CDC released the NHANES 2013/14 data cycle. CPSC staff prepared a document with staff's analysis of the NHANES 2013/14 data cycle titled, ''Estimated Phthalate Exposure and Risk to Women of Reproductive Age as Assessed Using 2013/2014 NHANES Biomonitoring Data.'' *See https://www.cpsc.gov/s3fs-public/Estimated%20Phthalate%20Exposure%20and%20Risk%20to%20Women%20of%20Reproductive%20Age%20as%20Assessed%20Using%202013%202014%20NHANES%20Biomonitoring%20Data.pdf.* The Commission published a notice of availability in the **Federal Register** seeking comments on CPSC staff's February 2017 analysis of the NHANES 2013/14 data cycle. 82 FR 11348 (February 22, 2017).

D. Public Comments

The NPR, which published in the **Federal Register** on December 30, 2014, requested comments by March 16, 2015. 79 FR 78324 (Dec. 30, 2014). The Commission extended the comment period for an additional 30 days to April 15, 2015. 80 FR 14880 (March 20, 2015). Additionally, the Commission requested comments on each of the staff's analyses of more recent NHANES data. 80 FR 35939 (June 23, 2015); 82 FR 11348 (February 22, 2017). The Commission received 91 comments on the NPR and an additional 18 comments on CPSC

staff's reports on more recent NHANES data cycles. The comments are available on *regulations.gov* under the docket: CPSC–2014–0033. Throughout this preamble, we discuss significant issues raised by these comments and CPSC's responses to those issues. As part of the briefing package that CPSC staff prepared for the Commission's consideration of this final rule, staff developed a more detailed summary of the public comments and staff's responses. These may be found at Tab B of the staff's briefing package: *https://www.cpsc.gov/s3fs-public/Final%20Rule%20-%20Phthalates%20-%20September%2013%202017.pdf* At the end of each comment summary in this preamble, we provide, in parentheses, the number of the relevant and more detailed comment/response in Tab B of the staff's briefing package.

E. Final Rule

The Commission has considered the CHAP report, CPSC staff's analyses, and comments submitted on the NPR and staff's reports concerning later NHANES data cycles. CPSC staff prepared a briefing package for the Commission that provides staff's analysis of these materials and gives staff's recommendations for the final rule. Staff's briefing package is available at: *https://www.cpsc.gov/s3fs-public/Final%20Rule%20-%20Phthalates%20-%20September%2013%202017.pdf* Based on consideration of these materials, the Commission issues this final rule, which is substantially the same as the proposed rule.

In the interest of clarity, the final rule restates the CPSIA's permanent prohibition on the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any children's toys and child care articles that contain concentrations of more than 0.1 percent of DEHP, DIBP, or BBP.

The final rule continues the interim prohibition concerning DINP and expands that restriction to prohibit all children's toys (not just those that can be place in a child's mouth) and child care articles that contain concentrations of more than 0.1 percent of DINP. After reviewing the information presented by the CHAP, CPSC staff, and commenters, the Commission concludes that continuing the interim prohibition regarding DINP will ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety. The Commission also determines that expanding the prohibition regarding DINP to cover all children's toys, not just those that can be placed in a child's mouth, is necessary to protect the health of children.

The final rule also prohibits children's toys and child care articles that contain concentrations of more than 0.1 percent of DIBP, DPENP, DHEXP, and DCHP. After reviewing the information presented by the CHAP, CPSC staff, and commenters, the Commission concludes that this restriction on the four additional phthalates is necessary to protect the health of children.

The final rule adds a paragraph, not in the proposed rule, that repeats the statutory provision stating that the phthalates prohibitions apply to plasticized component parts of children's toys and child care articles, or other component parts of those products that are made of materials that may contain phthalates. *See* 15 U.S.C. 2057c(c). This addition does not make any substantive change, but it provides clarity by placing this statutory language in the regulation.

As was proposed, the final rule will take effect 180 days after publication in the **Federal Register** and will apply to products manufactured or imported on or after that date. The Commission's rationale for the final rule is explained in the following sections of this preamble.

II. Legal Authority

A. Summary of Legal Authority

Section 108 of the CPSIA provides the legal authority for this rule. As directed by section 108(b)(2), the Commission convened a CHAP to study the effects on children's health of phthalates and phthalate alternatives. The CPSIA directs the CHAP to examine ''the full range of phthalates that are used in products for children,'' and to consider numerous issues specified in the statute (discussed further in section III.A of this preamble). As required by section 108(b)(2)(C), the CHAP prepared a report for the Commission that included recommendations to the Commission concerning any phthalates not already subject to the permanent prohibition or phthalate alternatives that should be prohibited. 15 U.S.C. 2057c(b)(2)(C).

The CPSIA further directs that, within 180 days of receiving the CHAP's report, the Commission shall promulgate a final rule in accordance with section 553 of the APA. 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.'' *Id.* 2057c(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.* 2057c(b)(3)(B).

A violation of the permanent or interim prohibitions or any rule the Commission subsequently issues under section 108(b)(3) ''shall be treated as a violation of section 19(a)(1) of the Consumer Product Safety Act.'' *Id.* 2057c(e). Additionally, section 108(f), concerning preemption, states that the permanent and interim prohibitions and the Commission's phthalates rule ''shall be considered consumer product safety standards under the Consumer Product Safety Act.'' *Id.* 2057c(f).

Section 108 of the CPSIA sets out the criteria for the Commission's determinations in this rulemaking. Regarding phthalates subject to the interim prohibition, the Commission is to determine, based on the CHAP report, whether their continued regulation is needed ''to ensure a reasonable certainty of no harm . . . with an adequate margin of safety.'' Regarding other children's products and other phthalates, the Commission is to evaluate the CHAP report and determine whether additional restrictions are ''necessary to protect the health of children.'' 15 U.S.C. 2057c(b)(3). Congress required the Commission to use these criteria for the phthalates rulemaking.

B. Comments Regarding Legal Authority

Comments raised various issues concerning the Commission's legal authority for this rulemaking. These comments focused primarily on: The CPSIA's requirements for the CHAP, the CPSIA's requirements for the rulemaking, relevance of (and compliance with) the Information Quality Act (IQA), and compliance with requirements of the Administrative Procedure Act (APA). This section summarizes and responds to key issues raised by comments related to the Commission's legal authority. Tab B of staff's briefing package provides a more detailed discussion of the comments and responses. *https://www.cpsc.gov/s3fs-public/Final%20Rule%20-%20Phthalates%20-%20September%2013%202017.pdf?nArsRDzq81e90J4Re2BFAzjdQHxq8Mh_.*

1. The Information Quality Act

Comment: IQA Applicability: Several commenters asserted that the CHAP report and the phthalates rulemaking must comply with the Office of Management and Budget's (OMB's) Guidelines issued under the IQA and CPSC's guidelines. The commenters stated that the OMB's IQA Guidelines require that agencies' disseminations meet a basic standard of quality for objectivity, utility and integrity, and that these requirements apply to the CHAP report and to CPSC's rulemaking. The commenters also asserted that the CHAP report is ''influential'' under the IQA Guidelines because it meets the OMB standard for influential, *i.e.,* has ''a clear and substantial impact on important public policies or private sector decisions.''

Response: The IQA, Public Law 106–554, required OMB to draft guidelines regarding ''the quality, objectivity, utility, and integrity of information . . . disseminated by Federal agencies'' and required each agency to issue its own guidelines. OMB issued ''Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integration of Information Disseminated by Federal Agencies'' (OMB Guidelines), 67 FR 8452. The CPSC issued its Information Quality Guidelines (CPSC Guidelines) in October 2002, which substantially follow OMB's Guidelines.[2] As provided in CPSC's Guidelines, we are responding to comments on the NPR to address a commenter's request for correction under the IQA.

OMB's Guidelines apply to federal agencies that are subject to the Paperwork Reduction Act (PRA), 42 U.S.C. chapter 35. 67 FR 8453. This includes the CPSC. Both OMB's and CPSC's Guidelines apply to information that the agency ''disseminates.'' OMB's Guidelines define the term ''dissemination'' to mean ''agency initiated or sponsored distribution of information to the public,'' with several exclusions. Under OMB's Guidelines, if an agency releases information prepared by an outside party, but the agency then distributes the information ''in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to the guidelines.'' 67 FR 8454. As the commenters noted, the CHAP report was not prepared by CPSC but by a third party. However, in the NPR, CPSC based its recommendations on the CHAP report as required by section 108 of the CPSIA. Thus, we agree that OMB's and CPSC's Guidelines apply to the CHAP report.

As discussed in the following comments/responses, OMB's Guidelines require agencies to adopt a basic standard of information quality that includes ''objectivity, utility, and integrity.''

OMB's Guidelines define ''influential'' as:

> ''Influential'', when used in the phrase ''influential scientific, financial, or statistical information'', means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions. Each agency is authorized to define ''influential'' in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

67 FR 8460. The definition of ''influential'' places significant emphasis on the agency's discretion to determine what information is influential. The OMB Guidelines state that influential information is held to a higher standard and must have a high degree of transparency. Even if the CHAP report is considered ''influential,'' it met the OMB Guidelines' provisions for such documents. As explained throughout this document, the CHAP was transparent about its data sources and processes. See the following comments and responses. (Comments 8.1 and 8.2).

Comment: Objectivity of CHAP report. Commenters asserted that the CHAP Report (and by extension, the rulemaking) does not meet the IQA Guidelines' standard of ''objectivity.'' In addition, the commenters argued that, because the CHAP Report is influential information regarding risks to health, safety, or the environment, it ''must be based on requirements drawn from the Safe Drinking Water Act (SDWA), to use 'the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and . . . data collected by accepted methods or best available methods . . . .'" (Comment 8.3).

Response: The OMB Guidelines state: '' 'Objectivity' includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner.'' 67 FR 8459. According to the OMB Guidelines, this involves presenting the information within a proper context and identifying the sources of the information. *Id.* The OMB Guidelines further state: ''In addition, 'objectivity' involves a focus on ensuring accurate, reliable, and unbiased information.'' In a scientific context, this means ''using sound statistical and research methods.'' *Id.*

The CHAP report met the ''objectivity'' standard enunciated in the OMB Guidelines. The fact that the commenters might have conducted the analysis differently does not mean that the CHAP's analysis was not ''objective.'' The CHAP report clearly set forth its data sources and noted that to assess studies, it used the criteria of reliability, relevance, and adequacy established by the Organisation for Economic Cooperation and Development. CHAP report at pp. 13–14. The CHAP held open meetings during the process of developing its analysis, inviting experts to present their latest research findings and taking submissions of a large volume of written material. The CHAP members were selected in accordance with section 28 of the CPSA through a process to ensure their independence from bias (*e.g.,* nominated by National Academy of Sciences; free from compensation by or substantial financial interest in a manufacturer, distributor or retailer of a consumer product; not employed by the federal government, with certain scientific/research related exceptions). The CHAP explained its choices, such as the decision to focus on the effects on male reproductive development, and the CHAP noted that this approach was consistent with a National Research Council (NRC) report.[3] Similarly, the CHAP explained its decision to conduct a cumulative risk assessment and explained the methodology that it used which, again, was consistent with one of the methods discussed in the NRC report.

For an analysis of risks to human health, safety, and the environment that an agency disseminates, OMB's Guidelines direct agencies to ''adapt or adopt'' the information quality principles of the SDWA. 67 FR 8460. The SDWA directs agencies to use: '' (i) The best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).'' *Id.* at 8457. The SDWA direction is very similar to the charge to the CHAP in section 108, which states, among other things, that the CHAP is to ''review all relevant data, including the most recent best available, peer reviewed, scientific studies of these phthalates and phthalate alternatives

[2] CPSC Information Quality Guidelines. Available at: *https://www.cpsc.gov/en/Research--Statistics/Information-Quality-Guidelines/.*

[3] NRC (2008).

that employ objective data collection practices or employ other objective methods.'' 15 U.S.C. 2057c(b)(2)(B)(v). As our discussion in section III of this preamble demonstrates, the CHAP report met this direction.

Comment: IQA deficiencies as basis to invalidate rule. A commenter asserted that the CHAP report had numerous methodological flaws that violated the IQA and that these deficiencies would invalidate the phthalates rulemaking unless they are corrected because the proposed rule was premised almost entirely on the CHAP report. The commenter further asserted that OMB's IQA Guidelines are ''binding'' on agencies. (Comment 8.4).

Response: Elsewhere in this document and in Tab B of staff's briefing package, staff responds to the specific methodological ''flaws'' the commenter identifies. Regarding the legal point, we note that OMB's Guidelines are not legally enforceable requirements—guidelines, which are essentially interpretive rules, by their nature do not establish binding requirements. *See, e.g., U.S. Iowa League of Cities* v. *EPA,* 711 F.3d 844, 873 (8th Cir., 2013) (''interpretive rules do not have the force of law''). Notably, the IQA directed OMB to ''issue guidelines . . . that provide policy and procedural guidance to Federal agencies.'' The IQA did not direct OMB or agencies to undertake substantive legislative rulemaking. Consolidated Appropriations Act of 2001, Public Law 06–554, 515 (codified at 44 U.S.C. 3516 Note). OMB's Guidelines repeatedly stress their flexibility, noting that they are not intended to be ''prescriptive, 'one-size-fits-all' '' and that OMB intends for agencies to ''apply them in a common-sense and workable manner.'' 67 FR at 8452–53. The IQA established a binding requirement that OMB issue guidelines and that each agency that is subject to the PRA must issue its own guidelines, but the guidelines themselves do not bind agencies. Courts that have examined the question of the legal status of the IQA have found that the IQA (and thus necessarily, OMB's guidelines) ''creates no legal rights in any third parties.'' *Salt Inst.* v. *Leavitt,* 440 F.3d 156, 159 (4th Cir. 2006). *See Mississippi Comm. on Environmental Quality* v. *EPA,* 790 F.3d 138 (D.C. Cir. 2015) (dismissing argument that IQA created a legal requirement for EPA to use ''best available science and supporting studies'').

2. CPSIA Requirements for the CHAP

Comment: Review of all relevant data. Several commenters noted that the CPSIA directed the CHAP to ''review all relevant data, including the most recent, best available . . . scientific studies . . . that employ objective data collection practices.'' A commenter asserted that the CHAP's ''selective use and systematic mischaracterization of the data'' did not meet this requirement. Commenters argued that the CHAP's reliance on the 2005/2006 NHANES data set, rather than later data sets that were available to the CHAP before the CHAP's stopping point (2007/2008, 2009/2010 and 2011/2012 data sets), violated the CPSIA's direction to review ''all relevant data'' and to include ''the most recent'' studies. The commenters asserted that the CHAP's failure to rely on later data sets is particularly important because, due to the drop in DEHP exposures, there has been a significant decline in total risk. One commenter asserted that the CHAP had ignored 32 relevant publications on phthalates. Other commenters stated that the CHAP's analysis ''represents the cutting edge and most current and best available science,'' a significant improvement over methodologies currently used for government review of chemical risk that considered one chemical at a time. (Comments 7.8, 8.17, and 10.2).

Response: The CHAP used 2005/2006 NHANES data on pregnant women to assess phthalate exposure as part of the CHAP's cumulative risk analysis, to satisfy the CPSIA's charge to ''examine the likely levels of children's, pregnant women's, and others' exposure to phthalates . . . '' 15 U.S.C. 2057c(b)(2)(B)(iii). This data set was the most recent data on pregnant women available at the time the CHAP completed its analysis in July 2012, CHAP report at p. 31, and it was the last data set to include a larger sample of pregnant women. CPSC staff subsequently analyzed NHANES WORA data from 2007/2008 through 2013/2014 using the CHAP's analytical methodology.

The CHAP considered new scientific information published up to the end of 2012, and used standard and acceptable methods for study review, conducting an unbiased literature search and publication identification and in-depth review and reporting of the most important publications. Specifically, the CHAP included many elements of systematic review methods in its work. The CHAP used a defined literature search strategy and limited the search to studies published through 2012. The CHAP considered the quality, relevance, and weight of evidence (WOE) of individual studies. The CHAP described criteria for evaluating published studies, CHAP report at pp. 19–23, and the CHAP ensured that all studies and data were publicly available. The CHAP also described the criteria used to formulate its recommendations on individual phthalates and phthalate alternatives. *Id.* at p. 79. The CHAP criteria included review of animal and human data, weight of evidence, study replication, human exposure, hazard, and risk. *Id.* at pp. 82–142. The CHAP conducted a thorough review of a large body of literature on a complex environmental health question using appropriate methods.

All current scientific publications and NHANES data sets have been analyzed by the CHAP and CPSC staff in preparation for the final rule. This fulfills the CPSIA's directive to review ''all relevant data'' and to include ''the most recent'' studies.

Regarding the assertion that the CHAP ignored 32 relevant publications, CPSC staff reviewed this claim. The CHAP cited approximately 250 articles using a systematic approach to select the most relevant and informative articles. Five of the 32 articles the commenter identified are not relevant because they considered effects that are not relevant to the CHAP's focus on male reproductive development (*e.g.,* onset of puberty in girls, estrogenic effects); they measured exposure, but not health effects; or did not accurately reflect exposure. The other 27 articles were review articles (which are considered secondary sources), several of which covered broad topics such as environmental chemicals. Staff's more detailed assessment of these publications is provided in the response to comment 7.8 at Tab B of the staff's briefing package.

Comment: Foreseeable use and likely exposure. Several commenters noted that the CPSIA required the CHAP to ''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.'' Commenters asserted that the CHAP failed to meet this requirement because the CHAP ignored the more recent data that shows a significant drop in DEHP exposure and the CHAP included permanent prohibitions involving phthalates in the analysis. (Comment 8.18).

Response: As explained, the 2005/2006 NHANES dataset that the CHAP used was the most recent data on pregnant women available at the time the CHAP completed its analysis in July 2012, CHAP report at p. 31, and included a larger sample of pregnant women. CPSC staff has since analyzed more recent NHANES data using the

same methodology used by the CHAP and using WORA as a surrogate for pregnant women because an insufficient number of pregnant women were sampled in the later data sets. The final rule considers the most recent NHANES data, as well as the CHAP report.

In accordance with the CPSIA's direction to the CHAP, the CHAP's cumulative risk analysis estimated phthalate exposure from all phthalates and all sources, not only toys and child care articles. Because the CPSIA prohibition covers only children's toys and child care articles, exposures to DEHP, DBP, and BBP still occur from other sources. Thus, the CHAP and subsequent staff analyses provide a robust assessment of the ''likely levels'' of current exposures to phthalates.

Comment: CPSIA direction to CHAP to conduct a cumulative risk assessment. One commenter stated that the CPSIA did not require the CHAP to conduct a cumulative risk assessment; the CHAP could have considered cumulative effects in a more general (qualitative) way. Other commenters asserted that a cumulative risk assessment was well within the CPSIA's direction to the CHAP, noting that the CPSIA provided a clear mandate to ''review the toxicity of phthalates cumulatively'' and to consider ''the exposure to all sources of these chemicals.'' One comment from a group of commenters stated Congress specifically required the cumulative risk analysis. (Comment 8.19).

Response: Several provisions in section 108(b)(2) called on the CHAP to consider cumulative effects of phthalates. Specifically, the statute directed the 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'';
- ''consider the potential health effects of each of these phthalates both in isolation and in combination with other phthalates''; and
- ''consider the cumulative effects of total exposure to phthalates, both from children's products and from other sources, such as personal care products.''

Thus, the CPSIA required the CHAP to use some method to evaluate the health effects of multiple phthalates from multiple products. The statute did not specify that the only way to do this was through a cumulative risk assessment. However, nothing in the statute prohibited the CHAP from conducting a cumulative risk assessment. As explained in the CHAP report, and in the NPR, based on the CHAP's knowledge and expertise, the CHAP decided that a cumulative risk assessment was the most appropriate method to fulfill the direction given to the CHAP. Furthermore, the CHAP used a cumulative risk assessment approach that was consistent with recommendations from a National Academy of Sciences committee that was convened specifically to consider methods for assessing the cumulative risks from phthalates. Thus, the CHAP used its judgment and provided an explanation for its reasonable choice.

Comment: Applicability of the Federal Hazardous Substances Act. A commenter argued that the CPSIA required the CHAP to present its analysis in terms of the criteria stated in the FHSA, and the commenter asserted that the CHAP failed to do so. Similarly, a commenter asserted that the CHAP's risk assessment improperly included consideration of exposures to substances that are excluded from the FHSA's definition of ''hazardous substance,'' such as foods and drugs. 15 U.S.C. 1261(f)(2). (Comments 8.27 through 8.29).

Response: The commenter bases its argument that the CHAP should have followed FHSA criteria on a phrase in CPSIA section 108 that also appears in the FHSA. However, neither section 108 nor the legislative history of that provision mentions the FHSA. Rather, section 108(b)(2)(B) provides detailed direction to the CHAP about the criteria that the CHAP is to consider in its examination. Moreover, section 108(f) states clearly that the statutory prohibitions and the Commission's future phthalates rule ''shall be considered consumer product safety standards under the Consumer Product Safety Act.'' It is not logical that Congress would expect the CHAP to apply FHSA criteria (without mentioning that statute) to provide a report to the Commission for a rule that is to be treated as a rule under the CPSA. In fact, section 108 established a unique procedure for phthalates, making it clear that Congress did not intend for the Commission to undertake rulemaking under the FHSA. The CHAP and the Commission followed the specific process and criteria set forth in section 108. The direction to the CHAP explicitly requires the CHAP to consider phthalates that are in products outside the CPSC's jurisdiction, directing the CHAP to consider effects ''both from children's products and from other sources, such as personal care products.'' 15 U.S.C. 2057c(b)(2)(B)(iv). Many personal care products are considered cosmetics and are under the jurisdiction of the U.S. Food and Drug Administration (FDA). Congress thus intended for the CHAP's examination to be broader than just products under CPSC's authority, even though CPSC's rulemaking applies only to products under CPSC's jurisdiction.

3. CPSIA's Requirements for the Rulemaking

Comment: Commission's role regarding the CHAP report. Comments questioned the Commission's reliance on the CHAP report in the NPR. Commenters asserted that the Commission cannot merely codify or ''rigidly adhere'' to the CHAP report without applying the Commission's own judgment. To do so, they argued, would raise serious Constitutional questions by vesting government powers in a private entity and would also conflict with the CPSIA and sections 28 and 31 of the CPSA (*e.g.,* the word ''advisory'' in the CHAP). Another commenter stated that CPSC acted appropriately on the CHAP report, noting that ''CPSC made its own decision, issued its own proposed rule, and solicited public comment from industry and others on its proposed rule.'' (Comment 8.20).

Response: Section 108(b)(3) of the CPSIA requires that the Commission's rule concerning the interim prohibition be ''based on'' the CHAP report and requires the Commission to evaluate the findings and recommendations of the CHAP to determine whether to prohibit any other children's products containing any other phthalates. We agree that the statutory language does not require rigid adherence to the CHAP report and that the Commission cannot simply ''rubber-stamp'' the CHAP's recommendations. Rather, the CHAP report is advisory, and the Commission must use its judgment to decide on appropriate regulatory action in accordance with the specific criteria stated in section 108(b)(3)(A) and (B) and must consider public comments that the Commission received. This is exactly the process the Commission followed. The NPR summarized the CHAP report, including the CHAP's recommendations. 79 FR 78326–78330. The NPR presented CPSC staff's evaluation of the CHAP report and the Commission's assessment of the CHAP's recommendations. *Id.* 78330–78338. Additionally, CPSC staff reviewed more recent NHANES data and conducted an analysis of the CHAP's evaluation of exposure data. Staff reviewed and considered the comments submitted in response to the NPR and the NHANES data analysis to develop recommendations to the Commission. All of this information provides the

basis for the Commission's decision on the final rule.

Comment: Meaning of ''reasonable certainty of no harm.'' Several commenters addressed the meaning of the phrase ''reasonable certainty of no harm.'' Some commenters asserted that the standard must be interpreted in the context of CPSC's other statutes and case law. In this view, the phrase essentially means ''reasonably necessary to prevent or reduce an unreasonable risk of injury,'' as would be required for a consumer product safety rule the Commission issues under sections 7, 8 and 9 of the CPSA. Commenters also discussed the level of certainty required for a ''reasonable certainty of no harm.'' One commenter noted that the FDA uses a similar standard for food additives. One commenter stated that in the NPR, the CPSC has applied the standard essentially to require absolute certainty. In contrast, another commenter emphasized that the CPSIA calls for ensuring a '''reasonable certainty of *no* harm' (emphasis added).'' (Comments 8.14, 8.22, 8.23, and 8.25).

Response: The requirements stated in section 108(b)(3) of the CPSIA, rather than sections 7, 8 and 9 of the CPSA, apply to this rulemaking. For the Commission to issue a consumer product safety rule under sections 7, 8 and 9 of the CPSA, the Commission must determine that the product presents an unreasonable risk of injury and that a rule is necessary to reduce or prevent the unreasonable risk. The term ''unreasonable risk'' does not appear anywhere in the criteria stated in section 108(b)(3) that the Commission is to use to determine appropriate phthalate regulations. Nothing in the legislative history of section 108 indicates that Congress intended the Commission to make ''unreasonable risk'' determinations. Nor is there any indication that Congress intended that the case law related to the Commission's rules issued under sections 7, 8 and 9 of the CPSA would apply to the phthalates rulemaking.

We are aware of two other statutory schemes that use somewhat similar language. The Food Quality Protection Act (FPQA) uses a similar phrase regarding tolerance levels for pesticide residue on food. That provision requires the U.S. Environmental Protection Agency (EPA) to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.'' 21 U.S.C. 346a(b)(2)(A)(ii)(I). Under the Federal Food, Drug, and Cosmetic Act (FDCA), food additives must be ''safe.'' 21 U.S.C. 348. FDA has issued regulations that define ''safe or safety'' to mean ''that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions or use.'' In a very general sense, CPSC's approach on phthalates is consistent with FDA and EPA in that CPSC's evaluation is based on expert scientific opinion (the CHAP), takes into account the cumulative effect of the substance at issue (phthalates), and provides appropriate safety factors (*e.g.,* for inter- and intra-species uncertainties). However, because the pesticide tolerance and food additive schemes differ significantly from the CPSIA's phthalates provision, FDA's and EPA's approaches do not provide CPSC with more specific guidance on ''reasonable certainty of no harm.''

Regarding the level of certainty required, the language ''ensure a reasonable certainty of no harm . . . with an adequate margin of safety'' calls for a highly protective standard, but not 100 percent certainty of no harm. Congress required ''a reasonable certainty of no harm,'' not an absolute certainty of no harm.

4. The APA's Requirements

Comment: Data and the CPSC's obligation under the APA. Some commenters argued that the Commission's reliance on certain data violated the APA. One commenter asserted that the NPR's reliance on ''decade-old data'' is not reasonable, and therefore, violates the APA. Some commenters stated that because the NPR ''rests on outdated data,'' CPSC should withdraw the NPR, conduct a reanalysis with current exposure data, and re-propose the rule with a new comment period. In comments on CPSC staff's analysis of recent NHANES data, a commenter asserted that under the APA, ''the Commission has an obligation to disregard the CHAP's report to the extent it is incorrect, unreasonable, inconsistent with existing CPSC policy, practice, regulations or governing statutes, or is based on data that is outdated or of poor quality.'' The commenter set out the minimum requirements of informal rulemaking: Adequate notice, sufficient opportunity for public to comment, and a final rule that is not arbitrary and capricious. (Comments 8.12 and 8.13).

Response: The NPR's reliance on the CHAP report and the data the CHAP used did not violate the APA. Rather, the Commission followed the CPSIA's direction to base the rulemaking on the CHAP report. As commenters requested, staff subsequently considered updated exposure data. As the CPSIA requires, the Commission's proposal regarding the interim prohibition was ''based on the CHAP report,'' and in addition, the Commission evaluated the CHAP report to determine whether to prohibit any children's products containing any other phthalates. Additionally, as required by the CPSIA, the Commission followed the notice and comment procedures of the APA. For the final rule staff considered more recent exposure data than the CHAP used. Several commenters asked the Commission to do this additional work. Staff conducted two analyses of more recent NHANES biomonitoring data sets, posted reports of staff analyses on the CPSC Web site, and the Commission requested public comment on each analysis. 80 FR 35938 (June 23, 2015) and 82 FR 11348 (February 22, 2017). We agree that under section 553 of the APA, the Commission must evaluate the CHAP report along with comments submitted in response to the proposed rule and engage in reasoned decision making to issue a final rule. This is the approach the agency has taken. The Commission provided adequate notice in the NPR (describing the CHAP report, providing staff's evaluation of the CHAP report and explanation of, and reasons for, the proposed rule); provided sufficient opportunity for the public to comment (even extending the comment period and obtaining comment on the two staff reanalysis documents); and the Commission explains its reasoning for the final rule in this preamble and supporting documents.

Comment: Restriction involving DINP and compliance with APA: A commenter asserted that continuing the interim prohibition involving DINP is arbitrary and capricious (in violation of the APA) because:

- There is a reasonable certainty of no harm without such a prohibition (due to permanent prohibition involving DEHP);
- DINP contributes only a small fraction to overall risk;
- the endpoint of antiandrogenicity is likely inappropriate;
- it is questionable that DINP should be included in a cumulative risk assessment;
- it is questionable that a cumulative risk assessment provides a reasonable basis for a regulatory decision;
- DEHP levels have dropped so that the Hazard Index (HI) is now well below one; and
- even using the 2005/2006 NHANES data, the contribution of DINP to the overall HI is minimal and the major source of exposures is diet—children's products account for only a small fraction of overall HI.

In contrast, another commenter stated that the CHAP's recommendation and the Commission's proposal to permanently prohibit children's toys and child care articles containing more than 0.1 percent of DINP are justified. The commenter stated that data indicating that DINP is a potential health risk have gotten stronger since release of the CHAP report. (Comment 8.16).

Response: In general, the APA requires that agencies' rulemaking be based on reasoned decision making. Staff's briefing package explains the reasons for staff's recommendations, satisfying this threshold requirement. The specific issues the commenter raised about regulation of DINP and the apparent reductions over time in exposure to DEHP are addressed in detail in section IV.D.1.a. of this preamble.

III. The CHAP

A. CPSIA Direction

The CPSIA directed the Commission to convene a CHAP ''to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles.'' 15 U.S.C. 2057c (b)(2). The statute provides very specific direction to the CHAP regarding its work. The CHAP must:

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.

Id. 2057c(b)(2)(B). In its 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. *Id.* 2057c(b)(2)(C).

B. The CHAP's Process

The CHAP's process was open and transparent. The CHAP met in public session (and webcast) seven times and met via teleconference (also open to the public) six times.[4] A record of the CHAP's public meetings, including video recordings and information submitted to the CHAP, as well as the final CHAP report, are available on the CPSC Web site.[5]

At a meeting on July 26–28, 2010, the CHAP heard testimony from the public, including testimony from federal agency representatives, who discussed federal activities on phthalates. The CHAP also invited experts to present their latest research findings at the meeting in July 2010 and during subsequent meetings. Members of the public who presented testimony to the CHAP at the July 2010 meeting included manufacturers of phthalates and phthalate substitutes, as well as representatives of non-governmental 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 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.[6] The CHAP report was due to the Commission on April 8, 2012. The CHAP submitted the final report to the Commission on July 18, 2014.

C. The CHAP Report

1. Health Effects

The CHAP reviewed all of the potential health effects of phthalates. The CHAP explained that, although phthalates cause a wide range of toxicities, the CHAP focused on male reproductive developmental effects (MRDE) in part because this is the most sensitive and extensively studied endpoint for phthalates. The CHAP noted that this focus was consistent with a 2008 report from the National Research Council.[7] The CHAP systematically reviewed literature on phthalate developmental and reproductive toxicology. CHAP report, at pp. 1–2 and 12–13. The CHAP found that ''[s]tudies conducted over the past 20 years have shown that phthalates produce a syndrome of abnormalities in male offspring when administered to pregnant rats during the later stages of pregnancy.'' *Id.* at p. 15. The CHAP explained its approach to selection of data so that its analysis would be based on the most appropriate and reliable toxicological data. *Id.* at pp. 19–22. The CHAP stated that this collection of interrelated abnormalities, known as the ''rat phthalate syndrome,'' is characterized by various effects on the male reproductive system: Malformations of the testes, prostate, and penis (hypospadias); undescended testes; reduced anogenital distance (AGD), and retention of nipples.[8] Male pups also have reduced fertility as adults. The CHAP noted that only certain phthalates produce these abnormalities, phthalates with certain structural characteristics (three to seven, or eight, carbon atoms in the backbone of the alkyl side chain). The CHAP referred to these phthalates as ''active'' or ''antiandrogenic'' phthalates. *Id.* at pp. 15–16.

The CHAP noted that, although there is a great deal of information on

[4] The CHAP met in one closed meeting as part of the peer review process, January 28–29, 2015.

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

[6] 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.

[7] NRC recommended, for example, that it is appropriate to perform a phthalate cumulative risk assessment for MRDE (phthalate syndrome); the cumulative risk assessment should consider all endpoints associated with MRDE or, alternatively, one sensitive endpoint such as reductions in testosterone. NRC also recommended using dose addition, a hazard index approach, assuming that mixture effects occur at low-doses, and including other (non-phthalate) antiandrogens.

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

phthalate syndrome in rats, there is relatively little on the phthalate syndrome in other animal species. The CHAP reviewed the existing data-exposing species, such as rabbits, mice, and marmosets, to phthalates. The CHAP concluded that these studies with animals other than rats show that most animals tested are more resistant to phthalates than rats, but due to the limitations on these studies (*e.g.,* small number of animals exposed, only one phthalate, only one dose, high experimental variation), the CHAP found that ''studies in rats currently offer the best available data for assessing human risk.'' *Id.* at p. 18.

The CHAP reviewed, and discussed in its report, studies examining the mechanism by which phthalates produce adverse effects. The CHAP concluded that the phthalate syndrome effects are largely due to the suppression of testosterone production, as well as reduced expression of the insulin-like hormone 3 gene. *Id.* at pp. 18–19.

In addition to studies on animals, the CHAP also reviewed studies on the effect that exposure to phthalates has on human health (epidemiological studies). The CHAP noted that rat phthalate syndrome resembles testicular dysgenesis syndrome (TDS) in humans. TDS includes poor semen quality, reduced fertility, testicular cancer, undescended testes, and hypospadias.[9] CHAP report at p. 2. The CHAP concluded that studies provide human data linking prenatal exposure to phthalates with certain effects on male reproductive development (such as reduced anogenital distance,[10] reduced sperm quality and infertility in male infants). In addition, the CHAP discussed studies that found associations between prenatal or neonatal exposure to phthalates and reductions in mental and psychomotor development and increases in attention deficits and behavioral symptoms in children. *Id.* at pp. 27–33; Appendix C.

2. 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 exposure to phthalates. *Id.* at pp. 34–48; Appendix D. The CHAP used two data sources for HBM: NHANES and the Study for Future Families (SFF). NHANES is conducted by the CDC, and 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 phthalate exposures in pregnant women and women of reproductive age (WORA). Because NHANES does not measure phthalate metabolites in children younger than 6 years old, the CHAP used measurements from the SFF to obtain exposure estimates for infants. SFF is a study of mother-child pairs, funded by the National Institutes of Health (NIH) and the EPA. The CHAP used this HBM data to derive daily intake (DI) estimates to use in its risk assessment calculations. The CHAP used the 2005/2006 NHANES data cycle in its analysis. The SFF data are from 1999 to 2005. From the HBM data, the CHAP concluded that ''exposure to phthalates in the United States (as worldwide) is omnipresent. The U.S. population is co-exposed to many phthalates simultaneously.'' *Id.* at p. 37. The CHAP also noted that, because the data indicate that sources and routes of exposure among high- and low-molecular weight phthalates are similar, it is highly likely that substitution of one phthalate will lead to increased exposure to another similar phthalate. *Id.*

The HBM data do not measure the sources of people's exposure to phthalates. For this, the CHAP used a scenario-based exposure assessment. *Id.* at pp. 49–60; Appendix E. The CHAP used estimations of phthalate concentrations in various sources to predict exposures to subpopulations (pregnant women/WORA, infants, toddlers, and children). For the scenario-based exposure assessment, the CHAP estimated the DINP exposure that would occur if DINP were allowed in children's toys and child care articles. The CHAP found that for most phthalates, food, rather than children's toys or child care articles, is the primary source of exposure for women and children. The CHAP examined exposures to various phthalates from these sources. The CHAP found that infants, toddlers, and children were primarily exposed to DINP, DEHP, and DIDP. For infants, exposure to DINP was primarily from diet, but exposure was also due to DINP in teethers and toys. *Id.* at pp. 50–51.

3. Phthalates Risk Assessment

a. Cumulative Risk Assessment

In accordance with the CPSIA's direction, the CHAP considered health effects of phthalates ''in combination with other phthalates.'' 15 U.S.C. 2057c(b)(2)(B)(ii). The CHAP found, based on published studies, that active phthalates act in an additive fashion. 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 CHAP stated: ''Experimental data on combination of effects of phthalates from multiple studies (*e.g.,* Howdeshell *et al.* (2008)) provide strong evidence that dose addition can produce good approximations of mixture effects when the effects of all components are known.'' *Id.* at p. 61. 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 report at pp. 26–27. Due to the additive effects of certain phthalates, the CHAP determined that it is appropriate to conduct a cumulative risk analysis to assess the antiandrogenic phthalates the CHAP identified. *Id.*

For its cumulative risk assessment, the CHAP used a Hazard Index (HI) approach which, the CHAP noted, is widely used in cumulative risk assessments of chemical mixtures. *Id.* To determine the HI, one first calculates the hazard quotient (HQ) for each chemical and then adds the HQs together. The ''HQ'' is generally defined as the ratio of the potential exposure to a substance and the level at which no adverse effects are expected. If the HQ is less than one, the expectation is that no adverse effects will result from exposure; but if the HQ is greater than one, adverse effects are possible. Rather than use acceptable daily intakes (ADI) or reference doses (RfDs) as the denominator of HQs, the CHAP used ''potency estimates for antiandrogenicity'' (PEAAs). The PEAA is an estimate of the level of exposure at which the risk of antiandrogenic effects is considered negligible. The CHAP estimated a PEAA for each phthalate by dividing the MRDE ''antiandrogenic'' point of departure (POD; toxicity endpoint) by an uncertainty factor (UF). The CHAP used three sets of PEAAs (the CHAP refers to these as Cases) to evaluate the impact of assumptions in calculating the HI. *Id.* at pp. 61–65.

The CHAP calculated the HI per woman and infant, using the NHANES data on pregnant women (representing exposure to the fetus) and the SFF data on children. The CHAP found that roughly 10 percent of pregnant women in the U.S. population have HI values that exceed 1.0 (pregnant women had median HIs of about 0.1 (0.09 to 0.14), while the 95th percentile HIs were

[9] A malformation of the penis.

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

about 5, depending on which set of PEAAs was used. The CHAP found that 4–5 percent of infants have HI values that exceed 1.0 (infants had median HIs about 0.2, while the 95th percentiles were between 0.5 and 1.0). *Id.* at p. 65 and Table 2.16. Based on this cumulative risk assessment, the CHAP recommended that phthalates that induce antiandrogenic effects (DINP, DIDP, DPENP, DHEXP, and DCHP should be permanently banned from use in children's toys and child care articles at levels greater than 0.1 percent. *Id.* at pp. 7–8.

Regarding the HQs for the individual phthalates, the CHAP found that DEHP dominated, ''with high exposure levels and one of the lowest PEAAs.'' *Id.* at p. 65. HQ values were similar for three phthalates (DBP, BBP, and DINP), while DIBP had the smallest HQs. *Id.*

b. Risks in Isolation

In accordance with the CPSIA's direction, the CHAP also considered the risks of phthalates in isolation. 15 U.S.C. 2057c(b)(2)(B)(ii). The CHAP used a margin of exposure (MOE) approach to assess the risks in isolation. CHAP report at p. 69. 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. *Id.* The CHAP found that, with the exception of DEHP, for all phthalates that it evaluated in isolation, the MOEs were within acceptable ranges. *Id.* at pp. 82–121.

4. CHAP's Recommendations to the Commission

a. Phthalates Subject to the Interim Prohibition

Diisononyl phthalate (DINP)

The CHAP recommended that the Commission permanently prohibit the use of DINP in children's toys and child care articles at levels greater than 0.1 percent. The CHAP explained that, although DINP is less potent than other active phthalates, it induces antiandrogenic effects in animals, and therefore, DINP can contribute to the cumulative risk from other antiandrogenic phthalates. *Id.* at pp. 95–99.

The CHAP explained that studies exposing rats to DINP during the critical period of fetal development showed effects on male reproductive development. The CHAP stated: ''Five such studies have shown that DINP exposure in rats during the perinatal period is associated with increased incidence of male pups with areolae and other malformations of androgen-dependent organs and testes (Gray *et al.,* 2000), reduced testis weights before puberty (Matsutomi *et al.,* 2003), reduced AGD (Lee *et al.,* 2006), increased incidence of multinucleated gonocytes, increased nipple retention, decreased sperm mobility, decreased male AGD, and decreased testicular testosterone (Boberg *et al.,* (2011)), and reduced fetal testicular testosterone production and decreased StAR and Cyp11a mRNA levels (Adamson *et al.,*2009; Hannas *et al.,* 2011b).'' *Id.* at pp. 96–97.

The CHAP report discussed the CHAP's determination of a NOAEL for DINP. *Id.* at pp. 97–98. The CHAP stated:

> Taken together, the data from Boberg *et al.* (2011), Hannas *et al.* (2011b), and Clewell *et al.* (2013a; 2013b) indicate that the developmental NOAEL, based on antiandrogenic endpoints (nipple retention, fetal testosterone production, and MNGs) is between 50 and 300 mg/kg–day. Taking a conservative approach, the CHAP assigns the NOAEL for DINP at 50 mg/kg–day. However, the CHAP also wants to point out that a simple extrapolation based upon relative potencies (as described in Hannas *et al.,* 2011b) with 2.3-fold lesser potency of DINP than DEHP (in terms of fetal testicular T reduction) would lead to a NOAEL of 11.5mg/kg–d for DINP. This scenario is reflected in case 2 of the HI approach.

Id. at p. 98. Regarding exposure, the CHAP observed: ''DINP has been used in children's toys and child care articles in the past.'' *Id.* The CHAP noted that metabolites of DINP have been detected in urine samples in NHANES surveys. *Id.*

Considering risk in isolation (following the MOE approach), the CHAP found MOEs that are generally considered adequate for public health. For male developmental effects, in infants (using the SFF study) the CHAP stated that the total exposure ranged from 640 to 42,000, using 95th percentile estimates of exposure. For pregnant women (using NHANES data), the CHAP stated that the MOE for total DINP exposure ranged from 1000 to 68,000. The CHAP stated: ''Typically, MOEs exceeding 100–1000 are considered adequate for public health; however, the cumulative risk of DINP with other antiandrogens should also be considered.'' *Id.* at p. 99. The CHAP also considered the effects of DINP on the liver, and it found that the MOEs were within an acceptable range.

In making its recommendation to the CPSC concerning DINP, the CHAP stated: ''The CHAP recommends that the interim ban on the use of DINP in children's toys and child care articles at levels greater than 0.1% be made permanent. This recommendation is made because 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.'' *Id.*

Di-*n*-octyl phthalate (DNOP)

The CHAP reviewed data on DNOP. *Id.* at pp. 91–95. The CHAP found that, although 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), ''DNOP does not appear to possess antiandrogenic potential.'' The CHAP estimated that MOEs for DNOP for infants and toddlers ranged from 2,300 to 8,200. The CHAP concluded: ''because the MOE in humans are likely to be very high, the CHAP does not find compelling data to justify maintaining the current interim ban on the use of DNOP in children's toys and child care articles.'' The CHAP recommended that the Commission lift the interim prohibition with regard to DNOP, but also recommended that ''agencies responsible for dealing with DNOP exposures from food and child care products conduct the necessary risk assessments with a view to supporting risk management steps.'' *Id.* at p. 95.

Diisodecyl phthalate (DIDP)

The CHAP reviewed data on DIDP. *Id.* at pp. 100–105. The CHAP found that, although DIDP is a potential developmental toxicant (causing supernumerary ribs) and a potential systemic toxicant (causing adverse effects on the liver and kidney), ''DIDP does not appear to possess antiandrogenic potential.'' The CHAP estimated the MOEs for DIDP range from 2,500 to 10,000 for median intakes and from 586 to 33,000 for 9th percentile intakes. *Id.* at p. 104. The CHAP found that DIDP's MOEs in humans are likely to be relatively high. The CHAP stated: ''The CHAP does not find compelling data to justify maintaining the current interim ban on the use of DIDP in children's toys and child care articles.'' The CHAP recommended that the Commission lift the interim prohibition with regard to DIDP, but suggested that ''agencies responsible for dealing with DIDP exposures from food and child care products conduct the necessary risk assessments with a view to supporting risk management steps.'' *Id.* at pp. 104–105.

b. Other Phthalates

Due to their adverse effect on male reproductive development (and thus their contribution to the cumulative risk from other antiandrogenic phthalates), the CHAP recommended that the Commission permanently prohibit the use of four additional phthalates at levels greater than 0.1 percent in children's toys and child care articles.

Diisobutyl phthalate (DIBP)

The CHAP found that DIBP is similar in toxicity to DBP, one of the phthalates subject to the CPSIA's permanent prohibition. The CHAP reviewed studies that found that exposure to DIBP had effects on male reproductive development. The CHAP stated: ''Six studies in which rats were exposed to DIBP by gavage during late gestation showed that this phthalate reduced AGD in male pups, decreased testicular testosterone production, increased nipple retention, increased the incidence of male fetuses with undescended testes, increased the incidence of hypospadias, and reduced the expression of P450scc, ins13, genes related to steroidogenesis, and StAR protein (Saillenfait *et al.,* 2006; Borch *et al.,* 2006a; Boberg *et al.,* 2008; Howdeshell *et al.,* 2008; Saillenfait *et al.,* 2008; Hannas *et al.,* 2011b).'' *Id.* at p. 110.

Regarding exposure, the CHAP noted that DIBP has been detected in some toys during routine CPSC compliance testing. The CHAP stated: ''DIBP is too volatile to be used in PVC but is a component in nail polish, personal care products, lubricants, printing inks, and many other products.'' *Id.* at 111. Metabolites of DIBP have been detected in human urine in NHANES surveys and in Germany.

Assessing risk, the CHAP found: ''The margins of exposure (95th percentile total DIBP exposure) for pregnant women in the NHANES study ranged from 5,000 to 125,000. For infants in the SFF study, the MOE (95th percentile total DIBP exposure) ranged from 3,600 to 89,000.'' *Id.* Although these MOEs are within an acceptable range, the CHAP stated that the cumulative risk should be considered. *Id.* Explaining its recommendation concerning DIBP, the CHAP stated:

> Current exposures to DIBP alone do not indicate a high level of concern. DIBP is not widely used in toys and child care articles. However, CPSC has recently detected DIBP in some children's toys. Furthermore, the toxicological profile of DIBP is very similar to that of DBP, and DIBP exposure contributes to the cumulative risk from other antiandrogenic phthalates. The CHAP recommends that DIBP should be permanently banned from use in children's toys and child care articles at levels greater than 0.1%.

Id. at pp. 111–112.

Di-*n*-pentyl phthalate (DPENP)

Although DPENP is not widely used, the CHAP found that it is the most potent phthalate with respect to developmental toxicity. According to the CHAP, two studies (Howdeshell *et al.* (2008) and Hannas *et al.* (2011a)) found that DPENP exposure reduced fetal testicular testosterone production, StAR Cyp11a, and ins13 gene expression, and increased nipple retention. *Id.* at p. 112. The CHAP stated that DPENP is not currently found in children's toys or child care articles and is not widely found in the environment. *Id.* at p. 113. In its recommendation, the CHAP stated: ''The CHAP recommends that DPENP should be permanently banned from use in children's toys and child care articles at levels greater than 0.1%. The toxicological profile of DPENP is very similar to that of the other antiandrogenic phthalates, and DPENP exposure contributes to the cumulative risk.'' *Id.*

Di-*n*-hexyl phthalate (DHEXP)

According to the CHAP, a National Toxicology Program review of DHEXP in 2003 reported that based on the limited data available at that time, DHEXP is a developmental toxicant at high doses (9900 mg/kg-d), but the data were not adequate to determine an NOAEL or LOAEL. The CHAP stated that since then, ''one developmental toxicity study has reported that DHEXP exposure reduced the AGD in male pups in a dose-related fashion and increased the incidence of male fetuses with undescended testes (Saillenfait *et al.,* 2009a).'' *Id.* at p. 114. The CHAP report stated: ''Saillenfait *et al.* observed reproductive tract malformations, including hypospadias, undeveloped testes, and undescended testes, in young adult male rats exposed prenatally to doses of 125 mg/kg-d DHEXP or greater (Saillenfait *et al.,* 2009b).'' *Id.* at p. 115.

The CHAP stated that DHEXP is currently not found in children's toys or child care articles and is not widely found in the environment. It is primarily used in the manufacture of PVC and screen printing inks and is also used ''as a partial replacement for DEHP.'' *Id.* at p. 116. Regarding risk, the CHAP stated: ''DHEXP is believed to induce developmental effects similar to those induced by other active phthalates. Due to low exposure, current risk levels are believed to be low.'' *Id.* The CHAP recommended that DHEXP be permanently banned from use in children's toys and child care articles at levels greater than 0.1%. The CHAP stated: ''The toxicological profile of DHEXP is very similar to that of the other antiandrogenic phthalates, and DHEXP exposure contributes to the cumulative risk.'' *Id.*

Dicyclohexyl phthalate (DCHP)

The CHAP found that studies on DCHP showed effects on male reproductive development. The CHAP report states: ''Two studies in rats exposed to DCHP by gavage during late gestation showed that this phthalate prolonged preputial separation, reduced AGD, increased nipple retention, and increased hypospadias in male offspring (Sallenfait *et al,* 2009a; Yamasaki *et al.,* 2009). One study in rats exposed to DCHP in the diet showed that DCHP decreased the AGD and increased nipple retention in F1 males (Hoshino *et al.,* 2005).'' *Id.* at pp. 116–117. The CHAP stated that DCHP is currently not found in children's toys or child care articles and is not widely found in the environment. FDA has approved it ''for use in the manufacture of various articles associated with food handling and contact.'' DCHP is also a component of hot melt adhesives. *Id.* at p. 117. The CHAP stated: ''DCHP induces developmental effects similar to other active phthalates. Due to low exposure, current risk levels are believed to be low.'' The CHAP recommended that DCHP be permanently banned from use in children's toys and child care articles at levels greater than 0.1%. *Id.* at p. 118.

c. Phthalate Alternatives

The CPSIA also directed the CHAP to consider health effects of phthalate alternatives and to include in its report to the Commission recommendations for any phthalate alternatives that should be banned. 15 U.S.C. 2057c(b)(2)(B)(viii) and 2057c(b)(2)(C). The CPSIA defines ''phthalate alternative'' as ''any common substitute to a phthalate, alternative material to a phthalate, or alternative plasticizer.'' *Id.* 2057c(g)(2)(A). Accordingly, the CHAP also reviewed phthalate alternatives. CHAP report at pp. 121–142. The CHAP did not recommend banning any phthalate alternatives. We also note that the Commission's rulemaking authority under section 108 of the CPSIA does not extend to phthalate alternatives. 15 U.S.C. 2057c(b)(3).

D. Comments Regarding the CHAP

Comments concerning the substance of the CHAP's analysis are discussed in section IV of this preamble. This section covers comments concerning the CHAP's process.

1. Peer Review

Comment: Applicability of OMB Peer Review Bulletin. Commenters asserted that the CHAP report was subject to OMB's peer review bulletin, that it qualifies as a ''highly influential'' scientific assessment, and that it should be subject to a peer review that comports with the highest standards for transparency, openness, and objectivity, as outlined in the OMB's peer review bulletin. (Comments 8.6 and 8.7).

Response: The OMB's bulletin, *Final Information Quality Bulletin for Peer Review* (70 FR 2664 (Jan. 14, 2005)) (OMB Bulletin), requires ''to the extent permitted by law,'' that agencies conduct peer review on all influential scientific information that the agency intends to disseminate. The OMB Bulletin defines ''influential scientific information'' as ''scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.'' *Id.* at 2675. We believe that the CHAP report could be considered ''influential'' under this definition. According to the OMB Bulletin, ''dissemination'' means ''agency initiated or sponsored distribution of information to the public.'' *Id.* at 2674. The preamble to the OMB Bulletin notes that the OMB Bulletin ''does not directly cover information supplied by third parties (*e.g.,* studies by private consultants, companies and private, non-profit organizations, or research institutions such as universities). However, if an agency plans to disseminate information supplied by a third party (*e.g.,* using this information as the basis for an agency's factual determination that a particular behavior causes a disease), the requirements of the OMB Bulletin apply, if the dissemination is 'influential.' '' *Id.* at 26676. Although the CHAP report was written by a third party, we believe that by relying on the CHAP report in support of the NPR, the Commission disseminated the CHAP report. Under the Bulletin, additional requirements apply to ''highly influential scientific assessments,'' which the Bulletin defines as a scientific assessment that:

(1) Could have a potential impact of more than $500 million in any year, or

(2) is novel, controversial, or precedent-setting or has significant interagency interest.

One might consider the CHAP report to be a ''novel, controversial, or precedent-setting'' report that it could be of ''significant interagency interest'' because, as the CHAP report indicates, many of the products that contain phthalates (*e.g.,* food and cosmetics) fall under other agencies' jurisdiction.

Comment: Compliance with OMB Peer Review Bulletin. Some commenters asserted that the CHAP failed to adhere to the OMB Bulletin requirements for the peer review of a highly influential scientific assessment. In contrast, other commenters supported the peer review process used for the CHAP report, stating that the peer review was part of an open and transparent process. (Comment 8.7).

Response: The peer review process used for the draft CHAP report complied with the additional requirements for highly influential scientific assessments. For example, as noted by some commenters, the peer review of the draft report was conducted by four independent scientists, using the same criteria for selecting the peer reviewers (by nomination of the National Academy of Sciences) required for selecting the CHAP members. The peer reviewers were not employed by manufacturers of the products under consideration or by the federal government, except the National Institutes of Health, the National Toxicology Program, or the National Center for Toxicological Research.

Additionally, the CPSC made public: The identity of the peer reviewers, the charge to the peer reviewers, the draft report that was reviewed, and the peer reviewers' comments. CPSC posted all of the information on the CPSC Web site at the same time the final CHAP report was released to the public; and the information is available on the CPSC's Web site, in accordance with the additional requirements for a highly influential scientific assessment.[11] Thus, the public would have ample opportunity to see the concerns reviewers raised and how the CHAP addressed the concerns.

Finally, regarding public comment, as discussed in the next response, the peer review process used by CPSC complied with the OMB Bulletin.

Comment: Peer review and public comment. Commenters asserted that as a ''highly influential'' assessment, the CHAP report should have been subject to an open public comment period, as set forth in the OMB Bulletin. Commenters asserted that the Bulletin establishes strict minimum requirements for the peer review of highly influential scientific assessments, including a requirement that an agency ''make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review . . . and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public.'' Commenters asserted that this would have allowed for comment on flaws in the CHAP's analysis. (Comment 8.8).

Response: The OMB Bulletin states: ''The selection of an appropriate peer review mechanism for scientific information is left to the agency's discretion.'' *Id.* at 2665. It also advises: ''[a]gencies are directed to choose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review.'' *Id.* at 2668. We also note that CPSC staff consulted with OMB staff before finalizing the peer review plan for the CHAP report, as recommended by the OMB Bulletin.

Although the OMB Bulletin uses the term ''requirements,'' the document emphasizes the intent to allow agencies flexibility in determining appropriate methods of peer review, *id.* at 2665, and the OMB Bulletin is a guidance document. The OMB Bulletin states that it ''is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity.'' *Id.* at 2677. *See Family Farm Alliance* v. *Salazar,* 749 F. Supp. 2d 1083 (E.D. Cal. 2010) (finding that a claim that the U.S. Fish and Wildlife Service had not conducted appropriate peer review was not judicially reviewable). Although the draft CHAP report was not provided to the public for comment at the time that the CHAP submitted the report for peer review, the agency was not required to do so, nor was the agency required to sponsor a public meeting on the peer review. CPSC staff and the CHAP members reasonably desired that the report should achieve a high level of quality before it was released to the public. Moreover, as explained in the next response, the CHAP report was developed through a very open public process that provided for public input as the CHAP was developing its report.

2. CHAP's Transparency and Openness

Comment: Transparency and openness of CHAP's process. Several commenters stated generally that the process for the CHAP report was not open and transparent, but had been conducted behind closed doors. Other commenters questioned the transparency of particular aspects of the CHAP report, such as the methods used to review the scientific health evidence

[11] *See https://www.cpsc.gov/chap.*

and assess cumulative risk. In contrast, other commenters asserted that the CHAP process was a sound and fair process, adding that the process was highly public, and that the CHAP considered public comments and written submissions (including from industry representatives who charged that the process was not open). (Comments 8.8 and 10.3).

Response: The CHAP's process for developing its report was open and transparent throughout. The CHAP developed its approach in public during seven public meetings and six public teleconference calls. During these public meetings, the CHAP discussed the methods that the CHAP would use to conduct the cumulative risk assessment. CPSC provided a page on its Web site to post all CHAP-related information. All of the data submitted to the CHAP, CPSC contractors' reports, and peer-reviewed staff reports used by the CHAP were posted on the CPSC's public Web site. The CPSC's Web site also included correspondence submitted to CPSC concerning the CHAP's work. In fact, the CHAP elected not to use industry studies on DINX and DPHP, for the very reason that the manufacturer would not make the toxicology studies available to the public. NHANES data (which the CHAP relied on) are available to the public from the CDC. Once the CHAP transmitted its final report to the Commission, CPSC posted the final report, the draft report that had been submitted for peer review, and peer reviewers' comments. The CHAP considered all subject matter expert comments from the peer review of the CHAP draft report. The initial pages of the CHAP report outlined changes to the CHAP report resulting from the peer reviewers' comments.

3. Weight of Evidence and Completeness of CHAP's Review

Comment: Nature of CHAP's review. Some commenters stated that the CHAP did not, but should have, conducted a systematic review and/or followed a weight of evidence (WOE) approach. Various commenters asserted that the CHAP should have: Employed a consistent WOE framework; demonstrated how the CHAP graded, rated, and interpreted the epidemiology studies; and specified a clear and systematic approach for addressing the uncertainties of the data equally. (Comment 10.1).

Response: The CHAP used the WOE approach in two different manners. First, the CHAP wrote a ''Weight of Evidence'' section for each recommendation for each phthalate and phthalate alternative. The CHAP also used WOE more broadly when developing overall recommendations for each phthalate or phthalate alternative. The CHAP explicitly stated factors it considered relevant to making its recommendations. CHAP report at p. 79. The CHAP stated, however, that ''Because of the nature of the subject matter and the charge questions, which involve different streams of evidence and information, the CHAP concluded that its review was not amenable to the systematic review methodology.'' *Id.* at p. 12. This does not mean that the CHAP's review was unsystematic and biased. Rather, the CHAP, which began in 2010, did not have all of the systematic review methods that are available today. However, the CHAP incorporated many of the elements that are now included in systematic review methods in their work. (See Response 10.1 of Tab B of staff's briefing package for more detailed response.)

IV. Final Rule and Rationale

This section presents the final rule and explains the Commission's rationale for the rule. The Commission has considered the CHAP report, staff's analysis of the CHAP report, staff's analysis of recent NHANES data, and the public comments submitted in response to the proposed rule and staff's NHANES reports. More specifically, we present the Commission's rationale for the rule by explaining the Commission's consideration of: Phthalates' effects on male reproductive development, human exposure to phthalates, assessment of phthalates' cumulative risk and risks in isolation, and assessment of risk for each phthalate that the CHAP considered. In addition, the Commission considered the appropriate concentration limit for the phthalates restrictions and the appropriate effective date for the rule. In this section, we also discuss phthalate requirements established by international standards and other countries.

A. Hazard: Phthalates' Effect on Male Reproductive Development

1. Summary

In accordance with the CPSIA's direction, the CHAP reviewed all available toxicity data on phthalates. The CHAP determined that the critical endpoint for its analysis was adverse effects on male reproductive development (MRDE) and other adverse effects on male fertility. This focus was consistent with the NRC's 2008 assessment. As noted in the NPR, CPSC staff supports the CHAP's choice to focus on this endpoint because: MRDE in animals is associated with many of the most common phthalates; for most active phthalates, these effects are the most sensitive health effect; and phthalate syndrome in animals resembles testicular dysgenesis syndrome (TDS) in humans. Moreover, phthalates' effects on male reproductive development are well studied. 79 FR 78331–32.

As the CHAP reported, ''Studies conducted over the past 20 plus years have shown that phthalates produce a syndrome of reproductive abnormalities in male offspring when administered to pregnant rats during the later stages of pregnancy.'' CHAP report at p. 15. These effects include: Reduced testosterone synthesis, reduced anogenital distance (AGD), nipple retention (normally does not occur in male rats), undescended testes, testicular atrophy, testicular histopathology, multi-nuclear gonocytes (MNGs), reduced production of insulin-like hormone 3 (insl3), underdeveloped gubernacular cords,[12] undescended testes, and genital malformations (hypospadias).[13] Effects may differ depending on the dose. The CHAP noted: ''the highest incidence of reproductive tract malformations is observed at higher phthalate dose levels, whereas changes in AGD and nipple/areolae retention are frequently observed at lower phthalate does levels.'' CHAP report at p. 15. These effects persist into adulthood and lead to reduced or absent reproductive ability. Many, but not all, phthalates cause phthalate syndrome.[14] The CHAP identified five phthalates (DBP, BBP, DINP, DIBP, and DEHP) that cause phthalate syndrome and for which human biomonitoring data were available to assess exposure.

As discussed in the CHAP report, studies have reported similar effects in species other than rats, such as guinea pigs, mice, rabbits, and ferrets.[15] The evidence of phthalate syndrome in mice is even stronger now than when the CHAP developed its analysis.[16] In addition, as the CHAP noted, ''there is a rapidly growing body of

[12] Underdeveloped gubernacular cords lead to undescended testes.

[13] Foster (2006); Foster *et al.* (2001); Howdeshell *et al.* (2016); Howdeshell *et al.* (2008).

[14] The CHAP referred to phthalates that cause phthalate syndrome as ''antiandrogenic,'' due to the importance of testosterone inhibition in causing phthalate syndrome. Antiandrogenic also serves to distinguish phthalates from other chemicals that act through the androgen receptor, which phthalates do not.

[15] 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)).

[16] Clewell *et al.* (2011) and Ding *et al.* (2011).

epidemiological studies on the potential association of exposure to phthalates with human health.'' CHAP report at p. 27. For example, the CHAP discussed two human studies linking prenatal phthalate exposure to effects such as reduced AGD in male infants. *Id.* at p. 28. TDS in humans bears similarities to rat phthalate syndrome. *Id.* at p. 2. The effects of TDS (*e.g.,* hypospadias, cryptorchidism, testicular cancer, impaired fertility) are observed with regularity in the U.S. population. Phthalates have been proposed as possible contributors to TDS.[17]

2. Comments Concerning Male Reproductive Developmental Effects

Several commenters raised issues concerning phthalates' effects on male reproductive development (MRDE). They asserted that studies do not support a determination that phthalates have the same effects on male reproductive development in humans (and other animals) as they do in rats. Commenters also asserted that, even if phthalates have some effect, humans are less sensitive and the CHAP failed to take this into account, especially through appropriate uncertainty factors. Additionally, commenters raised questions about the epidemiology studies the CHAP discussed, *i.e.,* studies concerning phthalates' effects on human populations. Commenters also asserted that, because MRDE would affect the developing fetus, this was not an appropriate endpoint for CPSC's consideration of a regulation on children's toys and child care articles. Commenters raised questions specifically about DINP's association with MRDE. A summary of key comments/responses concerning MRDE appears in this section. Comments/responses concerning DINP, in particular, are provided in section IV.D.1.a. of this preamble.

a. Animal Studies and Their Relevance to Humans

Comment: Studies on effects of phthalates on animals other than rats. Several commenters questioned the relevance of studies on rat phthalate syndrome in assessing effects on humans. Commenters asserted that studies involving animals other than rats (*e.g.,* hamsters and marmosets,) indicate that phthalates are not likely to have the same adverse effects in people that they have in rats. Commenters argued that marmosets, being primates and having reproductive organ development that is similar to humans, were more closely related to humans than rats and, therefore, are a better model for estimating human risk. Commenters focused particularly on one study (McKinnell *et al.* (2009)) that reported no observed effects for several relevant endpoints. Some commenters asserted that studies involving mice indicate that humans, who are more similar to mice than rats, are likely less sensitive to phthalates than rats. Commenters also cited xenograft studies (*i.e.,* transplanting human fetal testicular tissue into rats or mice) as supporting the conclusion that exposure to phthalates does not result in MRDE in humans, or at the least, humans are less sensitive than rats. (Comments 1.1 through 1.5).

Response: Phthalate syndrome has been reported to occur in multiple mammalian species, including guinea pigs, mice, rabbits, and ferrets. Although studies indicate that hamsters were resistant to the effects of phthalates due to their slow metabolism to the active metabolite, a study by Gray *et al.* (1982) shows that giving the active metabolite to hamsters causes phthalate syndrome. Regarding mice, the CHAP discussed studies that found some effects in mice (*e.g.,* disruptions in seminiferous cord formation, the appearance of multinucleated gonocytes, and suppression of insulin-like factor 3 (insl3)). CHAP report at p. 6. Some studies published after the CHAP completed its analysis provide additional evidence of phthalate syndrome effects in mice, including reduced testosterone levels, reduced testosterone production, testicular damage, reduced sperm count and quality, reduced AGD, delayed pubertal onset, and increased nipple retention.[18] Thus, there is now even stronger evidence of phthalate syndrome in mice than was available to the CHAP. The CHAP cautioned that differences in methodology could cloud the issue of which species is more sensitive. CHAP report at pp. 17 and 72. Even if mice or other species are less sensitive than rats, it is not possible to make a direct comparison to humans without dose-response information in humans.

Furthermore, the most sensitive species is generally used in assessing risks to humans.[19] The CHAP concluded that rats provide the most sensitive and most extensive studies in male developmental toxicity. CHAP report at pp. 1, 15, 16, 76. Phthalate syndrome in rats resembles the TDS in humans. *Id.* at pp. 2, 75. For these reasons, the CHAP concluded that studies in rats currently offer the best available data for assessing human risk. *Id.* at pp. 18, 75.

Regarding the marmoset studies, the CHAP paid particular attention to these studies and invited Richard Sharpe, the principal investigator of the Hallmark and McKinnell studies, to present his findings at the CHAP meeting in November 2011. Dr. Sharpe agreed with the CHAP that both studies were limited by the small numbers of animals used and the brief duration of exposure. Dr. Sharpe added that his studies were very preliminary and that it would be premature to use his studies' results to support public health decisions. Even though limited, the published studies do show that the phthalate metabolite suppressed steroidogenesis in neonatal marmosets.

Regarding the xenograft studies, commenters cited two studies in which rat fetal testes or human fetal testicular tissue were transplanted (xenografted) into rats (Heger *et al.* (2012)) or mice (Mitchell *et al.* (2012)). As discussed by the CHAP, these studies are subject to a number of limitations. CHAP report at p. 17. Most of the human fetal tissue samples were obtained after the human window of maximum susceptibility to phthalates, meaning that the tissues were less susceptible to MRDE induced by phthalates. In contrast, constant exposure to phthalates in the womb would always expose the fetal tissue to phthalates at their time of maximum sensitivity. Staff provides more detailed responses concerning these studies on animals other than rats in comment/responses 1.1 through 1.5.

Comment: Implications of *in vitro* studies and studies involving chemicals other than phthalates. Some commenters discussed studies in which human testicular tissue or cells were cultured *in vitro* and then exposed to phthalates.[20] Commenters asserted that these studies raise questions about whether phthalate-induced testosterone reduction in rats is relevant to humans. Commenters also asserted that studies (which were not cited by the CHAP) of chemicals with the same mode of action as phthalates, DES and finasteride, show that humans are resistant to phthalates. (Comments 1.6 and 1.7).

Response: In vitro studies use techniques that are performed in a controlled environment outside of a living cell or organism, while *in vivo* studies are performed inside living cells or organisms. CPSC staff reviewed the studies and concludes that the *in vitro* studies with human fetal testicular

[17] Scott *et al.* (2007); Skakkebaek *et al.* (2001).

[18] Doyle *et al.* (2013) and Ge *et al.* (2015).

[19] Barnes and Dourson (1988); CPSC (1992); EPA (1991).

[20] Desdoits-Lethimonier *et al. (*2012); Lambrot *et al.* (2009).

tissue are still preliminary and are generally not sufficient, by themselves, to support public health decisions. *In vivo* animal studies are generally given greater weight in risk assessment. As the CHAP noted, there is also a growing body of evidence in humans that shows associations between phthalate exposure and MRDE endpoints that are consistent with the rat data.

Regarding DES and finasteride, the CHAP assessed each phthalate based on the best available data for each individual chemical, and based its recommendations on those assessments. The CHAP did not base its conclusions on an assumption that all phthalates will behave the same way as DES or finasteride. The DES and finasteride publication cited by commenters implies that humans are less sensitive than rats to these two chemicals. However, this assertion does not mean that all phthalates will produce similar biological effects as DES or finasteride; phthalates do not have a similar chemical structure, are not metabolized or detoxified in the same way, and will not have similar dose-response curves to those of DES or finasteride.

b. Uncertainty Factors

Comment: Adjusting uncertainty factors. Some commenters asserted that, even if one accepts that studies on rats demonstrate that phthalates have some effect on humans, humans are less sensitive than rats, and one must adjust the interspecies uncertainty factor to avoid overestimating the risk to humans. Some commenters suggested that instead of an interspecies uncertainty factor of 10, which the CHAP used, the uncertainty factor should be 0.1 (*i.e.,* humans are 10x less sensitive than rodents) to 1 (humans are equally sensitive as rodents).'' Other commenters asserted that the CHAP should have used a different intraspecies uncertainty factor. They argued that the intraspecies uncertainty factor of 10 used by the CHAP is overly conservative because the PEAAs are already based on a sensitive population. Commenters on both types of uncertainty factors asserted that following their recommendations would have reduced the HI in the CHAP's cumulative risk analysis so that it would be less than one. (Comments 1.8 and 1.9).

Response: An uncertainty factor is used in risk assessments to account for differences among different species. An interspecies uncertainty factor of 10 is consistent with the general practice used by CPSC, EPA, and others in risk assessment, to account for interspecies differences.[21]

Humans are frequently more sensitive to reproductive and developmental effects than animals,[22] and human males are considered more vulnerable than other mammals.[23] Commenters cited xenograft studies to support the assertion that humans are less sensitive than rats to phthalates effects. As discussed in the response above, these preliminary studies do not provide sufficient support for reducing the interspecies uncertainty factor.

An uncertainty factor is also used to account for differences in how members of the same species could react to a chemical (*i.e.,* human variability). In deriving PEAAs, the CHAP applied an intraspecies UF of 10 to account for differences in sensitivity among individuals. CHAP report at pp. 63–66. CPSC staff expects that the population of infants and fetuses will have a broad range of sensitivity, because age, sex, genetic composition, nutritional status, and preexisting diseases may all alter susceptibility to toxic chemicals.[24] Multiple federal agencies use an intraspecies uncertainty factor of 10.[25] The CHAP used only the interspecies uncertainty factor and intraspecies uncertainty factor in its analyses. The CHAP did not apply an additional UF to protect infants.

c. Epidemiology Studies

Comment: Role of epidemiology studies in CHAP's report and recommendations. Some commenters suggested that human epidemiological evidence for phthalate-induced effects was equivocal or inconsistent with results from animal studies, and did not support the CHAP's conclusions and recommendations. Some commenters asserted that these studies did not show consistent results and have not established a cause and effect relationship between phthalate exposure and MRDE effects in humans. (Comment 7.1).

Response: The CHAP's assessment and recommendations to the Commission are based primarily on animal studies. However, the CHAP reviewed epidemiology studies as well. CPSC staff agrees with the CHAP that these epidemiology studies indicate an association of exposure to phthalates with human health. Under CPSC's Chronic Hazard Guidelines and other agencies' guidance, epidemiological studies establishing a causal relationship between exposure and effect are not required to conclude that a substance or mixture is ''probably toxic to humans.'' CPSC's Chronic Hazard Guidelines, 57 FR 46626, 46641 (Oct. 9, 1992). CPSC staff considers that there is sufficient evidence in animal studies to conclude that certain phthalates are probably toxic to humans. Epidemiological data provide supporting evidence for the animal data and also support the conclusion that the animal data are relevant to humans. In addition, staff states that the CHAP's conclusion is consistent with a recent NAS (2017) report that also concluded that there is a ''moderate level of evidence'' from epidemiological studies that DEHP and DBP induce MRDE in humans (based on changes in AGD). The NAS report's conclusions provide additional confidence that phthalates cause MRDE in humans. Although there are a few inconsistencies in the findings from epidemiological studies, inconsistencies among epidemiological studies are common, due to differences in study methods, characteristics of the study population, study size, and the statistical power of the study to detect associations. Establishing cause and effect in epidemiological studies is not required by federal and international agencies to conclude that a substance is likely to cause similar effects in humans.

Comment: Studies on reduced anogenital distance (AGD). Several commenters raised questions about an association between phthalate exposure and reduced AGD in males. Commenters noted inconsistencies in results among published studies and noted that effects occurred sporadically and inconsistently, even when performed by the same laboratory. Some commenters pointed to inconsistencies between epidemiological and animal studies. Other commenters took a different view, noting that ''these markers are linked with diminished reproductive health in males.'' (Comments 7.3 and 7.7).

Response: The CHAP considered and discussed the inconsistent epidemiological data, noting the need to evaluate carefully negative and positive findings. CHAP report at p. 21. The CHAP considered the available epidemiological evidence, along with the animal studies, and determined that human AGD is a relevant measure of the antiandrogenic mode of action of phthalates during fetal development. CPSC staff concludes that, with few exceptions, the epidemiology studies

[21] Barnes and Dourson (1988); CPSC (1992); Dankovic *et al.* (2015); EPA (1991); Pohl and Abadin (1995).

[22] EPA (1991).

[23] Klaassen (2001), p. 703.

[24] Pohl and Abadin (1995).

[25] Barnes and Dourson (1988); CPSC (1992); Dankovic *et al.* (2015); EPA (1991).

are generally consistent with one another and with the results of animal studies.

Reduced AGD is one of many effects associated with phthalate syndrome. Studies demonstrate that phthalates cause permanent effects on male reproductive development.[26] Jain and Singal (2013) reported that infants with undescended testis (cryptorchidism—an adverse clinical outcome) had a significantly shorter AGD and AGI when compared to infants with descended testis. Thankamony *et al.* (2014) reported the results of a comparative study involving AGD (and penile length) in infants that were normal and those with hypospadias or cryptorchidism. They determined that AGD was statistically reduced in boys with hypospadias or cryptorchidism when compared to boys without these pathologies. They concluded: ''The findings support the use of AGD as a quantitative biomarker to examine the prenatal effects of exposure to endocrine disruptors on the development of the male reproductive tract.''

Comment: DEHP exposure and medical procedures. One commenter stated that the lack of evidence showing effects occurring in adults and infants who are exposed to DEHP from intensive medical procedures makes it unlikely that less potent phthalates would induce adverse reproductive effects in humans. (Comment 7.4).

Response: Few studies have specifically investigated possible health outcomes from phthalate exposures from medical equipment. The commenter cited two studies, one that the CHAP also discussed. Although this study did not find phthalate-related health effects, the CHAP concluded that the very small sample size limits its usefulness. CPSC staff concludes that because of the uncertainties in the existing data, no conclusions can be drawn from high exposures to DEHP in medical procedures.

d. Relevance of Endpoint to Rulemaking

Comment: Disconnect between risk assessment's focus on fetus as target population and focus of rule. Commenters questioned how a rule restricting phthalates in children's toys and child care articles could reduce the risk of phthalate syndrome when the fetus, not infants and children who use toys and child care products, is the population primarily at risk for adverse effects on male reproductive development. Commenters noted that the CHAP's analysis shows that exposures of women to DINP from children's toys and childcare articles are negligible. (Comment 1.11).

Response: Although fetuses are considered to be the most sensitive population for MRDE, based on data from animal studies, the CHAP recognized that other populations such as infants, toddlers, and children also are susceptible to the effects of phthalates. CHAP report at p. 14. Testosterone production and other processes involved in reproduction remain critical throughout male development in animals and humans from the prenatal period through puberty.

Testosterone production is required throughout a male's lifetime to maintain the ability to reproduce.[27] Moreover, CPSC, like other federal agencies, uses the most sensitive and appropriate human target population in risk assessments. The practice of selecting the most protective endpoints and potency estimates (*i.e.,* PODs) based on the best available studies is consistent with the statutory mandate to provide a reasonable certainty of no harm with an adequate margin of safety. Using the lowest POD also is consistent with CPSC Chronic Hazard Guidelines, 57 FR 46626 (Oct. 9, 1992), and other federal agency practices.[28]

3. National Academy of Sciences Report on Endocrine Disruptors

In July 2017, the National Academies of Sciences, Engineering, and Medicine (NAS) released a report entitled, *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals* (NAS 2017).[29] The study responds to EPA's request that the NAS develop a strategy to evaluate the evidence for potential human health effects from endocrine active chemicals at low doses. The NAS selected phthalates as one of two chemicals to demonstrate the systematic review methods and integration of results. In a chapter titled, ''*Phthalates and Male Reproductive-Tract Development,*'' the NAS study evaluated three health effects (fetal testosterone, anogenital distance (AGD), and hypospadias). CPSC staff reviewed the NAS study.

Unlike the CHAP report, the NAS study is not a risk assessment. Rather, the NAS study reviewed individual phthalates and three individual health effects, focusing on whether enough quality data existed to term the particular phthalates a reproductive hazard to humans. In contrast, the CHAP considered all phthalate syndrome effects. In spite of these differences, the NAS report's conclusions are consistent with the CHAP and staff's hazard conclusions. The phthalates section of the NAS report focused on DEHP, and provided a ''final hazard conclusion'' for each of the endpoints. Thus, for fetal testosterone and AGD, DEHP is presumed to be a reproductive hazard to humans; for hypospadias, DEHP is suspected to be a reproductive hazard to humans (NAS 2017, pp. 78–81). For the other assessed phthalates, including DINP, the NAS report did not conduct the final analysis step that results in a ''final hazard conclusion.'' The report provides only the ''initial hazard evaluations'' for fetal testosterone, AGD, and hypospadias in humans. The report found for fetal testosterone, the phthalates BBP, DBP, DEP, DIBP, DINP, and DPP are presumed to be reproductive hazards to humans; DEP is not classifiable for this endpoint (NAS 2017, Table 3–30). AGD, BBP, DBP, and DEP are presumed to be reproductive hazards to humans, while DIBP, DIDP, and DINP are not classifiable (NAS 2017, Table 3–29). For hypospadias, BBP is suspected to be a reproductive hazard to humans and DBP is presumed to be a reproductive hazard to humans (NAS 2017, Table 3–31). The NAS committee did not evaluate DHEXP, DCHP, or DIOP.

With regard to DINP, the NAS study concluded:

- DINP effect on Fetal Testosterone: The NAS concluded: ''there is a high level of evidence that fetal exposure to DINP is associated with a decrease in fetal testosterone in male rats,'' and that there was ''inadequate evidence to determine whether fetal exposure to . . . DINP, . . . is associated with a reduction in fetal testosterone in male humans.'' Overall, the NAS' initial hazard evaluation of DINP and fetal testosterone in humans was that DINP was a ''presumed human hazard.''
- DINP effect on AGD: The NAS concluded: ''there is an inadequate level of evidence to assess whether fetal exposure to DINP is associated with a decrease in AGD in male rats,'' and: ''the available studies do not support DINP exposure being associated with decreased AGD.'' Overall, the NAS' initial hazard evaluation of DINP and AGD in humans was ''not classifiable.''

[26] *e.g.,* Boberg *et al.* (2011); Clewell *et al.* (2013b).

[27] Foster (2006).

[28] Barnes and Dourson (1988); EPA (1991).

[29] NAS (2017) Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. National Academies of Sciences, Engineering, and Medicine, National Research Council. Washington, DC: The National Academies Press. doi: *https://doi.org/10.17226/24758.*

CPSC staff provides a more detailed discussion of the NAS report in the final rule briefing package at section III.B. of the briefing memorandum.

B. Exposure to Phthalates

As noted, the CHAP considered exposure in two ways: Human biomonitoring studies that estimate total exposure to phthalates and the scenario-based assessment that estimates exposure to specific products and sources.

1. Human Biomonitoring

a. Summary

The CHAP used data from NHANES to estimate phthalate exposures to pregnant women. The CHAP also used human biomonitoring data from the SFF study to estimate exposures to infants and their mothers because NHANES does not collect data on children under 6 years old. The CHAP's analysis of NHANES data was based on the 2005/2006 data cycle. CPSC staff subsequently analyzed data from later NHANES data sets. Because the 2005/2006 data set was the last to sample a sufficient number of pregnant women to make reliable exposure estimates for pregnant women, CPSC staff's analyses are for women of reproductive age (WORA). Staff determined that WORA are a suitable surrogate for pregnant women. CPSC staff's June 2015 report; Tab A of staff's briefing package. CPSC staff then used the CHAP's methodology and later NHANES data sets (2007/2008, 2009/2010, 2011/2012) to estimate phthalate exposure, individual phthalate risk, and the cumulative risk (*i.e,* hazard index). *Id.* When CDC released another data set, 2013/2014, staff performed a similar analysis using that data. CPSC staff's February 2017 report; Tab A of staff's briefing package. No more recent SFF data are available.

In CPSC staff's analysis of NHANES data published following the CHAP's analysis, staff found that total phthalate exposures in WORA have changed. The median total exposure to the phthalates included in the CHAP's cumulative risk assessment (DEHP, DINP, BBP, DBP, DIBP) has increased by 20 percent in WORA. In particular, the estimated median DEHP exposure in WORA has declined over time, while the estimated median DINP exposure in WORA has increased fivefold since 2005/2006.[30] Although DEHP was the major contributor to the cumulative risk in 2005/2006, DINP now contributes about as much as DEHP. *See* TAB A of staff's briefing package, Figures 6 and 7, and Table 8.

No new data on infants or pregnant women are available to quantify the effects of changing exposures. Given that the overall phthalate exposures to WORA have declined since 2005/2006, it is possible that exposures to infants and pregnant women have also declined. In general, studies indicate that infants' and children's exposures to chemicals tend to be greater than in adults.[31] With regard to phthalates, daily intakes of the phthalates the CHAP examined in its cumulative risk assessment were generally twofold to threefold greater in SFF infants than in their mothers. CHAP report at Table 2.7. In the CHAP's scenario-based exposure assessment, estimated daily intakes were twofold to fivefold greater in infants than in women. CHAP report, Appendix E1, Table E1–18. Additionally, a study of German nursery school children found they had roughly twice the DEHP exposure as their parents.[32] Because CPSC does not have exposure data for children more recent than the SFF data used by the CHAP, staff can only make a qualitative assessment that infants and children could have greater exposure to phthalates than what the NHANES data indicate for WORA. In section IV.C.1. of this preamble, we discuss the effect of the more recent NHANES data on risk.

b. Comments Concerning Biomonitoring Data

i. Particular Data Sets

Comment: CHAP's use of 2005/2006 NHANES data. Several commenters criticized the CHAP's use of 2005/2006 NHANES data. Commenters noted that the CHAP report states: ''the stopping point for CHAP analysis and interpretation was information available by the end of 2012.'' However, commenters stated, both 2007/2008 data and 2009/2010 data were available by then. A commenter noted that the 2009/2010 data set was available in September 2012, nearly 2 full years before the final CHAP report was issued and before the CHAP cutoff date for consideration of new information (end of 2012). The commenter noted that the 2011/2012 data set was available in November 2013, ahead of the meeting in January 2014 at which the CHAP discussed the peer review of its report. (Comment 3.1).

Response: The CHAP used 2005/2006 NHANES data on pregnant women to assess phthalate exposure as part of the cumulative risk assessment, to satisfy the CPSIA's charge to ''examine the likely levels of children's, *pregnant women's,* and others' exposure to phthalates . . . .'' 15 U.S.C. 2057c(b)(2)(B)(iii) (emphasis added). This data set was the most recent data on pregnant women available at the time the CHAP completed its analysis in July 2012. CHAP report at p. 31. The 2005/2006 NHANES study was the last data cycle to include a large sample of pregnant women. The CHAP included summary phthalate metabolite data from the 2007/2008 data cycle in its report, *id.* at Tables 2.5, 2.6., but did not calculate exposure and risk because this data set did not have sufficient numbers of pregnant women. Partial data for 2009/2010 were first released in September 2012, after the CHAP completed its analysis in July 2012. Although the 2011/2012 data on phthalate metabolites were initially released in November 2013, the data were revised in October 2014, and other files that were needed to calculate exposure and risk were not published until January 2015, well after publication of the final CHAP report. Regarding the CHAP report's statement about a cutoff date, read in context, the cutoff date clearly refers to the final update of the CHAP's search of the biomedical literature for new peer-review publications in biomedical journals, specifically, National Library of Medicine databases. In any event, CPSC recognized that more recent NHANES data than the set on which the CHAP relied were available. Accordingly, CPSC staff analyzed the later NHANES data sets and used the most recent data in its analysis for the final rule.

Comment: Pregnant women and women of reproductive age. Some commenters stated that the 2005/2006 NHANES data on WORA were a reasonable surrogate for the data on pregnant women, and that the CHAP should have used WORA in its cumulative risk assessment because the WORA have an increased sample size in most NHANES datasets and phthalates exposures for both are statistically similar. Commenters asserted that the sample size for pregnant women in the CHAP's analysis was too small to yield reliable risk estimates. In contrast, another commenter supported the CHAP's decision to base its analysis on the 2005/2006 data that focused on pregnant women. (Comments 3.7 and 3.10).

Response: The CHAP stated that it chose to use biomonitoring data from the 2005/2006 NHANES and from the SFF ''because of the CHAP's task to

[30] Zota *et al.* (2014).

[31] CHAP 2014; Sathyanarayana *et al.* (2008a); Swan (2008); Swan *et al.* (2005).

[32] Koch *et al.* (2004).

investigate the likely levels of children's, pregnant women's, and others' exposure to phthalates and to consider the cumulative effect of total exposure to phthalates both from children's products and other sources.'' CHAP report at p. 35. Although, as the CHAP stated, there are indications that exposures may be higher in pregnant women than in women in general, the CHAP stated: ''the exposures were not found to be significantly different.'' *Id.* at p. 36. CPSC staff compared estimates from the 2005/2006 NHANES data set to determine whether WORA had similar daily intake (DI) and Hazard Index as Pregnant Women. CPSC staff found that median and 95th percentile estimates of the DI for five phthalates were generally similar when comparing WORA to pregnant women. Regarding the sample size of pregnant women, CDC calculated the sample size necessary for statistical analysis of NHANES data. In the data sets after 2005/2006, NHANES no longer oversampled pregnant women. Therefore, the numbers of pregnant women in data sets after 2005/2006 were too small to generate statistical estimates for pregnant women. *See* Tab A of staff's briefing package.

ii. Biomonitoring Methodology

Commenters raised concerns about various technical aspects of the NHANES data (*e.g.,* effects of fasting, spot sampling rather than averaging urine samples over time, using hydrolic metabolites for DINP and DIDP, and appropriate metabolite markers). Key points are discussed below. More details are provided in Tab B of the staff's briefing package, particularly comments 1.13, 3.6, 3.11, and comments 3.14 through 3.17.

Comment: Urinary spot sampling. Several commenters raised concerns about urinary spot sampling. They noted that biomonitoring studies (and NHANES in particular) take one spot urine sample as opposed to averaging urine samples collected over a longer period of time. Commenters claimed that spot sampling does not accurately reflect the duration of exposure necessary to develop MRDE. They stated that the exposure information should match the exposure scenario of that hazard data to which it is compared (*e.g.,* chronic exposure to chronic hazard). They asserted that spot sampling would not capture the day-to-day variability in urinary concentration of most phthalates and would overestimate the risk. However, another commenter stated that spot samples are as predictive of urinary concentration as 24-hour urinary samples. (Comments 1.13 and 3.11).

Response: The CHAP and CPSC staff estimated daily intake of each phthalate by modeling creatinine-related metabolite measurements across participants in NHANES. NHANES measured metabolites from one spot urine sample per individual in the study. Spot urine samples were collected at different sites and at various times of the day and days of the week. Additionally, because participants for each NHANES study cycle were randomly selected from civilian, non-institutionalized individuals in the United States, according to a probability-based complex, multistage sample design, the estimated daily intakes are representative of the U.S. population. The estimated daily intakes and the resulting HQs and HIs represent estimated population per capita phthalate exposure across the 2-year NHANES cycle, not average daily estimates of an individual's exposure across time. Thus, an estimated proportion of the population with an HI less than one, using HBM from NHANES, represents the estimated proportion of the population within that cycle that would have an HI less than one at any one given time of that cycle. Estimates based on NHANES HBM do not imply that individuals with HI less than one at a given time will continue to have an HI less than one for all 2 years of a NHANES study cycle.

CPSC staff notes that longer-term exposures are not necessarily required to cause MRDE. Numerous studies in animals have demonstrated that MRDE and related effects can occur after one or a few doses.[33] Shorter-term elevated exposure could be related to adverse health outcomes in the fetus, if the exposure occurs during the window of susceptibility. Although human phthalate exposures may vary from day-to-day or during the course of a day, humans are exposed to phthalates every day.

Comment: Fasting time differences. Some commenters discussed whether fasting times affected the concentration of phthalate metabolites in the urine in NHANES results and whether there were differences in fasting times in the data sets of different years. (Comment 3.6).

Response: The CHAP paid special attention to the possible effects of fasting on NHANES data. Staff reviewed NHANES documentation [34] [35] and spoke with CDC staff regarding fasting protocol changes between cycles. No fasting requirements changed. Therefore, fasting requirements were not a factor in the decision not to combine data from subsequent NHANES cycles with the 2005/2006 data. CPSC staff concludes that fasting may have an impact on food-borne phthalates; but if anything, this would result in underestimation of risk. CPSC staff concludes that the major conclusion or the recommendation of the CHAP report would not change whether the CHAP included the early NHANES data or not.

Comment: Urinary excretion rates and metabolites. Some commenters raised concerns about the urinary excretion rates and the metabolites used in the NHANES data. One commenter asserted that staff's analysis in its June 2015 report of the 2009/2010 and 2011/2012 NHANES data sets overestimated exposures because it did not consider urinary excretion rates. Another commenter stated that the metabolites used for DINP and DIDP could lead to underestimation of phthalate risk when compared to other phthalates, such as DEP, DBP, DIBP, and BBP. Five commenters asked CPSC to re-evaluate exposure using additional metabolite biomarkers for DINP, DNOP, and other phthalates and also re-evaluate using later NHANES data. One of the commenters asserted that the quantitative estimates of DINP risk from the 2017 analysis provided by CPSC staff were calculated incorrectly and were 17 percent too high. The commenter requested that staff use multiple metabolites (*e.g.,* MINP and MCOP) to estimate DINP exposure instead of just one (MCOP). The commenter noted that exposure estimated for DEHP used four metabolites. (Comments 3.14 through 3.17).

Response: Regarding staff's 2015 report and excretion rates, the additional information necessary to calculate directly urinary mass excretion rates was not collected during the 2005/2006 or 2007/2008 NHANES studies. Therefore, the extrapolation method was the only option available to the CHAP. Staff replicated the CHAP's reported exposure and risk estimates using the 2005/2006 NHANES data and

[33] Carruthers and Foster (2005); Creasy *et al.* (1987); Ferrara *et al.* (2006); Gray *et al.* (1999); Hannas *et al.* (2011); Jobling *et al.* (2011); Jones *et al.* (1993); Li *et al.* (2000); Parks *et al.* (2000); Saillenfait *et al.* (1998); Saitoh *et al.* (1997); Spade *et al.* (2015); Thompson *et al.* (2004); Thompson *et al.* (2005).

[34] National Health and Nutrition Examination Survey, 2005–2006 Data Documentation, Codebook, and Frequencies. Available at: *https://wwwn.cdc.gov/Nchs/Nhanes/2005-2006/FASTQX_D.htm.*

[35] National Health and Nutrition Examination Survey, 2003–2004 Data Documentation, Codebook, and Frequencies. Available at: *http://wwwn.cdc.gov/nchs/nhanes/2003-2004/PH_C.htm.*

applied the same methods to calculate estimates from the later NHANES studies. Regarding metabolite biomarkers, CPSC used MCOP to analyze phthalate exposure, as the CHAP did. This was appropriate because for exposed individuals, MCOP will be detected more frequently and at higher levels than other DINP metabolites. Regarding the use of both MINP and MCOP to estimate DINP exposures, staff does not agree that the estimated exposures for DINP in the 2015 and 2017 analyses were incorrect. CPSC staff used one metabolite, MCOP, to estimate DINP exposure in order to be consistent with the CHAP methodology and previous staff exposure and risk documents. The CHAP recognized that there are multiple ways to estimate phthalate exposure using individual and combined phthalate metabolites, and the CHAP provided a table of potential metabolites and associated fraction of the urinary metabolite excreted factors. CHAP report at Table D–1.

Comment: SFF data. A commenter noted that SFF data were collected before the CPSIA was implemented, and before an asserted sharp decline in DEHP exposure. Thus, according to the commenter, basing the NPR on the SFF data (which was the exposure data used to determine that 5 percent of infants have an HI greater than one) is not supportable. (Comment 3.5).

Response: Infants' and children's phthalate exposures tend to be greater than adults' exposure.[36] For the phthalates in the CHAP's cumulative risk assessment, daily intakes were generally twofold to threefold greater in SFF infants than in their mothers. CHAP report at Table 2.7. No more recent information on infant exposures is available than the 1999/2005 SFF data, which was used by the CHAP (and subsequently by CPSC in the NPR). Infant exposures may have changed since 2005, but staff has no infant data to quantify any change.

2. Scenario-Based Exposure Assessment

a. Summary

Because biomonitoring data do not provide any information about the sources of phthalate exposure, the CHAP also included a scenario-based exposure assessment in its report. CHAP report at pp. 49–60, Appendix E1. The exposure assessment evaluated exposure from individual sources, such as toys, personal care products, and household products. The assessment considered the exposure routes of inhalation, direct and indirect ingestion, and dermal contact. The CHAP stated that its goal was to determine the significance of exposure to phthalates in toys and to estimate exposure to toddlers and infants for all soft plastic articles, except pacifiers (because pacifiers do not contain phthalates). *Id.* at p. 49. For phthalates that are currently prohibited from being in children's toys and child care articles, the CHAP report provides estimated exposures that would hypothetically occur if phthalates were allowed in those products. *Id.* at pp. 49–50.

Scenario-based exposure estimates are developed using information about relevant sources of phthalate exposure (*e.g.,* concentrations of phthalates in soil, dust, and in products); data on migration or leaching of phthalates from products; physiological information (*e.g.,* body weight and skin surface area); and information about how the subpopulations use and interact with products, including frequency and duration of contact with products and environmental media.

The exposure assessment considered seven categories of exposure sources and activities involving those sources: Diet, prescription drugs, personal care products, toys, child care articles, indoor environment, and outdoor environment. *Id.* at p. 50. For each subpopulation (pregnant women/WORA, infants, toddlers, and children), the assessment provides estimated daily aggregate exposures to each of the eight phthalates included in the cumulative risk assessment. *Id.* at pp. 50–51 and Table 2.11. The relative contribution (percent of total exposure) for each activity was determined. The analysis found that for women, diet contributes more than 50 percent of the exposure to DIBP, DNOP, DEHP, DINP and DIDP. *Id.* at Appendix E1–26. For infants and toddlers, more than 50 percent of DIBP, DINP, and DIDP exposure and more than 40 percent of DEHP exposure comes from diet.

Although certain phthalates had not been permitted in children's toys and child care articles since 2008, the exposure assessment considered what contribution these products could make to overall phthalate exposure if those phthalates were allowed in children's toys and child care articles. The exposure analysis showed that, on average, mouthing and dermal exposure to toys could contribute around 12.8 percent to the overall DINP exposure of infants, if DINP were used in these products. CHAP report at Appendix E1, Table E–21. The same analysis shows that dermal contact with child care articles could contribute up to an additional 16.5 percent of the overall exposure to infants. Therefore, if DINP were used in all of the products that were included in the scenario-based exposure assessment, children's toys and child care articles could account for around 29 percent of infants' total exposure from all evaluated sources. *Id.*

It is not possible to accurately quantify the number of toys that might have DINP in them if the interim prohibition were lifted or to quantify the effect that changes in DINP exposure would have on the percentage of the population (infants, pregnant women, or WORA) with HI less than or equal to one.

b. Comments Concerning Scenario-Based Exposure Assessment

Comment: Exposure through diet. Commenters noted that diet is the primary source of exposure to phthalates for infants and children and that children's toys and child care articles contribute very little to overall phthalate exposures, especially for women of reproductive age and fetuses. They reasoned that, therefore, a prohibition on phthalate-containing children's toys and child care articles would have little effect on overall risk. (Comment 5.3).

Response: CPSC disagrees that the contribution from sources other than diet are negligible, especially for DINP. The scenario-based exposure assessment in the CHAP report shows that mouthing and dermal exposure to toys could contribute an average of 12.8 percent, 5.4 percent, and 1 percent of the overall DINP exposure to infants, toddlers, and children, respectively, if DINP were used in these products. CHAP report at Appendix E1, Tables E1–21, E1–22 and E1–23. Mouthing and handling soft plastic teethers and toys could contribute 12.8 percent (mean exposure) or 16.6 percent (95th percentile exposures) of total DINP exposure in infants. *Id.* at Appendix E1, Tables E1–21. Dermal contact with the evaluated toys and child care articles may contribute up to an additional 16.5 percent of exposures to infants. *Id.* Therefore, although infants' DINP exposure was primarily from diet, up to 29 percent may be due to the presence of DINP in the evaluated toys and child care articles (*Id.* Figure 2.1).

Comment: Exposure through house dust. One commenter noted that house dust contributed to background exposure, that DEHP was in 100 percent of dust samples, that consumer products and building materials were the source of such dust, and that the EPA soil screening levels for DEHP were exceeded by the concentrations found. (Comment 5.4).

[36] CHAP (2014); Sathyanarayana *et al.* (2008a); Swan (2008); Swan *et al.* (2005).

Response: The CHAP's and staff's analyses considered exposures to house dust. The CHAP's exposure scenarios estimated theoretical exposures from house dust. The CHAP found that for infants and toddlers, incidental ingestion of household dust contributed roughly 25 percent to the total BBP exposure and 15 percent to total DEHP exposure. For children, the CHAP found that household dust contributed about 18 percent to DEHP exposures. CHAP report at Appendix E1–35. Additionally, because NHANES includes exposures from all routes, the NHANES estimates would have included the survey individual's exposures to household dust.

C. Risk Assessment

As the CPSIA directed, the CHAP considered risks of phthalates in combination and in isolation. The CHAP conducted a cumulative risk assessment to evaluate the effects of multiple phthalates, specifically phthalates known to cause MRDE and other adverse effects on male fertility. As explained in section III.C.3, the CHAP used information from toxicity studies concerning MRDE and human biomonitoring studies to determine a hazard quotient (HQ) for each phthalate and the hazard index (HI) for each individual in the two populations of interest (pregnant women and children). To assess risks of phthalates in isolation, the CHAP used a margin of exposure (MOE) approach.

For reasons discussed in sections III.C.1 and IV.A.1. of this preamble, the CHAP and CPSC have focused on phthalates' association with MRDE. The CHAP's and CPSC's determination of risk associated with the use of phthalates in children's toys and child care articles is based on a cumulative risk assessment that considers the contribution that allowing antiandrogenic phthalates to be used in children's toys and child care articles would have on the overall cumulative risk from phthalates. Relying on this cumulative risk assessment, the Commission determines that, to meet the CPSIA's criteria of reasonable certainty of no harm and protection of the health of children, it is necessary to prohibit children's toys and child care articles containing concentrations of more than 0.1 percent of the phthalates that can cause MRDE (DINP, DIBP, DPENP, DHEXP, and DCHP). In this section, we discuss the cumulative risk assessment and related comments. We discuss each phthalate in section IV.D of this preamble.

1. Cumulative Risk Assessment

a. Summary

i. CHAP's Analysis and NPR

A cumulative risk assessment estimates the potential risk following exposure to multiple ''stressors,'' in this case, multiple phthalates. As discussed in section III.C of this preamble, the CHAP found, and CPSC agrees, that certain phthalates cause male reproductive developmental effects and may appropriately be considered in a cumulative risk assessment. CPSC concludes that a cumulative risk assessment is appropriate here because evidence indicates that phthalates are ''dose additive.'' That is, for phthalates that cause MRDE, the chemicals will act together; the effects of one such phthalate will add to the effects of another such phthalate. As the CHAP report explained, experimental studies show the additive effects of phthalates on MRDE.[37] The CHAP also demonstrated that the phthalates included in the CHAP's cumulative risk assessment share a common mechanism of action (primarily antiandrogenicity) and affect the same target organ (primarily the testes).

This rule is based on a cumulative risk assessment that uses the methodology employed by the CHAP, along with exposure data from the most recent NHANES data sets. The cumulative risk assessment follows a hazard index (HI) approach that is commonly used for cumulative risk assessments. The CHAP's cumulative risk assessment was consistent with the recommendations of a National Academy of Sciences report on cumulative risk assessment of phthalates. Cumulative risk assessment of chemical mixtures has been an established practice since the 1980s. The CHAP introduced a minor modification to the standard methodology: The CHAP calculated hazard indices for each individual sampled in NHANES rather than the more common HI approach of using population percentiles from exposure studies on a per-chemical basis. This allowed the CHAP to calculate hazard quotients (HQs) for each phthalate and an HI for each individual in each study. This avoids overestimating the risk for individuals with higher than average exposures, such as those at the 90th and 95th percentiles.

The CHAP calculated an HQ for each phthalate using three sets of ''potency estimates of antiandrogenicity'' (PEAAs). The PEAA is an estimate of the exposure at which the risk of MRDE is negligible. The CHAP estimated a PEAA for each phthalate by dividing the MRDE ''antiandrogenic'' point of departure (POD; toxicity endpoint) by an uncertainty factor (UF). The POD is the lowest dose level at which an adverse effect was seen. A UF is a quantitative factor that is used to account for uncertainties associated with available data (*e.g.,* interspecies, intraspecies, database, and toxicity uncertainties). The CHAP stated that it used three sets of PEAAs to explore the effect of different methodology (*e.g.,* different uncertainty factors and PODs) on cumulative risk estimates to ''determine the sensitivity of the results to the assumptions for PEAAs and the total impact on the HI approach.'' CHAP report at p. 4. Each case brings a different perspective to the risk assessment. The CHAP report discusses the three cases at pages 63–64. Case 1 was based on published, peer-reviewed values using a study by Kortenkamp and Faust.[38] Case 2 was based on a relative potency method with DEHP as the index chemical, using multiple-dose studies of *in-vitro* fetal testosterone production by Hannas *et al.* (2011).[39] For Case 3, the CHAP derived new PEAA values after considering all the available literature, including studies such as Boberg *et al.* (2011).[40] As explained in response to comments, CPSC staff concludes that each of the three cases has certain advantages, all three are appropriate, and the risks resulting from the three cases are quite similar.

The CHAP calculated HQs for each phthalate by dividing the exposure by the PEAA. The CHAP then calculated the HI by summing the HQs for each phthalate. If the HI is greater than one, there may be concern for antiandrogenic effects in the exposed population due to cumulative effects of phthalates. As explained previously, the CHAP used 2005/2006 NHANES data for exposure estimates for pregnant women and 1999–2005 SFF data for exposure estimates for mothers and infants. CPSC staff subsequently repeated the CHAP's analysis using more recent 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 report at Table 2.16. Infants had median HIs about 0.2, while the 95th percentiles were between

[37] Hannas *et al.* (2012); (2011); Howdeshell *et al.* (2007); (2016); (2008).

[38] Kortenkamp and Faust (2010).

[39] Hannas *et al.* (2011).

[40] Boberg *et al.* (2011).

0.5 and 1.0. About 5 percent of infants had HIs greater than one. *Id.*

The CHAP characterized the distribution of the estimated HIs, by reporting the central tendency measure (statistical median [41]) and the upper percentiles (95th, and 99th). CHAP report at Table 2.16. The CHAP's analysis showed that the median HIs for NHANES pregnant women were less than one (HIs of 0.09 to 0.14), but the 95th percentile HIs were greater than one (HIs of 3.6 to 6.1). Staff notes that the CHAP emphasized that an HI greater than one is the metric that defines excess exposure, relative to the acceptable exposure level; the CHAP did not indicate that the 95th percentile, or any other part of the cumulative risk distribution, should be used to establish unacceptable risk for risk management purposes. The CHAP, having determined that an HI greater than one was necessary to identify the population at risk, then used the distribution of HIs to identify the percentage of the population with an estimated HI greater than one. Staff notes that, while the CHAP presented the distribution statistics, described above, the CHAP focused on the proportion of the population with HIs exceeding one, not on any particular percentile of the distribution. To repeat, the CHAP neither used nor suggested a specific percentile as a threshold for recommendations or regulatory proposals.

The CHAP's HI approach is consistent with the CPSC's chronic hazard guidelines (Chronic Guidelines). The Chronic Guidelines discuss a safety factor approach to determine acceptable risk for a reproductive or developmental toxicant. 57 FR 46626, 46656 (Oct. 9, 1992). Under the safety factor approach, one determines the acceptable daily intake (ADI) for a substance by adding a safety factor to the lowest no observed effect level (NOEL) seen among relevant studies. The Chronic Guidelines state that if the hazard is ascertained from human data, a factor of 10 is applied to the NOEL, and if the hazard is ascertained from animal data, a factor of 100 is applied. *Id.* Staff states that the safety factor approach is similar to the HI approach that the CHAP followed. The CHAP's PEAA values are equivalent to an ADI, and the HI is the ratio of the daily exposure to the ADI. The Chronic Guidelines do not define the percentage of the population (*i.e.,* number of individuals versus the sample population or entire population) that must have an HI less than one to ensure a ''reasonable certainty of no harm . . . with an adequate margin of safety.''

As discussed in the NPR preamble, based on the CHAP report, the Commission proposed to prohibit children's toys and child care articles containing the antiandrogenic phthalates the CHAP had examined. The NPR stated that the Commission considers that an HI less than one is necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety and to protect the health of children. 79 FR at 78334. The NPR also stated that the Commission considers that an HI less than one is necessary to protect the health of children. *Id.* at 78335.

In the NPR, the Commission stated the CHAP's determination that approximately 10 percent of pregnant women and 5 percent of infants had an HI greater than one. The Commission did not establish directly, however, that there was a specific proportion of the population that must have an HI less than or equal to one to ensure a ''reasonable certainty of no harm with an adequate margin of safety'' or to ''protect the health of children.''

ii. Analysis Using Most Recent Data

After publication of the NPR, CPSC staff analyzed NHANES data for WORA (from 2007 through 2014). CPSC staff reports for 2015 and 2017; TAB A of CPSC staff's briefing package: Staff's analysis shows that the risk to WORA, as indicated by HI, has decreased. Median and 95th percentile HIs for WORA are both less than one. Staff estimates that between 98.8 and 99.6 percent of WORA have HIs less than or equal to one. Out of a sample of 538 WORA in the 2013/2014 cycle, 99.5 percent of WORA have an HI less than or equal to one when considering PEAA Case 1 and 99.6 percent when considering Case 3. For PEAA Case 2, an estimated 98.85 percent of WORA have an HI less than or equal to one in the same cycle. *See* Tab A of staff's briefing package. This means that some individual WORA in the NHANES sample have an HI greater than one for each PEAA case. Out of a sample of 538 WORA, for PEAA Case 1, three WORA had an HI greater than one; for PEAA Case 2, nine WORA had an HI greater than one; and for PEAA Case 3, two WORA had an HI greater than one. However, the national population projection for HI greater than one is not estimable at the upper percentiles of the distribution due to sampling variability. Thus, staff is unable to estimate the percentage of WORA with an HI greater than one in the population of approximately 60 million WORA in the United States.

As noted in Tab A of the staff's briefing package, the decreases in HI are primarily due to decreases in DEHP exposures. The HQ for DINP is replacing the HQ for DEHP proportionally for contributions to the total HI. In each PEAA case, DINP has less potency than DEHP; thus, even though DINP's proportion of contribution to total HI is increasing, the values of HI have still decreased overall across cycles.

CPSC does not have exposure data for infants that is more recent than the SFF data on which the CHAP relied. Because the risk to WORA has declined since 2005/2006, it is possible that exposures and risks to infants have also declined. However, because the routes of exposure (*e.g.,* food, medicines, products) are different for each target population, it is not possible to quantify the changes in one population based on the other. As explained in section IV.B.1, infants' exposures generally are two- to threefold greater than adults. Thus, CPSC concludes that phthalate exposures and risks in WORA probably underestimate the risks to infants and children.

CPSC's assessment of the risk (and the need for this rule) is also informed by the fact that, although the overall risk as portrayed in the cumulative risk assessment has decreased, DINP's contribution to the cumulative risk has greatly increased. It is not possible to quantify accurately the number of toys expected to have DINP or the effect of changes in DINP exposure on the percentage of the population (infants, pregnant women, or WORA) with HI less than or equal to one. However, any increase in exposure due to resumed or increased use of DINP in products is likely to decrease the percentage of the population with HI less than or equal to one. Allowing DINP to be re-introduced into children's toys and child care articles would open a pathway of exposure to a phthalate that studies have clearly demonstrated causes adverse effects on male reproductive development. Although DIBP, DPENP, DHEXP, and DCHP are not currently found in children's toys and child care articles (or only rarely), these phthalates

[41] The median is the midpoint of the distribution, where one-half of the values are smaller than *(i.e.,* below) the median value, and one-half of the values are larger than the median. The 95th percentile of the distribution is the value indicating 95 percent of values are smaller than this value, and 5 percent of values are larger. The median and 95th percentile values describe the data distribution, in this case the HI values estimated for the population of pregnant women or women of reproductive age who experience phthalate exposures. These values, by themselves, do not define acceptable risk levels. Rather, the acceptable risk level is a policy decision.

also cause MRDE and contribute to the cumulative risk.

b. Comments on Cumulative Risk

i. Appropriateness of Conducting a Cumulative Risk Assessment

Comment: General acceptance of cumulative risk assessment. Commenters asserted that cumulative risk assessment is not a generally accepted approach. They stated that cumulative risk assessment is not appropriate as a basis for regulatory action, but only as a screening analysis. However, another commenter noted that ''when multiple phthalates act on a similar biologic target, it is critical to understand and regulate based on their combined effect on human health.'' (Comments 2.1 through 2.3).

Response: Cumulative risk assessment is a well-established approach to evaluate risks posed by mixtures of multiple chemicals. EPA first issued guidelines for the risk assessment of chemical mixtures in 1986. Subsequently, ATSDR and the World Health Organization (WHO) issued guidance for cumulative risk assessment of chemical mixtures.[42] EPA routinely uses cumulative risk assessment to assess risks from pesticides, as required by the Food Quality Protection Act of 1996. Additionally, EPA and ATSDR use cumulative risk assessment to assess risks under Superfund.[43] EPA also has performed cumulative risk assessments, to assess phthalates.[44] The CHAP followed guidance issued by the National Academy of Science for conducting cumulative risk assessments with the one modification, explained above, that allowed the CHAP to calculate HQs for each phthalate and an HI for each individual in the NHANES and SFF studies. Regarding the assertion that the CHAP's cumulative risk assessment was only a screening-level analysis, CPSC concludes that the CHAP's analysis is a refined assessment that could be considered tier 3, the highest tier, under the framework established by the WHO. The CHAP's CRA began with a comprehensive review of the toxicology and exposure literature. The primary exposure assessment for the CHAP report was based on measurements of phthalate metabolites in a statistically representative population (NHANES study) of actual people. As required for tier 3 assessments under the WHO framework, the CHAP's analysis included probabilistic measurements of exposure and risk.

Comment: Dose additivity. Several commenters asserted that there was not sufficient evidence of dose additivity, especially at low doses, to conduct a cumulative risk assessment for phthalates. Some commenters asserted that one needs a common mode or mechanism of action to support an assumption that phthalates are additive, and they stated that evidence of a common MOA was lacking. Commenters stated that the CHAP had not considered all the relevant papers on dose additivity. (Comments 2.4 through 2.8).

Response: The CHAP did not need to present evidence of a common MOA or mechanism of action to justify performing a cumulative risk assessment because data from laboratory studies by Hannas and Howdeshell show that phthalate mixtures, in fact, act in a cumulative, additive fashion.[45] Thus, the CHAP did not have to make any assumptions about additivity. In fact, one of the reasons that the CHAP chose MRDE as the health effect for its CRA is that MRDE is the only health endpoint that was extensively studied in phthalate mixtures. CHAP report at p. 2. Moreover, even without a common mechanism of action, chemicals can have cumulative effects in mixtures.[46] Substances can act on the same process, but in different ways, to produce additive effects. In any event, CPSC concludes that evidence demonstrates that the phthalates in the CRA do have a common mechanism of action. As discussed, the phthalates all act on the male reproductive system. More specifically, they act by inhibiting testosterone production in the testis during a critical period in development by decreasing expression of genes involved in steroid synthesis.[47] Additional factors, such as reduced expression of insulin-like hormone 3 gene (insl3), also are at work.[48]

Regarding low doses, studies of phthalate mixtures at low doses do not exist, and the commenters did not present any evidence of a threshold for phthalate-induced MRDE. Although mixture studies at low (environmental) doses have not been performed, there are published studies in which the doses of the individual phthalates produced little or no effect, but the mixtures produced significant cumulative effects.[49] In a recent study, rats were exposed to phthalates and other antiandrogens at doses well below the NOAEL. Although the individual phthalates had no observable effect, the mixture induced MRDE-related effects.[50] Thus, additivity occurs even at doses where individual phthalates have no observable effect. As discussed in response to comments 2.6 and 2.7, CPSC concludes that the CHAP did consider all relevant papers and that dose addition is appropriate for assessing the cumulative effects of phthalates and other antiandrogens.

Comment: Mode or mechanism of action. Commenters asserted that the mechanism of action by which phthalates affect male reproductive development is not clear. They argued that, in the absence of clarity that phthalates share a common mechanism of action, the CHAP should not conduct a cumulative risk assessment. Some commenters focused particularly on DINP, asserting that DINP does not have the same mode or mechanism of action as other phthalates. (Comments 1.21 through 1.25).

Response: Knowledge of the mode or mechanism of action can help inform the risk assessment process. However, a detailed understanding of the mode/mechanism of action is never required to perform a risk assessment. Several studies have shown that the phthalates act by inhibiting testosterone production in the testis during any critical period in development,[51] by decreasing expression of genes involved in steroid synthesis. Reduced expression of insulin-like hormone 3 gene (insl3) is an additional pathway.[52] Furthermore, all of the phthalates in the cumulative risk assessment induce a similar spectrum of effects, known as the ''phthalate syndrome,'' and which is also described as ''antiandrogenic'' effects. DINP has been clearly established by multiple studies as causing the same pattern of effects (phthalate syndrome)[53] and by other studies as acting by the same MOA as other phthalates in the cumulative risk

[42] EPA (1986). EPA (2000b), ATSDR (2004), and WHO (Meek *et al.* 2011).

[43] ATSDR (2017; EPA (2017); Howdeshell *et al.* (2016).

[44] Christensen *et al.* (2014); Gallagher *et al.* (2015).

[45] Hannas *et al.* (2012); (2011); Howdeshell *et al.* (2007); (2016); (2008).

[46] Axelstad *et al.* (2014); Christiansen *et al.* (2009); Howdeshell *et al.* (2016); Levin *et al.* (1987); Rider *et al.* (2008; 2010; 2009).

[47] Foster *et al.* (2001); Gray *et al.* (2000); Mylchreest *et al.* (1998); Parks *et al.* (2000).

[48] Foster (2005); Howdeshell *et al.* (2016); NRC (2008); Wilson *et al.* (2004).

[49] Axelstad *et al.* (2014); Christiansen *et al.* (2010); Hotchkiss *et al.* (2004); Howdeshell *et al.* (2007); (2016); Rider *et al.* (2010).

[50] Conley *et al.* (2017).

[51] Foster *et al.* (2001); Gray *et al.* (2000); Mylchreest *et al.* (1998); Parks *et al.* (2000).

[52] Foster (2005), Howdeshell *et al.* (2016), NRC (2008), and Wilson *et al.* (2004).

[53] Adamsson *et al.* (2009); Boberg *et al.* (2011); Clewell *et al.* (2013b); Gray *et al.* (2000); Hannas *et al.* (2011); Masutomi *et al.* (2003).

assessment.[54] Other experts agree that the phthalates in the CHAP's cumulative risk assessment act by the same mechanism of action.[55] Staff also notes that mixtures studies including DINP show that the effects of DINP and other phthalates are additive.[56] Therefore, a common mechanism of action is not necessary to include DINP in the cumulative risk assessment.

Comment: Inclusion of permanently prohibited phthalates in CRA. Commenters asserted that it was not appropriate for the CHAP to include DEHP and other phthalates that are subject to CPSIA's permanent prohibition in the CHAP's cumulative risk assessment. Commenters asserted that nearly all of the risk in the CHAP's cumulative risk assessment is due to exposures to those phthalates, yet they can no longer contribute to the cumulative risk from exposure to children's products. At least one commenter stated that if the cumulative risk assessment excluded phthalates subject to the CPSIA's permanent prohibition, the HI would be less than one. The commenter reasoned that, therefore, there is a reasonable certainty of no harm from the use of any other phthalates in children's products. Thus, the statutory requirement to ''ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety'' is satisfied without continuing the interim prohibition. Another commenter stated that a cumulative risk assessment is useful when exposure to each single substance is below the level of concern, but exposures to multiple chemicals with the same mechanism of action (or that affect the same endpoint) at the same time rise to levels of concern. However, the commenter asserted, with phthalates, only one chemical (DEHP) poses a risk in isolation. (Comments 2.9 and 5.2).

Response: In accordance with direction in the CPSIA, the CHAP examined phthalates in isolation and in combination with other phthalates. 15 U.S.C. 2057c(b)(2)(B)(ii). Moreover, to accurately assess cumulative risk, it was appropriate for the CHAP to include DEHP (and other phthalate subject to CPSIA's permanent prohibition). Although DEHP is not allowed in children's toys and child care articles, it is permitted in other products. DEHP is found in drinking water, surface water, storm water, soil, and wildlife.[57] It is found in indoor and outdoor air, household dust, and indoor surfaces. DEHP has been found in gloves, footwear, personal care products, medical devices, paints, adhesives, sealants, wallpaper, flooring and food. Thus, given the number and variety of sources of exposure, DEHP should be included in the cumulative risk assessment. The results of staff's cumulative risk assessment using more recent NHANES data, show that, even though exposure to DEHP is decreasing, phthalate exposures are still high enough that some women in the data sample have HIs exceeding one. The CHAP's and staff's analyses indicate that risk is not entirely driven by DEHP. Considering 2013/2014 NHANES data, DINP contributes approximately 6 to 51 percent (medians) or 18 to 76 percent (95th percentiles) of the overall risk. *See* TAB A of staff's briefing package.

ii. NHANES Data in the Cumulative Risk Assessment

Comment: Using the CRA to assess individual's risk. Some commenters asserted that calculating risk using NHANES data (that uses spot urine sampling rather than measurements over time) is not an accurate indication of a person's real exposure to phthalates and thus the CHAP's HI calculations do not show true risk. They asserted it is inappropriate and not scientifically supportable to report results as a proportion of the population with an HI over one (because the individual spot urine samples are too variable and do not represent chronic exposures over time). For example, one commenter stated that an individual's HI from a spot urine sample ''has essentially no bearing on risk to the individual'' because it does not represent a repeat dose, longer term exposure is necessary to induce the adverse effects (phthalate syndrome) and that a few HIs (or HQs such as DINP) above one also are not representative of the population risk. Commenters thought that this approach was overly conservative and overestimated the risk. (Comments 3.11 through 3.13).

Response: Staff concurs that spot urine samples are variable and are not representative of long-term exposures, but also notes that numerous studies in animals have demonstrated that MRDE and related effects can occur after one or a few doses.[58] It is impossible to know whether a particular spot urine sample is overpredicting or underpredicting the actual exposure. HBM data are a direct measure of human exposure and, therefore, superior to alternatives such as modeled exposures. NHANES is a high quality study and provided exposure data that are representative of the U.S. population. Similar data with 24-hour or longer sampling times are not available.

Staff concludes that it is statistically appropriate to portray the individual NHANES data as a proportion of the NHANES sample population with an HI less than or equal to one. Staff notes that in the 2013/2014 NHANES sample of 538 WORA (of approximately 60 million WORA in the U.S. population), there were from two to nine individuals with a HI greater than one (*i.e.,* at risk), depending on the PEAA case. As described in section 5.4 of TAB A of staff's briefing package, the 2013/2014 NHANES data set cannot be used to estimate how many WORA in the U.S. population have HIs greater than one.

Comment: Impact of more recent NHANES data on CRA. Several commenters stated that CPSC staff's analysis of more recent NHANES data shows that the risk from phthalates has declined. Commenters noted that that even at the 95th percentile, the HI is uniformly less than one and has decreased further from the HI values calculated for the 2011/2012 data cycle. They concluded that the CRA using current exposure data shows that there is a reasonable certainty of no harm. Thus, the statutory requirement is satisfied without Commission action. (Comment 3.2).

Response: The CRA using current exposure data indicates that at least some of the actual WORA in the NHANES data had HIs greater than one, showing that there is not a reasonable certainty of no harm with an adequate margin of safety. Moreover, the CHAP did not indicate that the 95th percentile, or any other part of the cumulative risk distribution, should be used to establish unacceptable risk. Therefore, discussions of acceptable risk should not be limited to the 95th or other percentile. Staff concurs with commenters that through the NHANES cycles, the population of WORA with an HI greater than one has decreased. In the 2013/14 NHANES sample of 538 WORA, there were from two to nine actual women from the NHANES sample with a HI greater than one (*i.e.,* at risk), depending on the PEAA case.

[54] Gray *et al.* (2000); Hannas *et al.* (2011).

[55] Foster (2005); Howdeshell *et al.* (2016); NRC (2008).

[56] Hannas *et al.* (2012); (2011); Howdeshell *et al.* (2007); (2016); (2008).

[57] Clark (2009); Versar (2010).

[58] Creasy *et al.* (1987); Jones *et al.* (1993); Saitoh *et al.* (1997); Saillenfait *et al.* (1998); Gray *et al.* (1999); Parks *et al.* (2000); Li *et al.* (2000); Thompson *et al.* (2004); Carruthers and Foster (2005); Thompson *et al.* (2005); Ferrara *et al.* (2006); Hannas *et al.* (2011); Jobling *et al.* (2011); Spade *et al.* (2015).

The 2013/2014 NHANES data cannot be used to estimate how many WORA in the U.S. population have HIs greater than one.

Comment: Use of values above the 95th percentile. A commenter on the 2017 staff report asserted that it is ''scientifically inappropriate to go above the 95th percentile in evaluating either individual or cumulative risks to the fetuses of women of reproductive age as indicated by the CRA.'' The commenter stated that going above the 95th percentile values are too unstable to provide a basis for regulatory decisions. The commenter noted that EPA's 2014 paper on five phthalates reported the 95th percentile from the calculations of HIs for three of the five phthalates (and the CHAP and CPSC's previous analyses used the 95th percentile). (Comment 3.21).

Response: Neither the CHAP nor staff used the 95th percentile (or any other percentile) as a threshold for recommendations or regulatory proposals in evaluating individual or cumulative risks. The 95th percentile, as well as other measures such as the average, median, or 99th percentile, is a commonly used metric, included by the CHAP, to help characterize the distribution of exposure and risk in a population. The rule is not based on any particular percentile, but on the observation that actual women from the NHANES sample have HIs greater than one.

For its cumulative risk assessment, the CHAP addressed the range of HI in representative populations—including but not limited to the 50th percentile, 95th percentile, and 99th percentile. In all analyses of the updated NHANES data for WORA and in the rule, staff does not rely on any particular percentile as a threshold for recommendations or regulatory proposals, but on the fact that at least some of the actual WORA from the NHANES samples had HIs greater than one. Because at least some of the actual WORA from the NHANES samples had HIs greater than one in every NHANES data cycle analyzed, there is not a reasonable certainty of no harm with an adequate margin of safety. For example, for the 2013–14 NHANES data, between two and nine real women from the sample of 538 WORAs had an HI greater than one, depending on the case model used. The CHAP emphasized, and the Commission continues to agree, that an HI greater than one is the metric that defines excess exposure.

CPSC disagrees with the blanket statement that it is scientifically inappropriate to go above the 95th percentile in interpreting a cumulative risk assessment. There is no scientific basis for an assertion that the 95th percentile of a distribution is the largest value that can be considered. The commenter specified that the values above the 95th percentile are unstable. In this case, staff agrees that the values associated with the upper tail of the distribution of HIs (*e.g.,* above the 95th percentile) have large variance estimates, due to sample size (*i.e.,* statistically unstable). The large variances mean that we are precluded from estimating the precise number of WORA with HIs greater than one in the larger population from which the sample was selected. However, as noted above, actual women with HIs greater than one were observed in every NHANES data cycle analyzed. As the commenter mentioned, EPA's paper (Christensen *et al. (*2014)) states, ''we present findings for the 95th percentile of estimated phthalate intake recognizing that there may be more variability in these values, because this information provides insight into the potential risk at the highest levels of exposure in a general population setting.'' Staff considers EPA's discussion to be consistent with the CHAP's and staff's presentation of results because the goal is to provide insight into the risks among the most highly exposed individuals. The CHAP's and staff's analyses are based on human biomonitoring, *i.e.,* actual observations of people. These observations should be considered in risk management and decision-making.

iii. The Three Cases

Comment: Criticism of the three cases (PEAAs) the CHAP used. Commenters raised concerns about all three of the CHAP's cases. Some commenters asserted that the cases inappropriately combined points of departure (PODs) for different types of endpoints (for example, reduced testosterone production, observation of MNGs, and retained nipples) for different effect measures. Commenters stated that the cases had treated transient, non-adverse biomarkers in the same way as adverse effects when selecting PODs. (Comments 4.1 through 4.3 and 4.6).

Response: We discuss the major criticisms of the specific cases in the following comment/responses. As discussed in the section on MRDE, a wide variety of effects of different types and severities are included under the umbrella of phthalate syndrome. Staff disagrees with commenters' assertions that these effects cannot be considered equal when selecting PODs. Any observed effect related to the male reproductive system is a marker of biological activity that could lead to a broad range of effects in the organism. Thus, such markers should be given equal weight in quantifying the biological activity.

Comment: Case 1. Commenters criticized the study that was the basis for Case 1 (Kortenkamp and Faust), which calculated a potency estimate based on a lowest observed adverse effect level (LOAEL) rather than a no observed adverse effect level (NOAEL) which the commenters stated introduced greater uncertainties. Commenters also asserted that the publication of more robust studies since 2010 (*e.g.,* Boberg) indicating that the Case 1 PEAAs were overstated by a factor of 4 made Case 1 outdated. Commenters also criticized the use of larger uncertainty factors (UFs) for some phthalates. (Comments 4.7 and 4.8).

Response: CPSC agrees that more recent literature has been published regarding the selection of PODs and UFs for phthalates that cause phthalate syndrome. However, this does not mean that Case 1 should be excluded. Rather, alternate approaches (such as Case 1) to POD selection are useful to understand the potential effects of POD and UF selection on risk. Notably, the CHAP considered all relevant hazard studies (including those cited by the commenters) in its *de novo* review of the literature for Case 3.

Comment: Case 2. Commenters criticized various aspects of Case 2 and the study underlying it, (Hannas *et al.* (2011)). Several commenters asserted that CPSC should completely disregard Case 2. They asserted that Case 2 was based on a model that used a hypothetical NOEL for DINP and that the CHAP did not validate the assumptions in the model. The commenters stated that, because ''real world data'' exist that are more applicable and reliable, CPSC should not use Case 2. Commenters asserted that relative potency of DINP and DEHP was inappropriately estimated. For example, a commenter stated that an *in vivo* study (*i.e.,* using live animals) by Gray *et al.* (2000) had previously estimated that DEHP is 10–20 times more active than DINP, so the CHAP should not have used Case 2's estimate that DEHP is 2.3 times more active than DINP. A commenter asserted that the study underlying Case 2 (Hannas *et al.* (2011)) has several flaws and limitations, such as the rats were obtained from different labs, dose-response curves for DINP and DEHP were different, and the study used a low number of animals per group. (Comments 4.9 through 4.13).

Response: The CHAP established alternate approaches (such as Case 2) to POD selection that are useful in understanding the potential effects of POD and UF selection on risk. By stating that Case 2 was based on a model, commenters imply that *Hannas et al.* (2011) was not an *in vivo* study. However, Hannas *et al.* did expose live animals to phthalates. Measurements of the rate of testosterone synthesis were, by necessity, made in a biochemical assay (*in vitro* study) using tissue obtained from the animals. The CHAP's use of a study that included observation of effects from exposure both to DINP and DEHP allowed a direct comparison of the relative potencies of different phthalates because multiple phthalates were tested in the same laboratory using the same methods. This is the unique advantage of Case 2. Staff considers the estimation of relative potency in Hannas *et al.* (2011) to be valid and notes that substantially similar methods have been used in the estimation of relative potency.[59] Moreover, a 2009 review study estimated that DINP is 2.6 times less potent than DEHP.[60] This estimate is closer to the Hannas *et al* study underlying Case 2 than to the Gray study mentioned by commenters.

Regarding other alleged flaws in the Hannas *et al.* study, staff agrees that the rats used to study DEHP and DINP were obtained from different suppliers (as noted by Hannas *et al.*) and that control testosterone production was different for each group of rats (also identified in the publication). However, the study adequately controlled for these differences. Staff also concludes that the number of animals per dose group was appropriate.

Comment: Case 3. Commenters generally preferred Case 3. Some stated that the CHAP should have relied only on Case 3 in its cumulative risk assessment. However, some commenters had criticisms of Case 3. One commenter asserted that the POD for DINP was inadequately justified. A commenter characterized Case 3 as ''muddled'' and noted inconsistencies in how the CHAP discussed the NOEL for DINP. Comments questioned whether multi-nucleated gonocytes (MNGs), which are the basis of Case 3's point of departure for DINP, are relevant to antiandrogenicity and whether MNGs are an adverse effect. A comment questioned the choice of 50mg/kg/day as the POD for DINP, asserting that it is too conservative. (Comments 4.15 through 4.17).

[59] Furr *et al.* (2014).

[60] Benson (2009).

Response: For Case 3, the CHAP derived PEAAs for each phthalate based on the CHAP's own literature review considering all published peer reviewed studies on each phthalate. The CHAP considered studies by Clewell *et al.* (2013a, 2013b), Hannas *et al.* (2011), and Boberg *et al.* (2011) as most relevant and highest quality for identifying a NOAEL for DINP. CHAP report at pp. 97–98. The CHAP found that the lowest no effect level seen in these studies was 50 mg/kg-day based on observance of MNGs in the Clewell study. As the CHAP noted, this was a conservative estimate. It is common practice in risk assessment to select the most conservative health endpoint (from quality data sets) when performing a hazard assessment.[61] Although MNG formation is not directly linked to changes in testosterone production, and not necessarily a direct antiandrogenic effect of phthalate exposure, MNGs are a characteristic effect routinely observed in phthalate syndrome.[62] Thus, the observation of MNGs formed after DINP exposure is consistent with the occurrence of MNGs associated with exposure to other active phthalates and is a marker of phthalates' effects in the developing male reproductive system. Although MNGs might not be an adverse effect, finding MNGs following DINP exposure supports that DINP has a biological effect similar to the other active phthalates. Staff concludes that the CHAP's assignment of the NOAEL for DINP at 50 mg/kg-day based on the observation of MNGs, is reasonable.

2. Risk in Isolation

In accordance with the CPSIA's direction, the CHAP also considered the risk of phthalates individually. 15 U.S.C. 2057c(b)(2)(B)(ii). As discussed in section III.C.3.b, to do this, the CHAP used an MOE approach. The CHAP chose this approach, in part, due to the recommendation of a NRC report on risk assessment methodology.[63] Like the HI approach, the MOE is also widely accepted. *Id.* 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 report at pp. 20 and 69. The MOE approach is conceptually similar to the CPSC staff's default approach in CPSC's Chronic Hazard Guidelines for assessing non-cancer risks,[64] and would lead to similar conclusions about risk. We discuss the MOE for each phthalate the CHAP examined in section IV.D of this preamble, and we discuss comments concerning risks in isolation in that section as well.

[61] Barnes and Dourson (1988); CPSC (1992); EPA (1991).

[62] NRC (2008), Howdeshell (2016), and Gaido (2007).

[63] NRC (2009).

D. Assessments/Determination for Each Phthalate

The CHAP assessed and made recommendations concerning each of the phthalates that it examined. CHAP report at pp. 82–121. Based on the CHAP report, CPSC staff's assessment, public comments on the NPR and staff's NHANES reports, the Commission issues this rule prohibiting children's toys and child care articles that contain concentrations of more than 0.1 percent of DINP, DIBP, DPENP, DHEXP, and DCHP. The Commission concludes that, based on the best available scientific data, all of these phthalates cause MRDE and all contribute to the cumulative risk. Previous sections of this preamble have discussed the health effect of MRDE, exposure to phthalates, and the risk assessment for these phthalates. This section presents the Commission's evaluation of each of the phthalates covered under this regulation.

1. Phthalates Subject to the Interim Prohibition

The CPSIA established an interim prohibition on children's toys that can be placed in a child's mouth and child care articles that contain concentrations of more than 0.1 percent of DINP, DIDP, and DNOP. 15 U.S.C. 2057c (b)(1). The CPSIA directs 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.'' Thus, for each of these phthalates, the Commission must decide whether it is appropriate to make the interim prohibitions permanent under the statutory criteria.

As explained in the preamble to the NPR and above, for phthalates causing MRDE, the Commission considered the cumulative risk, which was based on the CHAP's HI estimates. Consistent with the CHAP report, the Commission considers that the acceptable risk is exceeded when the HI is greater than one. This is also consistent with the CPSC's chronic hazard guidelines. 57

[64] 57 FR 46626 (Oct. 9, 1992).

FR 46626 (Oct. 9, 1992). The CPSC's chronic hazard guidelines consider the ''acceptable risk'' for a reproductive or developmental toxicant to be equivalent to an exposure equal to or less than the ''acceptable daily intake'' (ADI), that is, an HI [65] of less than or equal to one for the population affected by the toxicant. Thus, the Commission considers that an HI less than or equal to one is necessary ''to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.'' The chronic hazard guidelines do not define the percentage of the population (*i.e.,* number of individuals versus the sample population or entire population) that must have an HI less than one in order to ensure a ''reasonable certainty of no harm . . . with an adequate margin of safety.''

In the NPR, the Commission proposed to prohibit children's toys and child care articles containing more than 0.1 percent of DINP, DCHP, DHEXP, and DPENP based on the CHAP's determination that approximately 10 percent of pregnant women and 5 percent of infants had an HI greater than one. 79 FR at 78334–35. Thus, in issuing the NPR, the Commission concluded that the proportion of populations not affected by cumulative exposure to phthalates (at least 90 percent of pregnant women and 95 percent of infants) did not meet the standard of ''a reasonable certainty of no harm with an adequate margin of safety.'' The Commission did not establish directly, however, that there was a specific proportion of the population that must have an HI less than or equal to one to ensure a ''reasonable certainty of no harm with an adequate margin of safety'' or to ''protect the health of children.''

Staff's analysis of the most recent NHANES data showed that exposures to phthalates have changed. Using the CHAP's cumulative risk assessment methodology and the most recent NHANES data, staff has determined that between 98.8 and 99.6 percent of WORA (2013/2014 NHANES) had an HI less than or equal to one. As in previous NHANES data cycles, some individuals in the 2013/2014 NHANES data set still have an HI greater than one. Depending on the PEAA case used for analysis, between two and nine of the approximately 538 WORA in the NHANES 2013/2014 data sample had an HI of greater than one.[66] Thus, a portion of WORA is exposed to phthalates at levels that can induce MRDE or other phthalate syndrome effects. For non-antiandrogenic phthalates (*i.e.,* those that do not cause MRDE), the Commission considered the MOE, as estimated by the CHAP to assess risk. As mentioned previously, MOEs greater than 100–1,000 are generally considered adequate to protect human health. Thus, 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'' or to ''protect the health of children.''

a. Diisononyl phthalate (DINP)

i. Summary

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 report at p. 99. The CHAP stated that it made this recommendation ''because 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.'' *Id.* As discussed in section III.C.4.a. of this preamble, the CHAP cited multiple published studies that showed antiandrogenic effects after DINP exposure in rats. *Id.* at 96–97. DINP is less potent, by perhaps two- to 10-fold, than DEHP.[67] However, DINP contributes to the cumulative risk from all antiandrogenic phthalates. The CHAP found that 10 percent of pregnant women and up to 5 percent of infants have a HI greater than one based on data at that time.

CPSC staff examined more recent NHANES data than the dataset the CHAP considered. Using the CHAP's methodology and the 2013/2014 NHANES exposure data, CPSC staff determined that approximately 99 percent of WORA in the U.S. population now have an HI less than or equal to one (using the 2005/2006 NHANES data, 97 percent of WORA had an HI less than or equal to one). Additionally, CPSC staff's evaluation of recent NHANES data shows that exposure to DINP has increased approximately five-fold since 2005/2006. DINP now contributes as much to the cumulative risk as DEHP.

As shown by the scenario-based exposure assessment included in Appendix E–1 of the CHAP report, lifting the interim prohibition on children's toys that can be placed in the mouth and child care articles containing more than 0.1 percent DINP could increase exposure to DINP from these products, compared to exposures if DINP is not allowed in these products. If DINP were used in all of the products that were included in the scenario-based exposure assessment, DINP exposure from children's toys and child care articles could account for up to about 29 percent of infants' total DINP exposure from all evaluated sources. Staff does not know the extent to which manufacturers would return to using DINP in children's toys and child care articles if the interim prohibition were lifted. Staff is also unable to quantify the impact of increased DINP exposure on the percent of WORA or infants that have an HI less than or equal to one. However, staff notes that increased exposure will increase the MRDE risk to the population.

The CHAP also assessed the risks of DINP in isolation and found that the MOEs ranged from 830 to 1,500. CHAP report at pp. 95–99. As discussed previously, MOEs of at least 100 are adequate to protect public health. CPSC agrees with the CHAP's analysis that the MOEs for DINP in isolation, did not present a risk. However, DINP exposure has been increasing since the CHAP completed its analysis. Current analysis suggests that DINP MOEs, in isolation, (*e.g.,* the MOE is now 220 to 14,000 at the 95th percentile) are below the upper limit, and are nearing the lower limit considered adequate for protecting public health. Based on the CHAP's analysis and staff's analysis of more recent NHANES data (and after consideration of the comments discussed below), the Commission determines that continuing the interim prohibition concerning DINP is necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.

The Commission proposed to expand the scope of the restriction on DINP's use so that the rule would prohibit all children's toys and child care articles containing DINP rather than only children's toys that can be placed in a child's mouth and child care articles. 79 FR at 78335. Likewise, the final rule prohibits all children's toys and child care articles containing concentrations of more than 0.1 percent of DINP. The

[65] HI is the ratio of the daily exposure to the ADI. The CHAP's PEAA values are equivalent to an ADI, EPA reference dose (RfD), ATSDR minimal risk level (MRL), or similar terms used by other agencies.

[66] The NHANES data was analyzed using 3 methods (Cases 1–3) For Case 1, three WORA had HIs greater than 1. For Case 2, nine WORA had HIs greater than 1. For Case 3, two WORA had HIs greater than 1.

[67] Gray *et al.* (2000); Hannas *et al.* (2011b).

Commission determines that this expansion of scope is necessary to protect the health of children. Covering all children's toys means that the rule will protect against exposure to DINP through dermal contact (through the skin from handling toys), indirect oral exposure from children handling a toy and then placing their hands in their mouths, and all mouthing behavior. The CHAP's estimates of oral exposure from mouthing toys included any behavior in which the toy contacts the mouth. CHAP report at Appendix E. However, the interim prohibition covers only toys that can be placed in a child's mouth. The CPSIA provides the following definition of ''toy that can be placed in a child's mouth'':

> For purposes of this section a toy can be placed in a child's mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children's product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth.

15 U.S.C. 2057c(g)(2)(B). Thus, continuing the interim prohibition with regard to DINP without expanding the scope would exclude toys that are 5 centimeters or larger in one dimension (or have parts 5 centimeters or larger) even though children may be exposed to phthalates from licking or otherwise contacting the toy with the lips and tongue. Additionally, although staff does not have exposure estimates for indirect oral exposure from handling toys and normal hand-to-mouth behavior, staff concludes that exposures from handling toys will further contribute to the cumulative risk. Based on the analysis provided in Appendix E of the CHAP report, the Commission believes that the rule should encompass any behavior in which the toy contacts the mouth because this behavior provides a pathway of exposure to antiandrogenic phthalates.

ii. Comments Concerning DINP

As noted in section IV.A, commenters presented numerous arguments questioning whether phthalates are antiandrogenic, *i.e.,* cause MRDE, and about the cumulative risk assessment. This section discusses the comments that focused on DINP.

(a) Health Effects of DINP Exposure

Comment: DINP and MRDE. Numerous commenters questioned whether DINP is antiandrogenic, that is, whether it causes MRDE. Commenters asserted that studies do not consistently show that DINP induces the effects associated with rat phthalate syndrome (*e.g.,* decreased fetal testosterone, changes in anogenital distance, nipple retention, reproductive tract malformation, decreased sperm production). They cited numerous studies to support their assertions that DINP is not antiandrogenic and they stated that, for these reasons, the CHAP should not have included DINP in the cumulative risk assessment. However another commenter supported the inclusion of DINP in the cumulative risk assessment because DINP is antiandrogenic. (Comment 1.14).

Response: The CHAP found, and CPSC agrees, that DINP-induced effects are consistent with phthalate syndrome in rats. Clewell *et al.* found changes in testosterone, nipple retention, and AGD, among other observations, by multiple laboratories, which indicate that DINP exposure is associated with outcomes similar to the effects of other phthalates such as DEHP and DBP that cause MRDE; these findings support the conclusion that DINP causes phthalate syndrome. CHAP report at pp. 97–98. CPSC's conclusions are based on the weight of the evidence from review of multiple studies (discussed in comment responses 1.15 to 1.20). Phthalate syndrome is a spectrum of effects and thus one does not expect to observe all phthalate syndrome effects in all studies. The CHAP noted that effects of the phthalates it evaluated were dose-related. CHAP report at p. 2.

Although DINP is less potent than other antiandrogenic phthalates, DINP can contribute to the cumulative risk from other phthalates. DINP has similar effects as other antiandrogenic phthalates, and thus is considered antiandrogenic in the context of the cumulative risk assessment. CPSC concludes that because DINP causes phthalate syndrome, it was appropriate for the CHAP to include DINP in its cumulative risk assessment and for the Commission to prohibit children's toys and child care articles containing DINP.

Comment: DINP and effects on testosterone production. Some commenters stated that studies showed inconsistent results regarding the effect of DINP on the production of testosterone and that this indicates DINP does not induce rat phthalate syndrome. (Comment 1.15).

Response: As the commenters recognize, some studies *do* show reductions in testosterone following DINP exposure.[68] CPSC staff agrees that some studies (*e.g.,* Clewell *et al.* (2013a);(2013b)) involving repeated measurements over time have not shown permanent or persistent changes in testosterone. Sometimes this was due to differences in study design. However, permanent or persistent changes in testosterone are not required to have an adverse impact on male reproductive development; rather, transient reductions in the rate of testosterone synthesis at the critical period of development do have permanent effects (*e.g.,* structural, functional) on male reproductive organs.[69] Furthermore, staff agrees with the study by Hannas *et al.,* showing that the rate of testosterone synthesis, rather than plasma or testicular levels, is the most relevant measure of phthalate-induced effects on testosterone.[70] Additionally, testosterone measurements made after dosing lab animals with DINP has ended do not account for the possible effects of ongoing exposure, as could be expected for humans with exposures occurring after birth from food, water, or contact with consumer products. Staff notes that its conclusions are consistent with findings from a recent NAS systematic review of the DINP scientific literature.[71] In that review study, the authors asserted with high confidence that DINP could be considered a ''presumed human hazard'' because of its potential to reduce testosterone in male fetal rats.

Comment: Effect of DINP on anogenital distance. Some commenters cited studies showing little or no effect on anogenital distance (AGD, *i.e.,* the distance from the anus to the genitalia) after dosing with DINP. They asserted that these studies show DINP does not induce phthalate syndrome. A commenter questioned the results of one study where a significant decrease in AGD was observed, because of the very small differences between the treated and control groups. (Comment 1.16).

Response: Reduced AGD is one of the abnormalities that characterizes rat phthalate syndrome. CHAP report at pp. 1–2. The commenter questioned the AGD reductions observed in the Boberg *et al.* (2011) and Clewell *et al.* (2013b) studies; however, these results were actually larger than the magnitude considered by the commenter as unlikely to be biologically significant. Overall, the weight of evidence in the studies cited by the commenter demonstrates that DINP causes permanent effects on male reproduction. Thus, the commenter's contention regarding a transient nature of DINP's effects on AGD conflicts with the body

[68] Boberg *et al.* (2011); Borch *et al.* (2004); Clewell *et al.* (2013a); (2013b).

[69] Hannas *et al.* (2011).

[70] Hannas *et al.* (2011).

[71] NAS (2017).

of evidence that DINP leads to phthalate syndrome. Furthermore, the animal studies, which involve short term exposures, do not reflect the continuous exposures that occur in humans.

Comment: Nipple retention. Commenters questioned whether nipple retention is a relative endpoint when considering phthalates' effects on humans and questioned the results of studies by Boberg *et al.* (2011) and Gray *et al.* (2000). Commenters also noted that Clewell *et al.* (2013b) reported no significant difference in nipples in male rats exposed to DINP. (Comment 1.17).

Response: The CHAP specifically discussed nipple retention as a relevant endpoint for antiandrogenic activity, and concluded that nipple retention in male animals is consistent with phthalate-induced reductions in testosterone levels. CHAP report at p. 16 and Appendix A–2. Staff notes that nipple retention is sensitive to exposure of the developing animal during key windows of susceptibility. Studies cited by the commenters that indicate the dosing ends during gestation or within the early part of the postnatal period do not consider possible effects of ongoing exposure, as could be expected for humans with exposures occurring after birth, but within early life periods of vulnerability from food, water, or contact with consumer products. As noted previously, phthalate syndrome is a spectrum of effects; all effects will not be present in every study.[72] Although nipple retention in animals may not correspond to a specific endpoint in humans, nipple retention is an antiandrogenic effect that could manifest in different ways in humans.

Comment: Reproductive tract malformations. Commenters noted that a number of animal studies involving DINP have not reported male reproductive tract malformations, such as cryptorchidism or hypospadias. For example, commenters stated that in the study by Gray *et al.* (2000), the significance of the changes after DINP exposure were unclear and questionable. (Comment 1.18).

Response: Staff recognizes that the same specific male reproductive tract malformations have not been consistently observed following DINP exposure. As noted previously, phthalate syndrome is a spectrum of effects and not all effects will be observed in every study. As the CHAP recognized, the observation of effects depends on the dose level used in each study. CHAP report at p. 2. The three studies described by the commenter as ''definitive'' studies (Hellwig *et al.,* Hushka *et al.,* and Waterman *et al.*) were not designed or intended to detect phthalate syndrome effects. In fact, one of the ''definitive'' studies (Hushka *et al.*) was on DIDP, which does not cause phthalate syndrome. Staff acknowledges that the Clewell study demonstrates that DINP induces limited or no phthalate syndrome effects following dietary dosing to rats. In spite of this, the authors themselves conclude that DINP has less potency than DEHP or DBP, but more than DEP when considering effects on the male reproductive tract. They additionally state ''DINP is simply less potent than DBP and DEHP, *i.e.,* it has lower potency in causing any adverse responses.'' Staff also notes that this study involved oral dosing via feed, which is different than oral dosing using a tube inserted into the stomach (gavage dosing), which is used in typical developmental toxicity studies for determining phthalate syndrome effects. Different dosing strategies may account for the lack of effects seen in the Clewell study. Staff responds to commenters' criticisms of other studies in comment/response 1.18 in Tab B of the staff's briefing package.

Comment: DINP's effects on sperm. Several commenters asserted that there is no strong evidence that DINP adversely affects sperm production or quality. They discussed a number of studies regarding DINP's effects on sperm parameters, male mating behavior, and fertility. (Comment 1.19).

Response: Three studies that commenters described as definitive were not actually designed or intended to detect phthalate syndrome effects. One of them was on DIDP, which does not cause phthalate syndrome. Inconsistencies could be due to study parameters or to the lower potency of DINP compared to other phthalates that have more consistent effects on sperm and fertility. Staff provides a more detailed response in comment/response 1.19 in Tab B of the staff's briefing package.

Comment: Multi-nucleated gonocytes (MNGs). Several commenters disagreed with the CHAP's use of MNG formation as a phthalate syndrome endpoint, and asserted that MNG formation is not a consequence of exposure to DINP. Some commenters asserted that MNG induction should not be considered an adverse effect because the MNGs are eliminated within a few weeks after birth. (Comment 1.20).

Response: Although MNG formation is not linked directly to changes in testosterone production, and not necessarily a direct antiandrogenic effect of phthalate exposure, MNGs are a characteristic effect routinely observed after dosing with phthalates.[73] Thus, the observation of MNGs formed after DINP exposure is consistent with results after exposure to other active phthalates, such as DBP, and is a marker of phthalates' effects in the developing male reproductive system. Furthermore, one study suggests that the presence of MNGs may be linked to reduced fertility or testicular germ cell cancer in humans.[74]

Comment: Human epidemiology data and DINP antiandrogenicity. One commenter asserted that the available epidemiology data do not support the assertion that DINP is associated with reproductive effects in humans. The commenter presented a review of four studies that evaluated DINP's association with adverse human reproductive effects.[75] The review found lack of correlation or equivocal results in these studies. The commenter also found that a more recent study that reported slight reductions in AGD associated with DINP metabolites in mother's urine was equivocal.[76] Another commenter noted that statistical chance may have been responsible for some of the epidemiology studies' positive association. The commenter concluded that the weight of the current information did not support that humans developed reproductive or developmental issues following exposure to phthalates. (Comment 7.5).

Response: Of the four studies mentioned by the commenter, two were of adults and one was of boys aged 6–19 years. The CHAP concluded that studies in adult men were less relevant to the CHAP's work because exposures measured during adulthood cannot be used to infer childhood or early life exposure. Observational epidemiology studies control for the possibility of random chance, bias, or confounding in their study design and analysis. The primary studies that commenters mentioned discuss the studies' efforts to minimize these effects. Staff concludes that most of the studies cited by the commenters are not relevant to the current rulemaking on children's toys and child care articles because they involved adults or older children. Because humans are simultaneously exposed to multiple phthalates, it is difficult to distinguish the effects of different phthalates in epidemiology studies. Staff concludes that the overall

[72] Howdeshell *et al.* (2016).

[73] Spade *et al.* (2015).

[74] Ferrara *et al.* (2006).

[75] The studies were (Joensen *et al.* (2012); Jurewicz *et al.* (2013); Main *et al.* (2006); Mieritz *et al.* (2012).

[76] Bornehag *et al.* (2015).

weight of the evidence demonstrates an association between prenatal phthalate exposure and MRDE effects in infants.

(b) DINP and Risk

Comment: DINP's contribution to risk. Several commenters asserted that DINP contributes little to the cumulative risk. They noted that the CHAP's cumulative risk assessment showed that the estimated risks associated with phthalate exposure were driven by DEHP and DBP, and that DINP contributed only a small portion of the combined risk (less than one percent). A comment on CPSC staff's 2017 report stated that as DINP continues to replace DEHP, the risk will continue to fall, thus increased replacement of phthalates by DINP will lower the cumulative risk further than it currently is. Along these lines, the commenter asserted that lifting the interim prohibition regarding DINP would have only an ''inconsequential effect'' on cumulative risk. Some commenters asserted that, because DINP is less potent than DEHP, even if DINP entirely replaced DEHP, the 95th percentile HI would be far below one. (Comments 3.3, 3.4, and 5.1).

Response: CPSC agrees that the median and 95th percentile HIs would be less than one if all CRA phthalate exposures were considered to be from DINP. However, a certain number of WORA in the 2013/2014 NHANES sample have HIs and DINP HQs greater than one. Any increase in DINP exposure could increase these individuals' risk. In addition, there are a number of individuals that have HIs and DINP HQs near one. Additional DINP exposure to these individuals could increase the risk to greater than an HI of one (see comment response 3.2 and TAB A). Based on the scenario-based exposure assessment, lifting the interim prohibition on children's toys that can be placed in a child's mouth and child care articles containing more than 0.1 percent of DINP could result in children's toys and child care articles accounting for up to about 29 percent of total DINP exposure to infants. However, if DINP is not allowed in children's toys and child care articles, such products would not contribute to total DINP exposure. Staff is unable to quantify the impact of changes in DINP exposure on the percent of WORA or infants that have an HI less than or equal to one, although staff notes that an increased exposure will increase the MRDE risk to the population. Staff does not consider that increasing MRDE risk to the population is ''inconsequential,'' particularly to those affected.

As the commenter points out, in reality DINP would not replace all of the other phthalates because the differences in properties among the phthalates limit their use depending on the intended application. WORA with HQs greater than one were measured in each NHANES cycle despite the interim prohibition on children's toys that can be placed in a child's mouth and child care articles containing DINP. Any further increase in DINP exposure could increase the risk from DINP.

Comment: ''Reasonable certainty of no harm'' and DINP. Some commenters asserted that the standard ''reasonable certainty of no harm'' is met without continuing the interim prohibition regarding DINP. They reasoned that, because the CPSIA permanently prohibited children's toys and child care articles containing DEHP, DBP and BBP, those phthalates cannot contribute to any cumulative risk from these children's products in the future; and without those phthalates, the HI clearly is less than one, so there is a reasonable certainty of no harm from use of DINP in these children's products. In contrast, other commenters asserted that it ''turns logic upside-down'' to suggest that ''as DEHP is replaced by less toxic phthalates, there is a reasonable certainty of no harm from increasing exposures to the remaining phthalates,'' because the level of future replacement is unknown, but it is known that the replacement phthalates present hazards.

Commenters on the staff's analysis of more recent NHANES data asserted that CPSC staff's analysis clearly demonstrates that the interim prohibition involving DINP can be lifted while meeting the ''reasonable certainty of no harm'' standard set forth in the CPSIA because the NHANES 2013/2014 data show that cumulative risk for WORA continues to decline with the HI consistently below one for the 50th and 95th percentiles. (Comment 3.20).

Response: As explained, studies show that DINP contributes to the cumulative risk. The CPSIA's permanent prohibition keeps DEHP, BBP, and DBP out of children's toys and child care articles; however these phthalates continue to be used in other products and thus they contribute to the cumulative risk. The CRA demonstrates that HIs greater than one were observed in actual WORA sampled, in all NHANES data cycles, including the most recent (2013/2014). Thus, male children born to these women could be at risk for MRDE. Because a portion of the potentially sensitive population is still near the level of concern (HI greater than 1), permanently prohibiting children's toys and child care articles containing DINP is still necessary to ''ensure a reasonable certainty of no harm'' to children and pregnant women with an ''adequate margin of safety.''

Comment: Diet as source of exposure to DINP. Several commenters noted that diet is the primary source of exposure for DINP, as well as other phthalates, in infants and children. They asserted that DINP contributes so little to the combined risk from exposure to phthalates from all sources that a permanent prohibition on DINP's use in children's toys and child care articles would have little effect on the overall risk and, thus, the prohibition is not supported. (Comment 5.3).

Response: The CHAP report does show that food, rather than children's toys or child care articles, provides the primary source of phthalate exposure to women and children. CHAP report at pp. 49–53. The other main contributors were soft plastic toys and teethers (via mouthing), and personal care products such as lotions, creams, oils, soaps, and shampoos via dermal contact. *Id.* Figure 2.1.

The scenario-based exposure assessment included in the CHAP report shows that mouthing and dermal exposure to toys could contribute an average of 12.8 percent, 5.4 percent, and 1 percent of the overall DINP exposure to infants, toddlers, and children, respectively, if DINP were used in these products. *Id.* at Appendix E1, Tables E1–21, E1–22, and E1–23. Mouthing and handling soft plastic toys and teethers could contribute 12.8 percent (mean exposure) or 16.6 percent (95th percentile exposures) of total DINP exposure in infants. *Id.* at Table E1–21. Dermal contact with the evaluated toys and child care articles may contribute up to an additional 16.5 percent of exposures to infants. *Id.* Therefore, although infants' DINP exposure was primarily from diet, up to 29 percent may be due to the presence of DINP in the evaluated toys and child care articles. *Id.,* Figure 2.1.

Comment: DINP in isolation. Commenters asserted that the CHAP found no significant health risk from exposure to DINP by itself (considered in isolation), given the very large MOE estimates for median exposures, as well as for the 95th percentile of exposure. Commenters concluded that because of the high MOEs for DINP from all sources, the margins of safety must be even larger for the children's products' contribution to DINP exposure, and thus, there is no basis for a permanent prohibition on children's toys and child care articles containing DINP. A commenter also stated that replacement of DEHP by DINP would not be expected to increase the risk because of DINP's lower potency. A commenter

also asserted that even a doubling in DINP exposures would not increase the risk substantially, thus, restricting DINP's use is unwarranted. (Comment 5.5).

Response: As discussed previously, the CHAP's recommendations and the Commission's rule are based on the cumulative risk from DINP in combination with other phthalates. We note, however, that due to the increased exposure to DINP (as seen in the 2013/2014 NHANES data), DINP's risk in isolation has increased. Thus, DINP alone may dominate the cumulative risk in the future, and DINP exposure in isolation may approach the level of concern, especially considering Case 2. Using the most recent NHANES data, the MOEs for WORA exposed to DINP range from 2300 to 150,000 (median) and 220 to 14,000 (95th percentile) for all three cases.

CPSC disagrees with the assertion that doubling the DINP exposure would not increase the risk substantially, and notes that currently, a certain proportion of actual WORA have a DINP HQ greater than one and a certain proportion of actual WORA have DINP HQs near one. Increasing exposure to DINP may increase the number of individuals with an HQ greater than one or may increase the HQs of individuals with an HQ greater than one. Furthermore, doubling DINP exposures would lower the MOE for DINP to 110 to 7000 (95th percentile). The CHAP noted that MOEs exceeding 100 to 1000 are typically ''considered adequate for protecting public health.'' CHAP report at p. 4. Current analysis suggests, therefore, that DINP MOEs, in isolation, (*e.g.,* the MOE is 220 for Case 2) are below the upper limit, and are nearing the lower limit considered adequate for protecting public health.

Comment: Safety of DINP compared to alternatives. Numerous commenters expressed concern about prohibiting the use of DINP in children's toys and child care articles when not much is known about the toxicity and safety of alternative chemicals. Some commenters stated that the safety of alternative plasticizers should be thoroughly tested before placing restrictions on DINP. Commenters stated that DINP is well studied, has been used for over 50 years, and has been found safe for its intended uses. Commenters were concerned that prohibiting the use of DINP in children's toys and child care articles could potentially put people at greater risk as substitutes with uncertain safety are used instead. (Comment 10.5).

Response: CPSC shares the commenters' concerns about the shift of chemical use from phthalates with known toxicity to phthalate alternatives with less toxicity or exposure information. The CHAP identified several data gaps for phthalate alternatives. CPSC agrees with the CHAP's recommendation that appropriate federal agencies should perform additional research and risk assessment activities on phthalates and phthalate alternatives to fill in data gaps. However, CPSC does not believe that the lack of data on alternative plasticizers means we should not take action regarding DINP. DINP has in fact been covered by the interim prohibition since February 2009. As explained in the NPR and throughout this document and the staff's briefing package, based on the CHAP report and staff's analysis, we conclude that DINP causes adverse effects on male reproductive development and contributes to the cumulative risk of these effects from other antiandrogenic phthalates. Thus, the Commission determines that prohibiting children's toys and child care articles containing concentrations of more than 0.1 percent of DINP is necessary to ensure a reasonable certainty of no harm and to protect the health of children.

(c) Scope of Prohibition Regarding DINP

Comment: Support for expanding scope to all children's toys rather than those that can be placed in a child's mouth. Several commenters stated that the Commission lacked justification to expand the restriction on DINP from ''children's toys that can be placed in a child's mouth'' to all children's toys. One commenter noted that it is not clear the CHAP intended to recommend this expansion. Other commenters noted that because the MOEs for DINP show that it does not present a risk in isolation, there is no basis for expanding the interim prohibition to cover all children's toys. Commenters asserted that the Commission had little justification for the change and that it would have little effect on the risk. They noted that any risk comes primarily from mouthing. However, other commenters, citing evidence that DINP is associated with MRDE and the CHAP's CRA analysis, stated that the CRA clearly supported the proposed prohibition involving DINP and the proposed expansion of scope from toys that can be placed in a child's mouth to all children's toys. (Comments 6.1 and 6.2).

Response: As discussed previously, this rule is based on the cumulative risk analysis demonstrating that DINP (and other antiandrogenic phthalates) causes MRDE and, and the most recent NHANES data that shows that there were from two to nine individuals with a HI greater than one in a sample of 538 WORA. Limiting the rule to children's toys that can be placed in a child's mouth would exclude toys that could also expose children to DINP through mouthing behaviors other than placing the toy in the mouth and through hand to mouth exposure (*e.g.,* licking) as well as direct exposure through dermal contact. The 2013/2014 NHANES data indicate that exposure to DINP is increasing, even with the CPSIA's interim prohibition in effect. Covering all children's toys (rather than only those that can be placed in a child's mouth) will decrease exposure to DINP and thus reduce the risk of MRDE.

Comment: Reliance on low cost and low dermal exposure as rationale in NPR. Commenters asserted that the NPR had provided faulty rationales for the expansion. A commenter asserted that the Commission had inappropriately based the expansion to all children's toys on consideration of testing costs rather than on risk. A commenter stated that the reasoning stated in the NPR in favor of expanding the rule to all children's toys was inconsistent with the reasons CPSC had stated for not expanding the prohibition to all children's products. The commenter understood that CPSC did not propose to cover all children's products because of negligible exposure due to the infrequency of mouthing of children's products (that are not children's toys or child care articles). The commenter asserted that this same rationale indicates that the rule should not be expanded beyond children's toys that can be placed in a child's mouth. (Comment 6.3 and 6.6).

Response: The NPR mentioned that the proposed expansion would have little impact on testing costs. 79 FR 78335. However, the NPR merely noted this anticipated impact; the reason for the expansion is to reduce the risk of adverse health effects. Regarding any inconsistency between proposing to expand the interim prohibition to all children's toys and proposing not to cover additional children's products, we note that the proposal concerning all children's products was based primarily on a lack of information to assess the impact on children's health.

Comment: Reliance on European assessment as rationale in NPR. Commenters objected to the NPR's discussion of the Europe Union's regulations on phthalates. Commenters noted that the NPR stated that the European Commission's 2005 directive on phthalates had distinguished between all children's toys and toys that

can be placed in the mouth due to uncertainties about DINP, DNOP and DIDP. The NPR suggested that, now that the CHAP had issued its report, these uncertainties no longer exist. Commenters objected to the NPR's reliance on this reasoning to support the expansion of the regulation of DINP. In addition, the EU submitted a related comment noting that the European Chemicals Agency (ECHA) conducted an extensive review in 2010 on DINP, DIDP and DNOP, and concluded that exposure other than mouthing did not present further risk. (Comments 6.4 and 6.5).

Response: Regarding the ECHA's re-evaluation, that report did not specifically address the distinction between children's toys and toys that can be placed in a child's mouth. Additionally, the 2013 ECHA report used different health end points (liver toxicity) as the focus, rather than the MRDE focus used by the CHAP and CPSC. Moreover, the 2013 ECHA report did not consider cumulative health risks from multiple phthalates.

b. Di-n-octyl phthalate (*DNOP*)

The CHAP concluded that DNOP does not lead to male developmental reproductive toxicity in animals and, therefore, does not contribute to the cumulative risk. Although DNOP does cause other developmental (supernumerary ribs) and systemic effects (liver, thyroid, immune system, and kidney), the MOEs in humans are very high. Therefore, the CHAP recommended that the current prohibition involving DNOP be lifted. CHAP report at pp. 91–95. The NPR noted that DNOP levels in people are so low that they are not detectable in about 90 percent of humans, and that DNOP is not antiandrogenic, and, therefore, does not contribute to the cumulative risk. 79 FR 78334. Based on the CHAP report and staff's analysis, the Commission concludes that continuing the prohibition of children's toys that can be placed in a child's mouth and child care articles containing more than 0.1 percent 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.

c. Diisodecyl phthalate (DIDP)

The CHAP concluded that DIDP does not lead to male developmental reproductive toxicity in animals and, therefore, does not contribute to the cumulative risk. The CHAP considered the risk of DIDP in isolation and found that DIDP does cause other developmental (supernumerary ribs) and systemic effects (liver, and kidney). However, because the MOEs in humans are sufficiently high (range from 2,500 to 10,000 for median DIDP exposures and 586 to 3,300 for upper-bound exposures), the CHAP recommended that the interim prohibition involving DIDP be lifted. CHAP report at pp. 100–105. As noted in the NPR, DIDP exposure would need to increase by more than 250 times to exceed an acceptable level. 79 FR 78334. Based on the CHAP report and staff's analysis, the Commission concludes that continuing the prohibition of children's toys that can be placed in a child's mouth and child care articles containing more than 0.1 percent 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.

d. Comments Concerning DNOP and DIDP

Comment: Prohibition concerning DNOP and DIDP should be made permanent. Some commenters asked the Commission to make the interim prohibition regarding DNOP and DIDP permanent. Commenters reiterated the CHAP's conclusions 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. They noted that the CHAP stated that DIDP was a 'probable toxicant' based on reproductive and developmental effects, and adverse systemic effects on the liver and kidney. A commenter suggested that ''there could be a cumulative impact from exposures to a mixture of DINP, DNOP and DIDP, which would enhance the concern about harm.'' Commenters asserted that without enough data to conduct a robust risk assessment, lifting the prohibition involving DNOP and DIDP will lead to elevated exposure to these two phthalates when others are covered by prohibitions. (Comments 5.8 and 5.9).

Response: The CHAP concluded that DIDP and DNOP do not appear to possess antiandrogenic potential and therefore the CHAP did not include them in the cumulative risk assessment. As discussed above, the CHAP's analysis of DIDP and DNOP in isolation showed high MOEs (greater than 1,000 for all populations) that are sufficient to protect human health. The CHAP found that DNOP exposure levels are so low that one of the metabolites, MNOP, was not detectable in about 90 percent of humans. CHAP report at Table 2.6. Exposures would have to increase by a large measure before the acceptable levels of exposure would be exceeded. Thus, the CHAP report and staff's analysis do not support a conclusion that prohibiting the use of DNOP or DIDP in children's toys that can be placed in a child's mouth and child care articles is necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.

Comment: ''Reasonable certainty of no harm'' and DNOP and DIDP. Some commenters asserted that lifting the interim prohibition concerning DNOP and DIDP while banning other phthalates would raise questions about whether such action meets the ''reasonable certainty of no harm'' standard. They noted that the CHAP report found exposure to these chemicals from toys and child care articles and that the CHAP reported developmental and systemic toxic effects caused by these chemicals in animal studies. (Comment 5.9).

Response: The CHAP concluded that DIDP and DNOP do not appear to possess antiandrogenic potential and therefore the CHAP did not include these two phthalates in the cumulative risk assessment. Assessing these chemicals in isolation, the CHAP found that the margins of exposure were sufficiently high to protect human health. Therefore, staff concludes that there is no justification to continue the prohibition involving DNOP or DIDP.

2. Phthalates Subject to the Rule But Not Currently Prohibited Under the CPSIA. In addition to determining what action to take regarding the interim prohibition, the CPSIA directed 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.'' 15 U.S.C. 2057c(b)(3)(B).

In the absence of a definition or other guidance on the meaning of the phrase ''necessary to protect the health of children,'' CPSC interprets the phrase in the context of the CHAP report and CPSC's chronic hazard guidelines,[77] which consider that an HI less than or equal to one is necessary to protect the health of children. As explained in the CHAP report, the four additional phthalates all cause male reproductive developmental effects and would contribute to the cumulative risk.

[77] 57 FR 46626 (Oct. 9, 1992).

The CHAP reviewed the potential health risks associated with eight phthalates that were not prohibited by the CPSIA, and it recommended that four additional phthalates (DIBP, DPENP, DHEXP, and DCHP) be prohibited from use in children's toys and child care articles. The CHAP found that these four phthalates are associated with adverse effects on male reproductive development and contribute to the cumulative risk from antiandrogenic phthalates. CPSC staff has reviewed the CHAP's assessment and agrees with the recommendation. Based on the CHAP's evaluation and the staff's assessment, the Commission proposed to prohibit children's toys and child care articles containing more than 0.1 percent of DIBP, DPENP, DHEXP, and/or DCHP. 79 FR 78335–78337. The Commission determines that prohibiting children's toys and child care articles that contain concentrations of more than 0.1 percent of DIBP, DPENP, DHEXP, and/or DCHP is necessary to protect the health of children and issues this final rule to establish this prohibition.

Although current exposures to these four phthalates are low, these phthalates could be used as substitutes for the phthalates subject to prohibition, thus increasing human exposures from MRDE phthalates. All of these four phthalates are capable of contributing to the cumulative risk. A 2014 study demonstrated that three of these four phthalates (DPENP, DHEXP, and DCHP) had much greater potency than DEHP which the CPSIA permanently prohibits from use in children's toys and child care articles.[78] The potency of the fourth (DIBP) was slightly less or similar to DEHP.[79] In addition, these four phthalates may have a greater potential for exposure than DINP, because lower molecular weight plasticizers generally have higher migration rates.[80]

a. Diisobutyl Phthalate (DIBP)

The CHAP recommended prohibiting the use of diisobutyl phthalate (DIBP) in children's toys and child care articles. CHAP report at pp. 110–113. DIBP is associated with adverse effects on male reproductive development and contributes to the cumulative risk from antiandrogenic phthalates. Furthermore, as noted in the NPR, DIBP has been found in some toys and child care articles during compliance testing by CPSC. The CHAP estimated that DIBP contributes up to 5 percent of the cumulative risk in infants from all products and sources. CHAP report at Table 2.16. More recent biomonitoring data show that DIBP exposures and risks have increased by about 50%. TAB A of staff briefing package.

DIBP is similar in toxicity to DBP, 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. The CHAP found that current exposures to DIBP are low. When considered in isolation, DIBP has a MOE of 3,600 or more. CHAP report at pp. 24, 110–111. DIBP contributes roughly 1 to 2 percent of the cumulative risk from phthalate exposure to pregnant women and 1 percent to 5 percent in infants. However, the CHAP based its recommendation on cumulative risk.

Based on evaluation of the CHAP report and staff's review, the Commission concludes that there is sufficient evidence to conclude that DIBP is antiandrogenic and contributes to the cumulative risk. The Commission also concludes that, applying the CPSC chronic hazard guidelines, this phthalate is considered ''probably toxic'' to humans based on sufficient evidence in animal studies. As discussed previously, the Commission considers that a HI less than or equal to one is necessary ''to protect the health of children.'' Using the most recent biomonitoring data, some WORA in the sample have an HI that exceeds one. For PEAA Case 1, three WORA had an HI greater than one; for PEAA Case 2, nine WORA had an HI greater than one; and for PEAA Case 3, two WORA had an HI greater than one. In addition, CPSC staff has identified DIBP in a small portion of toys and child care articles during routine compliance testing. Therefore, the rule prohibits children's toys and child care articles containing concentrations of 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 children's toys and child care articles.

b. Di-n-pentyl Phthalate (DPENP)

The CHAP recommended prohibiting the use of DPENP in children's toys and child care articles. CHAP report at 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. Prohibiting the use of DPENP would prevent its use as a substitute for other banned phthalates. The Commission agrees with the CHAP's recommendation for DPENP. Based on the CHAP report and previous toxicity reviews by CPSC staff and a contractor,[81] the Commission concludes that there is sufficient evidence that DPENP is antiandrogenic and contributes to the cumulative risk. For example, the CHAP noted studies by Howdeshell *et al.* and Hannas *et al.,* which found that exposure to DPENP reduced fetal testicular testosterone production. *Id.* at p. 112. The Commission also concludes that, applying the CPSC chronic hazard guidelines, this phthalate is considered ''probably toxic'' to humans, based on sufficient evidence in animal studies. Furthermore, DPENP is roughly two- to three-fold more potent than DEHP.[82] Although CPSC staff has not detected DPENP in children's toys or child care articles, metabolites of DPENP have been detected in humans,[83] indicating that some exposure to DPENP does occur. In the CHAP's analysis, up to five percent of infants and up to 10 percent of pregnant women exceed the negligible risk level (HI greater than one). Using the most recent biomonitoring data, some WORA in the sample have an HI greater than one. 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 less than or equal to one is necessary ''to protect the health of children.'' Therefore, the rule prohibits children's toys and child care articles containing concentrations of 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.

c. Di-n-hexyl Phthalate (DHEXP)

The CHAP recommended prohibiting the use of DHEXP in children's toys and child care articles. CHAP report at 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 the CHAP report and previous review by CPSC staff and a contractor,[84] the Commission concludes that there is sufficient evidence that DHEXP is antiandrogenic and contributes to the cumulative risk. The

[78] Furr *et al.* (2014).

[79] Furr *et al.* (2014); Hannas *et al.* (2011).

[80] Dreyfus and Babich (2011).

[81] Patton, (2010).

[82] Hannas *et al.* (2011a).

[83] Silva *et al.* (2010).

[84] Patton (2010).

CHAP report noted a 1980 study by Foster *et al.* that found severe testicular atrophy in rats, among other effects. *Id.* at p. 114. The Commission also concludes that, by applying the CPSC chronic hazard guidelines, this phthalate may be considered ''probably toxic'' to humans based on sufficient evidence in animal studies. The CHAP found that up to five percent of infants and up to 10 percent of pregnant women exceed the negligible risk level (HI greater than one). Using the most recent biomonitoring data, some WORA in the sample have an HI that exceeds one. 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 less than or equal to one 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 rule prohibits children's toys and child care articles containing concentrations of 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.

d. Dicyclohexyl Phthalate (DCHP)

The CHAP recommended prohibiting the use of DCHP in children's toys and child care articles. CHAP report at pp. 116–118. DCHP is associated with adverse effects on male development and contributes to the cumulative risk from antiandrogenic phthalates.

The Commission agrees with the CHAP's recommendation for DCHP. Based on the CHAP report and previous reviews by CPSC staff and a contractor,[85] the Commission concludes that there is sufficient evidence that DCHP is antiandrogenic and contributes to the cumulative risk. For example, the CHAP noted two studies that found such effects as reduced AGD and nipple retention in rats exposed to DCHP. *Id.* at p. 116. The Commission also concludes that, by applying the CPSC chronic hazard guidelines, this phthalate is considered ''probably toxic'' to humans based on sufficient evidence in animal studies. 57 FR 46626 (Oct. 9, 1992). The CHAP found that up to five percent of infants and up to 10 percent of pregnant women exceed the negligible risk level (HI greater than one). Using the most recent biomonitoring data, some WORA in the sample have an HI that exceeds one. 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 less than or equal to one 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. Therefore, the rule prohibits children's toys and child care articles containing concentrations of more than 0.1 percent of DCHP. 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.

e. Comments Concerning Phthalates Subject to the Rule But Not Currently Prohibited Under the CPSIA

Comment: Regulating DIBP, DPENP, DHEXP, DCHP. One commenter stated that DIBP, DPENP, DHEXP and DCHP are not widely used in children's toys and child care articles and are not prohibited in the European Union. The commenter stated that the proposed rule ''inevitably will extend inspection range, add cost to manufacturers and exporters and result in an unnecessary trade barrier.'' (Comment 5.7).

Response: CPSC agrees that DIBP, DPENP, DHEXP and DCHP are not widely used in children's toys and child care articles. However, as explained above, studies demonstrate that these four phthalates all cause MRDE and they are as, or more, potent than DEHP. Regarding the commenter's assertion that the prohibition of children's toys and child care articles containing these four phthalates would add costs and result in a trade barrier, because these phthalates are not widely used in children's toys and child care articles, the cost to manufacturers to reformulate the few products that might contain these phthalates should be small. Moreover, third party testing is already required for children's toys and child care articles containing prohibited phthalates and the incremental cost of adding the additional phthalates to the analysis is expected to be very small. Staff estimates that the additional materials needed would cost $0.35 per test or about 0.1 percent of a typical $300 phthalates test for a component part or material. The data analysis procedure would need to be modified to include the new phthalates, but staff does not expect this would additional burdens to qualified laboratories.

f. Children's Products

The scope of this rule covers children's toys and child care articles. The CPSIA authorizes the Commission to ''declare any children's product containing any phthalates to be a banned hazardous product'' if such action is necessary to protect the health of children. 15 U.S.C. 2057c(b)(3)(B). As explained in the NPR, the Commission is not expanding the rule to cover other children's products. 79 FR 78337–78338. Only limited data on exposure to phthalates from other children's products exist. The general information available does not support a determination that prohibiting any products other than children's toys and child care articles is necessary. Toys are more likely than many other children's products to be made of materials that could be plasticized with phthalates. Toys and child care articles are more likely than other children's products to provide a pathway of exposure to phthalates both through oral exposure (from direct contact with the mouth and indirect contact when children place their hands in their mouths) and dermal exposure. We received few comments in response to the NPR that addressed expansion of the scope of the regulation to all children's products.

Comment: Expanding the scope to all children's products. One commenter expressed disappointment that CPSC is not expanding the scope of the provisions involving phthalates to include other children's items such as raincoats, footwear, backpacks, school supplies, and clothes. The commenter asserted that a lack of data does not mean CPSC should assume there is no problem. (Comment 6.6).

Response: Staff has not found new information that would change the basis underlying the Commission's decision not to propose expanding the scope of the rule to all children's products. There is not enough information to adequately assess the health impact of children's products other than children's toys and child care articles. In contrast to children's products in general, a wealth of information regarding use exists for children's toys and child care articles from other agencies, such as EPA, and in scientific publications. The general information available indicates that exposure from children's products is comparatively less than that from children's toys and childcare articles.

[85] Versar/SRC (2010b).

g. Other Phthalates Not Included in the Rule

The CHAP examined 14 phthalates: The three subject to the CPSIA's permanent prohibition, the three subject to the CPSIA's interim prohibition, and eight additional phthalates. Of the eight additional phthalates, the CHAP recommended that four be prohibited from use in children's toys and child care articles, that three (Dimethyl Phthalate (DMP), Diethyl Phthalate (DEP), Di(2-propylheptyl) Phthalate DPHP) be free of any restriction, and the one (Diisooctyl Phthalate (DIOP)) be subject to an interim prohibition. CHAP report at pp. 1118–119. As discussed in the NPR, DIOP has a chemical structure consistent with other antiandrogenic phthalates. However, the CHAP concluded that there is not sufficient evidence to support a permanent prohibition. 79 FR 78337. The CPSIA did not provide for an interim prohibition as an option for the Commission's rule under section 108, and as the CHAP explained, insufficient data exists to determine that a permanent prohibition of DIOP is necessary to protect the health of children. We received a few comments concerning phthalates that the CHAP assessed but are not covered by CPSC's rule.

Comment: DIOP. Some commenters suggested that the CPSC permanently prohibit children's toys and child care articles containing DIOP. They stated that the CHAP had noted DIOP's structural similarity to antiandrogenic phthalates and they concluded that CPSC should not assume that it would meet the CPSIA criteria when hazard and exposure data are lacking. (Comment 5.10).

Response: Although the CHAP recognized that the structure of DIOP suggests that it may be associated with antiandrogenic effects, no experimental data exist that would support a conclusion that DIOP causes MRDE. Additionally, potency and exposure data are lacking. Thus, there is no basis for regulatory action on DIOP at this time.

Comment: Prohibitions involving other phthalates. Some commenters asserted that ''The CHAP's lack of recommendations for additional regulatory action on phthalates like DIOP, DMP, DEP, DPHP or many of the alternatives evaluated is not an endorsement of their safety'' because of the lack of sufficient hazard and exposure data on these chemicals. The commenters suggested that CPSC continue to review and monitor these phthalates and to recommend that other federal agencies take appropriate actions. (Comment 10.4).

Response: CPSC staff participates in several interagency collaborations to discuss issues of mutual interest, including phthalates. CPSC will continue these cooperative activities.

E. The Concentration Limit

For both the permanent and interim prohibitions, the CPSIA established a concentration limit of 0.1 percent. The CHAP stated:

> 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 report at p. 79. As discussed in the NPR, this concentration limit is not based on risk, and the Commission found no risk-based justification to change the limit from the 0.1 percent specified in the CPSIA. Thus, the Commission proposed to maintain this concentration limit. 79 FR 78338. We did not receive any comments concerning the concentration limit. The final rule retains the 0.1 percent concentration limit.

F. International and Other Countries' Requirements for Children's Toys and Child Care Articles Containing Phthalates

1. Summary of Requirements

Other countries have restrictions concerning the use of various phthalates in children's toys and child care articles. The requirements vary, but the following countries have some regulatory restrictions on phthalates that can be used in children's toys and child care articles: The European Union (EU), Denmark, Canada, Japan, Australia, Brazil, Argentina, Taiwan, and Hong Kong. The requirements differ on the phthalates restricted and products covered. Unlike CPSC's rule, these restrictions are based on evaluations of phthalate exposures in isolation, not in combination with other phthalates. There is no international standard that establishes substantive requirements for phthalates in children's toys and child care articles. International Organization for Standardization (ISO) 8124–6:2014 specifies a method for testing toys and children's products to determine if they contain phthalates; it does not establish any content limits. We provide a summary of other countries' requirements concerning phthalates in children's toys and child care articles:

DINP:

- *Denmark:* Prohibits all phthalates at concentrations above 0.05 percent in toys and child care articles intended for children under 3 years old.
- *EU:* Limits the use of DINP (as well as DIDP and DNOP) individually or as mixtures in toys and child care articles which can be placed in the mouth by children to no greater than 0.1 percent by weight of the plasticized material.
- *Canada:* Limits use in the vinyl in any part of a toy or child care article that can be placed in the mouth of a child under four years of age to no greater than 0.1 percent of DINP, DIDP or DNOP.
- *Japan:* For toys that are intended to come in contact with the mouth (excluding pacifiers and teething rings), parts made from plasticized materials that are intended to come in contact with the mouth must not contain more than 0.1 percent DINP (or DIDP or DNOP); PVC parts not intended to come in contact with mouth must not use DINP as a raw material.
- *Brazil:* Limits use of DINP in plastic materials in all kinds of toys for children under three to no greater than 0.1 percent.
- *Argentina:* Limits use of DINP in toys and child care articles made of plastic material that can be placed in the mouth to no greater than 0.1 percent.
- *Taiwan:* Limits DINP use in toys and child care articles to no greater than 0.1 percent individually or in combination with DEHP, DBP, BBP, DIDP, or DNOP.
- *Hong Kong:* Limits the combination of DINP, DIDP and DNOP to no greater than 0.1 percent of the total weight of the plasticized materials in toys or children's products any part of which can be placed in the mouth of a child under four years of age.
- *Australia:* Considered but rejected limiting DINP in children's toys and child care articles.

Other Phthalates Covered by CPSC's Rule (DIBP, DPENP, DHEXP, DCHP)

- *Denmark:* In 2009 instituted a national prohibition on all phthalates at concentrations above 0.05 percent in toys and child care articles intended for children under 3 years old. This covers all four phthalates: DIBP, DPENP, DHEXP, DCHP.
- No restrictions concerning DIBP, DPENP, DHEXP, DCHP in children's toys and child care articles in other countries.

As this summary demonstrates, requirements concerning DINP in

children's toys and child care articles vary across different countries. However, even if the precise requirements differ, numerous countries have some limitation on the use of DINP in children's toys and child care articles, and one other country restricts the use of DIBP, DPENP, DHEXP, and DCHP in children's toys and child care articles.

2. Comments Concerning Other Countries' and International Requirements

Comment: Differences between CPSC's proposed rule and other countries' requirements. Some commenters observed that CPSC's NPR differed from restrictions in other countries. These comments focused on CPSC's expansion of the interim prohibition regarding DINP to cover all children's toys. Commenters noted the inconsistency between the EU's requirements concerning DINP and the CPSC's proposed rule. Two commenters stated that the CPSC's rule is consistent with the EU. A commenter expressed concerns that the rule might be a barrier to international trade under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) due to the differences between CPSC's rule and other countries' approaches. (Comment 5.6).

Response: As discussed above, CPSC's rule concerning DINP differs from other countries' restrictions. However, there is variation among these countries; no uniform consensus on regulation of DINP in children's toys and child care articles exists. Regarding the TBT, we note that there is no international standard establishing restrictions on phthalates in toys. ISO 8124–6:2014 only specifies a test method to determine if toys and children's products contain phthalates. Rather, countries have established their own technical regulations. The TBT states that technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective. CPSC's rule would not be a barrier to trade because it will apply equally to both domestic manufacturers and importers. We also note that the TBT recognizes that protection of human health or safety is a legitimate objective.

G. Description of the Final Rule

The text of the final rule is the same as the proposed rule with one exception. For clarity, we have added language from section 108(c) of the CPSIA (as amended by Pub. L. 112–28) regarding the application of the rule. This addition does not change the substance of the rule because the statutory provision applies regardless of whether it is stated in the rule. Section 108(c) of the CPSIA states that the permanent and interim phthalate prohibitions, and any phthalates rule the Commission issues under section 108(b)(3) of the CPSIA, ''shall apply to any plasticized component part of a children's toy or child care article or any other component part of a children's toy or child care article that is made of other materials that may contain phthalates.'' 15 U.S.C. 2057c(c).

The Commission received comments on various aspects of the substance of the proposed rule. These comments and responses to them are summarized throughout this document. More detailed comment summaries and responses are at Tab B of staff's briefing package.

Section 1307.1—Scope and Application

Section 1307.1 describes the actions that the rule prohibits. 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

Section 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 rule text restates them for convenience. We did not receive comments on these definitions, which re-state statutory definitions.

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

Section 1307.3(a) states the products the rule prohibits. For convenience, this section provides both the items that are subject to the CPSIA's existing permanent prohibition and the items that are subject to prohibition under the 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, both statutory and regulatory.

Paragraph (a) sets out the CPSIA's existing permanent prohibition which 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 was established by section 108(a) of the CPSIA. This statutory prohibition is not affected by the rule, but is merely restated in the regulatory text.

Paragraph (b) 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 DINP, DIBP, DPENP, DHEXP, and 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 and presented the Commission with a report of its findings and recommendations. After reviewing the CHAP's report, the most recent exposure data, and public comments, the Commission is finalizing this rule in accordance with section 108(b)(3) of the CPSIA.

For the reasons explained in this preamble, the Commission concludes that prohibiting children's toys and child care articles that contain concentrations of 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. 15 U.S.C. 2057c(b)(1). Section 1307.3(b) changes the scope of regulation of DINP from the current interim scope of ''any children's toy that can be placed in a child's mouth'' [86] (and child care articles) to include all children's toys. Based on the recommendations in the CHAP report, the Commission is not continuing the interim prohibitions on DIDP and DNOP.

Additionally, § 1307.3(b) prohibits children's toys and child care articles

[86] 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.''

containing four phthalates that are not currently subject to restrictions under the CPSIA: DIBP, DPENP, DEXP, and DCHP. For the reasons explained previously, the Commission concludes that prohibiting children's toys and child care articles containing concentrations of more than 0.1 percent of DIBP, DPENP, DEXP, or DCHP is necessary to protect the health of children.

The final rule adds paragraph (c) to § 1307.3 to clarify the application of the rule. Section 108(c), as amended by Public Law 112–28 (August 12, 2011), addresses the application of the Commission's phthalates rule. For convenience and clarity, we are restating that statutory provision in § 1307.3 (c).

H. 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 proposed an effective date of 180 days after publication of the final rule in the **Federal Register**. The final rule provides a 180-day effective date. As discussed in the NPR and in section V. of this preamble, the Commission expects that this rule will have a minimal impact on manufacturers, and that changes to testing procedures to include children's toys and child care articles containing the four additional prohibited phthalates would require minimal effort by testing laboratories. 79 FR 78339. In accordance with the CPSIA, restrictions on the use of certain phthalates in children's toys and child care articles are currently in effect. This rule does not affect the permanent prohibition on children's toys and child care articles containing more than 0.1 percent of DEHP, BBP, and DBP. The CPSIA's interim prohibition currently applies to children's toys that can be placed in a child's mouth and child care articles containing DINP. Thus, with regard to DINP, the impact from the rule would be only on children's toys that cannot be placed in a child's mouth. CPSC expects that a relatively small percentage of children's toys that cannot be placed in a child's mouth would need to be reformulated to remove DINP. Because the four additional phthalates (DIBP, DPENP, DHEXP, and DCHP) are not widely used in children's toys and child care articles, few manufacturers will need to reformulate products to comply with this aspect of the rule. Regarding third party testing, testing laboratories are already testing children's toys and child care articles for the permanently prohibited phthalates and are testing children's toys that can be placed in a child's mouth and child care articles for DINP. Testing laboratories can expand their procedures to include the four additional phthalates with minimal effort. CPSC received a few comments, summarized below, concerning the effective date.

Comment: Effective date. Two commenters stated that the Commission should set an effective date of at least 1 year from finalizing the rule. They asserted that DIDP and DINP are difficult to differentiate through testing, and that if the interim prohibition concerning DIDP was lifted while DINP continues to be restricted, laboratories would need additional time to address the technical testing difficulties. Another commenter urged the Commission to shorten the proposed 180-day effective date based on the minimal impact CPSC anticipates to ''ensure that there is no gap in the protections from DINP.'' Another commenter asked for clarification that the rule would not be retroactive (back to 2011). (Comment 5.11).

Response: CPSC acknowledges that differentiating DINP and DIDP may be difficult. However, laboratories can differentiate DINP and DIDP using currently available equipment and methods. Manufacturers can maintain current formulations while they address any perceived challenges differentiating DINP and DIDP. As explained above, CPSC expects that the rule will require minimal changes for manufacturers and testing laboratories. Therefore 180 days from publication in the **Federal Register** should be sufficient time for the rule to take effect. We see no need to shorten the effective date. The interim prohibition established by section 108(b)(1) remains in effect until this rule becomes effective. We confirm that the rule is prospective and will apply to products manufactured and imported on or after the effective date. As mentioned, however, the interim prohibition remains in place until the final rule takes effect.

V. Regulatory Flexibility Act

A. Certification

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 Administrative Procedure Act 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. 5 U.S.C. 603 and 605. Small entities include small businesses, small organizations, and small governmental jurisdictions. The Commission certified in the NPR that this rule will not have a significant impact on a substantial number of small entities pursuant to section 605(b) of the RFA, 5 U.S.C. 605(b) in the NPR. 79 FR 78324, 78339–41. Some comments expressed general concerns about the economic impact of the proposed rule, but none provided information or evidence that the rule would have a significant impact on a substantial number of small entities. Summaries of these comments and CPSC's responses are provided below. More detailed summaries and responses are in Tab B of the staff's briefing package. None of the comments received by the Commission changes the basis for the certification, nor has Commission staff received any other information that would require a change or revision the Commission's previous analysis of the impact of the rule on small entities. Therefore, the certification of no significant impact on a substantial number of small entities is still appropriate.

As explained in greater detail in the NPR, the certification is based on CPSC's determination that:

(1) Few, if any, manufacturers would need to alter their formulations to comply with the rule because:

- Children's toys that can be placed in a child's mouth and child care articles containing DINP have been prohibited since 2009. Thus, no manufacturer would have to reformulate any products in these categories.
- Only children's toys that cannot be placed in a child's mouth (no dimension of the toy is less than 5 cm) containing DINP would have to be reformulated. Thus, only a small subset of children's toys that cannot be placed in a child's mouth would be affected by the rule.
- DIBP, DPENP, DHEXP, and DCHP are not widely used in children's toys and child care articles. Therefore, relatively few manufacturers would have to reformulate products to eliminate these phthalates due to the rule.

(2) The rule would have a small marginal impact on the cost of third party testing because:

- All children's toys and child care articles are already subject to third party testing for DEHP, DBP, and BBP.
- Currently, children's toys that can be placed in a child's mouth and child care articles must also be tested for the presence of DINP.
- Laboratory equipment and methods are already in place for testing the prohibited phthalates, therefore the additional cost of testing for DIBP,

DPENP, DHEXP, and DCHP would be very low.

• Identification and quantification protocols for prohibited phthalates would need minimal modification to include DIBP, DPENP, DHEXP, and DCHP because each of these phthalates can be isolated at unique elution times by gas chromatography. Thus, the additional cost of analysis would be very low.

• The additional cost of laboratory materials would be very low. Chemical standards for testing would be required for the four additional phthalates, but the standards for DNOP and DIDP would no longer be required. Therefore, the number of chemical standards needed would increase by two which CPSC expects would increase the cost of third party testing for phthalates by less than 35 cents per test, which is relatively small compared to current cost of phthalate testing (approximately $300 per product or component part).

B. Comments Concerning Impact on Small Business

Comment: Testing costs. Two commenters agreed with CPSC that the rule will have a small impact on testing costs. One commenter asked for CPSC to clarify how testing of technical mixtures of DINP and DIDP would be performed, noting that when DINP is detected in a sample, additional analytical steps are needed (at additional cost) to determine if the DINP is present as a 'pure' chemical or if the DINP is part of a technical mixture. Some commenters asked the Commission to take action to reduce testing costs. (Comment 9.1).

Response: For the reasons explained above, CPSC expects that the additional burden associated with the rule is small, with no significant impact on a substantial number of small entities. Regarding testing of mixtures of DINP and DIDP, the restriction on DINP applies whether DINP is in the product intentionally or unintentionally. Thus, laboratories will not need to undertake any additional effort to determine the source of DINP found in a children's toy or child care article. Regarding steps to reduce testing burdens, the Commission has recently issued determinations that will lower testing costs for some children's toys and child care article manufacturers. 82 FR 41163 (August 30, 2017). The determinations rule went into effect on September 29, 2017.

Comment: Costs and benefits of NPR. Regarding the NPR's determination that the proposed rule's economic impact would be minimal, one commenter stated CPSC had not considered the effect on consumers or the possibility that smaller manufacturers would be burdened by the rule in the future, ''which offers no demonstrated public health benefits in exchange for even 'minimal' costs.'' The commenter asserted that the rule would take a ''safe and useful chemical'' away from consumers. (Comment 9.4).

Response: Because CPSC followed the rulemaking requirements stated in section 108 of the CPSIA, which differ from rulemaking requirements under the CPSA and the FHSA, CPSC did not prepare a regulatory analysis of the costs and benefits of the rule. However, as discussed above, CPSC did conduct an analysis of the impact of the proposed rule on small entities. The commenter did not explain how future small manufacturers would be burdened. For the reasons explained above and in the NPR, CPSC expects the costs for small businesses subject to this rule would be small.

VI. 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). The final rule for 16 CFR part 1307, ''*Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates,*'' is 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 the permanent and interim prohibitions state in 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). In this same issue of the **Federal Register** the Commission is publishing a notice of proposed rulemaking that would update the existing NOR for the phthalate-containing products prohibited by this final rule.

VII. Paperwork Reduction Act

The final 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.

VIII. 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.'' 15 U.S.C. 2057c(f). This provision indicates that the preemptive effect of section 26(a) of the CPSA will apply to the final rule.

IX. 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.

X. List of References

This section provides a list of the documents referenced in this preamble and in the staff's briefing package.

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List of Subjects in 16 CFR Part 1307

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

■ For the reasons discussed in the preamble, the Commission amends title 16 of the Code of Federal Regulations by adding part 1307 to read as follows:

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

Sec.

Authority: Sec. 108, Pub. L. 110–314, 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, sec. 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), and dicyclohexly phthalate (DCHP) is prohibited.

(c) In accordance with section 108(c) of the CPSIA, the restrictions stated in paragraphs (a) and (b) of this section apply to any plasticized component part of a children's toy or child care article or any other component part of a children's toy or child care article that is made of other materials that may contain phthalates.

Alberta E. Mills,

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

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