United States
Consumer Product Safety Commission

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Memorandum

TO: The Commission
Alberta E. Mills, Secretary

DATE: November 9, 2022

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SUBJECT: Staff Responses to Request for Comments on Final Rule: 16 CFR Part 1307 "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates"

I. Background

Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) established permanent and interim prohibitions on the sale of children's toys and child care articles containing specific phthalates. The CPSIA also directed the CPSC to convene a Chronic Hazard Advisory Panel (CHAP) to study the effects on children's health from 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 should be prohibited in addition to those already permanently prohibited. Section 108 of the CPSIA required the Commission to promulgate a final rule after receiving the final CHAP report.

On October 27, 2017, the Commission published the final rule required by section 108 of the CPSIA in the *Federal Register* with an effective date of April 25, 2018. (82 FR 49938). The final rule made permanent one of the three interim prohibitions of specified phthalates in section 108 of the CPSIA and expanded the scope of covered products to which the interim prohibitions applied, from children's toys that can be placed in a child's mouth and child care articles, to all children's toys and child care articles. The scope of

covered products that included all toys and child care articles was consistent with the existing, permanent phthalates prohibitions in the CPSIA. The final rule prohibits any children's toys and child care articles that contain concentrations of more than 0.1 percent of specified phthalates, including diisononyl phthalate (DINP).

In December 2017, the Texas Association of Manufacturers, and others, petitioned the U.S. Court of Appeals for the Fifth Circuit ("the court") to review the CPSC's final phthalates rule. In March 2021, the court remanded the rule to the CPSC to address two procedural defects found by the court. The court held, in particular, that the final rule had failed to: (1) provide adequate notice and comment regarding a change in the primary justification from the proposed rule to the final rule; and (2) consider the costs and benefits of continuing the interim prohibition on DINP. While the court remanded the rule back to the Commission, it did not vacate the final rule, and thus the rule remains in effect.

In March 2022, the Commission published a Request for Comments (RFC) in the *Federal Register* (87 FR 16635, March 24, 2022) in response to the court's remand. The notice sought public comment on the justification for the final rule, and on a staff analysis of the costs and benefits of continuing the interim prohibition on DINP. The notice provided a link to staff's cost-benefit analysis (CBA) for the public to review. CPSC received four public comments (excluding duplicates). The commenters were:

- the American Chemistry Council (ACC),
- a group response from the Natural Resources Defense Council, the Environmental Justice Health Alliance for Chemical Policy Reform, Public Citizen, Coming Clean, Earthjustice, the Campaign for Healthier Solutions, and Breast Cancer Prevention Partners (NRDC et al.), and
- two individuals (Maranda and Harding).

The RFC noted that "Only comments submitted regarding the rationale for the final rule and/or the cost-benefit analysis of continuing the DINP interim prohibition will be considered." The purpose of the *Federal Register* notice was to address the procedural deficiencies in the final rule identified by the court in its remand. Most of the issues raised by commenters on the scientific analysis performed by the CHAP and CPSC staff justification for the final rule were out of scope for the RFC, because while they suggested using different data sources, they did not comment on the rationale used to justify the final rule, or they repeated comments that were previously submitted on the proposed rule and considered and addressed at that time. Similarly, the comments on the staff CBA brought up information that staff had included in the CBA, or suggested that the CBA should have considered issues other than costs of compliance or benefits to consumers, such as the cost to foreign companies that deliberately violate the rule. Two of the four comments were largely supportive of the rule (Harding and NRDC et al),

and of the staff analysis. Two of the four comments (Maranda and ACC) were critical of the rule and of the staff analysis but did not present new data or information that were in the scope of the RFC.

This document provides staff's responses to the comments received. Comments on the final rule's rationale are discussed first, followed by comments on the staff's CBA, followed by out-of-scope comments. Based on the issues raised by the comments, and the scope of the court's remand, CPSC staff assesses no action is necessary to revise the final rule. Staff recommends publishing a *Federal Register* notice providing the public with access to the staff responses to the comments, and confirming the final rule.

II. Issues Raised by Comments

A. Issues Regarding Data Justification for Final Rule

The court found that, "The Commission must allow industry to comment and consider the new justification for the Final Rule."[1] This reference to the new justification generally refers to the fact that there was a change in the percentage of the population with a Hazard Index (HI) greater than one in some of the data analyzed in the proposed rule versus the data used in the justification for the final rule.

Summary of Staff Response to Comments on Data Justification for Final Rule

The justification for the proposed rule was based, in part, on the CHAP's finding that about 10 percent of pregnant women and 5 percent of infants had an HI greater than one (CHAP 2014) [2], which exceeds the acceptable daily intake. However, CPSC did not specify that either 10 percent or 5 percent (or any other particular percentage) was a regulatory threshold or primary rationale. Rather, the justification was that a portion of each population exceeded the acceptable risk. In the years between the CHAP's 2014 report and when the final rule was issued in 2017, additional data showed that phthalate exposures in women of reproductive age (WORA) had declined in the United States. Updated information on infants and pregnant women was not available, but it is likely that their exposures also declined. However, because some WORA still had HIs greater than one, exceeding the acceptable daily intake, CPSC concluded that phthalate exposures and risks still failed to satisfy 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." 15 U.S.C. 2057c(b)(3)(A).

The decline in phthalate exposures evident since the CHAP's analysis may be due to one or more of several related reasons, including:

[1] Texas Association of Manufacturers et al. vs. U.S. Consumer Product Safety Commission, 989 F.3d 368, 389-390 (5th Cir. 2021).

[2] For full citations of documents referenced (in parentheses), please see list of references at the end of this document.

(1) The impact of the statutory prohibition on phthalates in children's products in the United States that this regulation made permanent,[3] as well as similar regulations in Europe [4] and Canada;[5]

(2) Voluntary actions by manufacturers to remove phthalates from children's products "intended to be mouthed," including teethers and rattlers in 1999 (CPSC 2002, p. 307);

(3) Voluntary actions by manufacturers to remove phthalates from flooring materials that began in Europe as early as 2009 and in North America beginning as early as 2010 (Tarkett 2022; Weaver 2012), with a phase-out by most major retailers beginning in 2015 (SaferChemicals 2019); and

(4) General awareness among manufacturers and the public that certain phthalates may lead to adverse health effects.

The fact that exposures and risks have declined since the CHAP's analysis does not justify removing existing mandatory or voluntary limits on phthalate use, because removing those limits would remove a protection that likely is contributing to the decline, and may lead to increased exposures and risks. Without CPSC's regulation, consumers would have to rely on State-level regulations and enforcement of those regulations. As discussed in the CBA, some States have more stringent thresholds for phthalate content in toys and child care articles than the CPSC regulation, but most States have no restrictions on phthalate content in consumer products.

The court directed the Commission to request comment regarding a change in the primary justification from the proposed rule to the final rule, that is, the change in the percentage of the population with HI greater than one. However, the court did not disrupt the scientific analysis presented by the CHAP or the staff analysis. To the contrary, the court specified in the remand decision that "We are not free to second-guess the Commission's determinations as to statistical methods and scientific data." (989 F.3d at 389.) The court thus did not remand the rule because it found the justification deficient, but rather because it found that CPSC had not provided an opportunity for public comment on the justification for the final rule. Most of the public comments did not directly address the issue regarding the changed justification. Instead, commenters reiterated previous comments on the technical details of the CHAP's and staff's analyses. To that extent, most of the comments are not responsive

[3] CPSC (2014) Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates. Federal Register 79(249):78324-78343. December 30, 2014.
[4] (Directive 76/769/EEC, 2005/84/EC, Annex I [XXa]); Commission Regulation (EC) No 552/2009; REACH Annex XVII ent. 51/52, 2015).
[5] https://www.canlii.org/en/ca/laws/regu/sor-2010-298/latest/sor-2010-298.html; https://canadagazette.gc.ca/rp-pr/p2/2016/2016-07-13/html/sor-dors188-eng.html.

to the 2022 RFC directed by the court. The comments related to the court remand are discussed in this section, while the out of scope comments on various issues are discussed in section II.C.

Topic: Whether the Data Justify that the Rule is Necessary to Provide a Reasonable Certainty of No Harm to Children, Pregnant Women, or Other Susceptible Individuals with an Adequate Margin of Safety

Comment: The Natural Resources Defense Council and other organizations (NRDC et al.) commented that CPSC's rationale for making the interim DINP prohibition permanent was well-supported. They noted that biomonitoring data from the CDC's National Health and Nutrition Examination Survey (NHANES) from 2013-2014 showed that women in the actual population were exposed to phthalate levels that could result in adverse effects in their male offspring. They noted that this supports CPSC's conclusion that continuing the DINP prohibition was necessary to "ensure a reasonable uncertainty of no harm with an adequate margin of safety."

Response: CPSC staff agrees that the percentages of the pregnant women, infants, or WORA, as estimated by the CHAP using NHANES data from 2005/2006 (CHAP 2014) and by the staff using NHANES data from 2013/2014 (CPSC 2017a), [6] were sufficiently high that the DINP prohibition is necessary to ensure a "reasonable certainty of no harm" *and* include an "adequate margin of safety," as required by the CPSIA. Note that the phrase "ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals *with* an adequate margin of safety" (emphasis added) has two parts. Staff understands this to mean that BOTH conditions must be satisfied to meet the statutory standard specified in the CPSIA section 108.

Topic: New Data Analysis

Comment: NRDC et al. commented that CPSC should not evaluate any new exposure data at this point, because the court remanded the rule to correct procedural issues, not to question the underlying science or examine new data obtained after the final rule was issued in 2017.

Response: CPSC staff agrees that new exposure data obtained after the final rule was issued are not relevant to the court's remand. However, staff notes that the apparent decline in exposures since the CHAP's report is likely due to a combination of regulations in the United States and elsewhere, as well as State level regulations and

[6] There is a significant time lag between NHANES sample collection and when the samples are analyzed and results are released to the public. For example, the results from samples collected in 2013/2014 were not available until 2016.

voluntary actions by manufacturers. Removing any restrictions could result in increased exposures to DINP and other phthalates.

Topic: Whether the Data Support the Rule

Comment: The American Chemistry Council (ACC) commented that, initially, CPSC used the 95th percentile single point estimate approach, and that in 2017, CPSC released an analysis of new data, which demonstrated a decline in phthalate exposures, and a decline in the percentage of WORA with HI>1, such that the 95th percentile HI did not exceed 1. An individual (Maranda) commented that, given the decline in phthalate exposures and risk, there is not enough evidence to support the phthalates regulation.

Response: The ACC comment is similar to comments that ACC submitted on the proposed rule (CPSC 2017c; pp. 324-326).[7] The justification for the proposed rule was based, in part, on the CHAP's finding that about 10 percent of pregnant women and 5 percent of infants had a Hazard Index (HI) greater than one (CHAP 2014), which exceeds the acceptable daily intake. CPSC staff did not specify that either 10 percent or 5 percent was a regulatory threshold. Rather, the justification was that a portion of each population was exposed at a level that exceeded the acceptable risk. In the years between when the CHAP's 2014 report (CHAP 2014) was published and when the final rule was issued in 2017, exposures to WORA declined in the United States (CPSC 2017b). Updated information on infants and pregnant women was not available, but it is likely that their exposures also declined. However, some WORA still had HIs greater than one, exceeding the acceptable daily intake, and staff therefore concluded that phthalate exposures and risks still failed to satisfy the statutory requirement "…to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals *with*[8] an adequate margin of safety." 15 U.S.C. 2057c(b)(3)(A).

Topic: Whether New Data Published After the Final Rule Undermines the Rule

Comment: ACC commented that the most recent CDC National Health and Nutrition Examination Survey (NHANES) data (2017/2018) indicate that there are no individuals with HI>1, including pregnant women, WORA, and male infants 36 months of age. Therefore, ACC concluded that there is no evidence to maintain the prohibition on DINP.

[7] See TAB B of the Final Rule briefing package, Responses to Public Comments, sections 3.2 to 3.3.
[8] Emphasis added.

Response: This comment is similar to comments that ACC submitted on the proposed rule regarding NHANES data sets published after the CHAP analysis. (CPSC 2017c; pp. 324-326).

CPSC staff notes that the NHANES data from 2017/2018 included only 14 pregnant women and 50 three-year-old males (as compared to 130 pregnant women representing 5.3 million pregnant women in 2005/2006 NHANES, as well as over 340 pregnant women and over 290 infants in the Study for Future Families (SFF), that were included in the data used in the CHAP's analyses) (CHAP 2014; p. 39). Given the small numbers of pregnant women and male infants in the 2017/2018 sample, the 2017/2018 NHANES data likely do not provide a statistically meaningful analysis of exposures in those two subpopulations as represented in the national population. Therefore, ACC's analysis of the 2017/2018 data set primarily applies to WORA. While WORA are viewed as surrogates for pregnant women, there are physiological differences between pregnant women and WORA (CPSC 2015, p. 8). There may be small differences in exposure, especially in more highly-exposed individuals (CPSC 2015, p. 9). However, CPSC has not identified any statistically significant differences between exposures in pregnant women and WORA (CPSC 2015, p. 10). The NHANES data also include exposures in the general population.

In any event, the decline in phthalate exposures is irrelevant to the court's remand. As noted above, DINP and phthalate exposures have declined in recent years, likely for several reasons, including: (1) the impact of the statutory prohibition on phthalates in children's products in the United States that CPSC's regulation made permanent, [9] as well as similar regulations in Europe [10] and Canada; [11] (2) voluntary actions by manufacturers to remove phthalates from children's products "intended to be mouthed" in 1999 (CPSC 2002, p. 307); (3) voluntary actions by manufacturers to remove phthalates from flooring materials in Europe as early as 2009 and in North America as early as 2010 (Tarkett, Weaver), with a phase-out by most major retailers beginning in 2015 (SaferChemicals 2019); and (4) General awareness among manufacturers and the public that certain phthalates may lead to adverse health effects. The fact the exposures and risks have declined for reasons like these does not justify removing existing mandatory or voluntary limits on phthalate use, because removing those limits may lead to increased exposures and risks. Rather, the new NHANES data suggest that regulations and voluntary actions are having the intended effect on phthalates

[9] CPSC (2014) Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates. Federal Register 79(249):78324-78343. December 30, 2014.
[10] (Directive 76/769/EEC, 2005/84/EC, Annex I [XXa]); Commission Regulation (EC) No 552/2009; REACH Annex XVII ent. 51/52, 2015).
[11] https://www.canlii.org/en/ca/laws/regu/sor-2010-298/latest/sor-2010-298.html; https://canadagazette.gc.ca/rp-pr/p2/2016/2016-07-13/html/sor-dors188-eng.html.

exposure. Looking at a relevant analogy, children's blood lead levels (BLLs) have declined significantly since lead was removed from gasoline, household paints, and children's products. Applying the reasoning from this comment, all lead regulations issued in the past 50 years should be withdrawn because median lead levels in children have dropped about 96 percent since the 1970s. CPSC staff strongly disagrees with ACC's reasoning.

Topic: The CHAP's Findings on DINP

Comment: An individual commenter (Maranda) stated that the CHAP proved that DINP is safe. This commenter further stated that if DINP is removed from products it could be replaced by poorly studied alternatives, which may lead to regrettable substitution.

Response: CPSC staff does not agree that DINP is "safe," nor did the CHAP find that DINP is "safe." Rather, as explained in detail by the CHAP and NASEM, DINP causes male reproductive development toxicity. The risk depends on exposure, which has decreased due to a combination of regulatory and voluntary actions (see earlier discussion in response to other comments). In the CHAP's review of phthalate alternatives, the CHAP found that none of the alternatives they reviewed was shown to be hazardous to consumers, although the CHAP noted some data gaps (CHAP 2014, pp. 121-142). CPSC staff continues to evaluate the potential risks from phthalate alternatives, as recommended by the CHAP.

The CHAP analyzed multiple phthalates and phthalate substitutes, and recommended that the interim prohibition end on DIDP and DnOP, because those plasticizers were found to be less hazardous than DINP and certain other phthalates. As discussed in the CBA and in the Final Rule briefing package, there are many effective and safer substitutes for DINP, and many plastics that do not use a phthalate plasticizer.

B. Issues Regarding Cost Benefit Analysis of Continuing the Interim Prohibition on DINP

All four comments on the RFC addressed the CBA. Many of the issues raised by commenters are not within the scope of the request for comments or instruction of the court, or commenters did not provide quantitative evidence to support their comments.

Comments on Costs Analysis

Topic: Estimating the Costs of Compliance

Comment: The ACC stated that CPSC "underestimated the likely economic costs of maintaining the ban by at least an order of magnitude," because the CBA did not consider the scenario of foreign suppliers of products containing DINP deliberately violating the rule or the associated costs of such violations (e.g., confiscation at the port of entry). The ACC further claimed that because companies would deliberately violate the rule, their costs of production for DINP alternatives must be much higher than CPSC estimated.

The NRDC et al. stated that CPSC overstated the costs of the rule because a CPSC staff study cited in the CBA found that only 30 percent of soft plastic toys sampled were made of plastics that might contain phthalates. Using that 30 percent estimate, the commenter suggested that the maximum cost of compliance is about $376,000 per year rather than $934,500.

An individual (Harding) commented generally in support of the cost analysis, noting that the CBA showed that the prohibition on DINP in toys and child care items "does not hurt the market for the phthalate DINP" and that the rule would protect vulnerable populations "without significant costs."

Response: None of the commenters on the cost analysis provided any new data on costs of compliance. Staff agrees with Harding that the costs are not significant; cost analysis in the CBA found that the incremental cost of replacing DINP with another plasticizer would be insignificant as a percentage of the retail price of a toy, if costs increased at all.

The appropriate scope of the cost analysis, as specified in the CBA (CPSC CBA, 2022), is the cost to toy and child care suppliers to comply with the rule, and the indirect impact on suppliers of DINP. CPSC does not predict the number of violators of a proposed rule or consider the cost of violations for industry (i.e., product interception and destruction) in its regulatory analysis. Violators may be subject to penalties under the CPSA or seizure of unlawfully imported products. In addition, while the CBA provided specific data on how many toys and child care articles CPSC import surveillance intercepted for violative phthalate content in 2017-2019, the ACC based their analysis of the extent of violative products on interception data from four Eastern European countries (Slovakia, the Czech Republic, Poland, and Hungary). The ACC stated that the referenced study showed those countries "found 45 percent of the tested products had impermissible levels of phthalates." The study ACC referenced found that 35 percent of the

intercepted items contained prohibited levels of phthalates.[12] Also, as cited in the study, about 4 percent of the violative items were destroyed by the relevant authorities, while ACC's analysis assumed all in-scope items would be confiscated. CPSC's data, as discussed in the CBA, shows that relatively few (about 106 per year on average for the 2017-2019) violative products for phthalates content were intercepted each year in the U.S., from a total import volume of more than $20 billion in value for toys alone per year. Thus, even if cost to deliberate violators were considered, it would be minimal using data provided in the CBA of violative items intercepted in the U.S.

The ACC did not provide any data on prices of toy or of DINP before or after the rule to support the claim of higher production costs for DINP substitutes, or for toys containing DINP substitutes supplied to the U.S. market. No comments from toy manufacturers, importers, or retailers were received. The CBA analyzed multiple private and government sources that found prices of DINP substitutes were in some cases lower than prices of DINP, and furthermore noted that any plasticizer is a small fraction of the total production cost of soft plastic toys and child care items.

Staff assesses that the NRDC et al. comment that the maximum cost of compliance is about $376,000 per year is an optimistic view of costs. The CBA stated that the cost of compliance "could be as high as $934,500," but "is likely much lower." While the lower NRDC et al. estimate could be accurate, it is not the *maximum* cost of compliance, as it is possible that more than 30 percent of toys and childcare items are made of flexible plastic in any given year, or that toy sales by unit volume in subsequent years are higher than estimated in the CBA.

Topic: Alternate "Baseline Scenarios"

Comment: ACC provided a description of alternate "baseline" scenarios that estimated the costs and benefits of the rule given its allegation that many suppliers currently do not comply with the rule (as evidenced by interceptions of violative products in Eastern Europe). ACC stated CPSC should have considered the costs to suppliers of illegally imported products with violative levels of DINP where such products were confiscated and destroyed. In addition, ACC commented that the rule reduced consumer utility by preventing consumers from purchasing toys with high DINP content that were prohibited from entering the United States, although they also noted there could be some reduction in health benefits from that scenario. ACC further claimed that OMB Circular A4 requires analysis of such alternate baselines, that CPSC's CBA failed to follow best practices, and that therefore the CBA was "foundationally deficient."

[12] Kobylecka, Anna "Collaboration of authorities in enforcement of chemical legislation", presented at the second conference on REACH, CLP and Biocides Enforcement, Brussels, 2018 https://ec.europa.eu/docsroom/documents/32505/attachments/1/translations/en/renditions/native

Response: The CBA analyzed the costs of compliance with the rule for all applicable suppliers, and the benefits to consumers and society from the reduced exposure to phthalates as a result of that compliance. This was the scope of analysis required by the court remand. It also reflects standard practice for cost benefit analyses of consumer product regulations, where the cost is the cost of compliance, and the benefits to the general public are the benefits of reduced harm from regulation. As described above, violators may be subject to penalties or product seizure as allowed by law.

CPSC is an independent agency, and therefore not required to follow OMB Circular A4, nor did the court's direction require an A4 analysis. Also, OMB Circular A4 does not require or recommend using multiple baselines; it requires that costs and benefits be evaluated against the same baseline. Specifically, OMB Circular A4 states "Benefits and costs are defined in comparison with a clearly stated alternative. This normally will be a 'no action' baseline: what the world will be like if the proposed rule is not adopted." This is what the CBA did – compare the costs and benefits of continuing the interim prohibition on DINP to the costs and benefits that would occur if the rule had ended the interim prohibition. The CBA provided a break-even analysis of the continuation of the prohibition on DINP content in toys and child care articles. OMB Circular A4 specifically recommends a break-even or "threshold" analysis in cases such as this one where the benefits are large but unquantified.

Regarding consumer utility, CPSC received no evidence or data from commenters representing consumers, toy suppliers, or child care article suppliers that the rule had raised the price of toys or childcare articles. CPSC received no comments from consumers stating that they wished to purchase such items with unrestricted DINP content. As discussed in the CBA, the Bureau of Labor Statistics (BLS) data shows that the price of toys steadily declined during the interim prohibition and continued to decline after the publication of the rule.

Topic: Costs to Foreign Businesses and Importers

Comment: The ACC, citing information from the CBA on the cost of reformulation for toy suppliers (Section V.b of the CBA, "Cost of Reformulation for Toy Suppliers"), stated that there is evidence that DINP is still cost-effective after the CPSIA interim prohibition because it is being used in toys sold in foreign countries. Therefore, foreign manufacturers would have additional costs to transition to compliance that are not sufficiently considered in the CBA. Additionally, the CBA does not consider costs to importers from intercepted products violating the rule.

Response: The ACC did not provide new information or data that CPSC could use to quantify the impacts on foreign businesses or importers, which CPSC discussed and analyzed in the CBA. The ACC did not provide any new information demonstrating an

ongoing cost of reformulation or that the cost was passed on to U.S. importers or consumers. (The cost to foreign manufacturers of reformulating products is not relevant to the cost of compliance with this rule unless that cost is passed on to U.S. importers or consumers, of which there is no evidence given the steadily declining price of toys in the U.S.) Nor did ACC provide data contrary to the CPSC staff analysis of multiple private sector and government data sources that showed some DINP substitutes are less costly than DINP.

The information from the CBA cited by the ACC also shows that toys with DINP are still being produced in foreign countries, so the rule is necessary to prevent those toys from entering the United States. The CBA also addressed this issue by stating that "there is some evidence that DINP is still a cost-effective plasticizer for use in mouthable children's toys and child care articles, based on its continued use in other countries, and on CPSC import surveillance." The CBA also noted that given the widespread regulatory restrictions on DINP content in toys in Europe and much of Asia, there are significant economies of scale for suppliers who can sell toys that meet the regulatory restrictions of multiple markets. As discussed in detail in the CBA, the great majority of imported toys in the U.S. are from China, which has a national mandatory standard restricting phthalate content (including DINP) in toys. China's national standard was published in 2014 and became effective in 2016,[13] before the CPSC final rule was published. Lastly, costs to importers that deliberately violate the phthalates rule, as well as violating the general third-party testing rule and the rule on certificates of compliance, are not costs of compliance.

Topic: The Impact of the DINP Prohibition on Markets For Other Consumer Products

Comment: The ACC commented that the rule created a "stigma" around DINP and thus had a negative impact on markets for other consumer goods, causing consumers to demand DINP-free flooring in particular. The NRDC et al. commented that the CBA "appropriately rejects" the notion that the interim prohibition on DINP or the final rule "meaningfully affected the general market transition away from phthalates to non-phthalate plasticizers."

Response: As discussed in the CBA (Section III of the CBA, "Regulation of DINP in U.S. and Foreign Countries"), consumer opposition to phthalates in consumer products other than toys began before the enactment of the CPSIA or the promulgation of the final rule and has continued after the final rule went into effect, as evidenced by recent state level legislation that applies to many products outside the scope of the CPSC jurisdiction. For example, voluntary restrictions on phthalates in mouthable toys began in multiple countries in the 1990s, before passage of the CPSIA. A major flooring

[13] https://hkmb.hktdc.com/en/1X09YBJK/hktdc-research/China-publishes-new-toy-safety-standards-GB6675-2014.

manufacturer announced plans to remove phthalates from their flooring products in Europe as early as 2009, and 2010 in North America, before the NPR was published. ACC provided no data to support the claim that the rule affected prices or production of other consumer goods. NRDC et al. provided no new information on consumer opposition to phthalates in other consumer products before or after the rule.

Topic: The Interim Prohibition's Effect on Toy Prices

Comment: The ACC noted that although the price of toys declined during the interim prohibition, the CPSC did not prove that the rule had no impact on the retail price of toys, because prices could have been even lower absent the rule. The ACC suggested that CPSC should have done more analysis of other inputs and production costs that might have impacted the price of toys for consumers. NRDC et al. generally expressed support for the analysis in the CBA that the continuation of the interim prohibition on DINP had no measurable impact on the prices for either DINP or for toys.

Response: The ACC did not provide any new data showing that other input or production costs had increased, or that any such changes had increased the price of toys to U.S. consumers. The CBA did not state that the rule had no impact on the price of toys, but rather that "the impact was minor, both in absolute terms and compared to other impacts on the market." No commenters representing consumers stated that the rule had raised the price of toys or child care articles, nor did any toy or child care article importers provide such comments.

Topic: The Interim Prohibition's Impact on Prices for Plasticizers

Comment: The ACC commented that there may have been additional negative effects on the market for phthalates and plasticizers that CPSC failed to analyze. As noted above, NRDC et al. generally expressed support for the analysis in the CBA that the continuation of the interim prohibition on DINP had no measurable impact on the prices for either DINP or for toys.

Response: Commenters did not provide any new information to support or counter the analysis in the CBA, which concluded there might be additional, non-quantifiable effects on the markets for both plasticizers and toys. As discussed in the CBA, toys and child care articles are not a significant portion of the market for plasticizers.

Topic: Consistency with State and Foreign Regulations

Comment: ACC and NRDC et al. both addressed CPSC's characterization of the consistency of the final rule with state and international regulations and laws. The ACC indicated that staff had overstated the consistency with other regulations, some of which only apply to mouthable toys, while NRDC et al. commented that the analysis was correct.

Response: Commenters did not provide new information on this subject, or how it would impact the costs. The CBA did not claim the final rule was identical to regulations in other states and countries, but rather that the rule was largely consistent. As specified in the CBA, some U.S. states have regulations with wider scope or that have more stringent restrictions on DINP content, while foreign country regulations generally apply only to mouthable toys.

Topic: Whether a Cost Benefit Analysis was Required

Comment: NRDC et al. stated that in their view, CPSC did not need to conduct a cost benefit analysis, because the CPSIA's requirement that the final rule provide a "reasonable certainty of no harm… with an adequate margin of safety" made no mention that cost should be a criteria. They further stated that the CBA, while unnecessary, did demonstrate that continuing the interim ban on DINP is necessary to ensure a reasonable certainty of no harm and is cost-beneficial as well.

Response: The court decision found that the agency is required to conduct a cost benefit analysis on continuing the interim prohibition on DINP in the final rule. The CBA demonstrated that the rule met the criteria of a "reasonable certainty of no harm… with an adequate margin of safety."

Comments on the Benefits Analysis

Topic: General Comments on Benefits Analysis

Comment: Two commenters, NRDC et al. and an individual (Harding), found the benefits analysis generally persuasive. NRDC et al. supported the CBA's conclusion that "the benefits of continuing the ban outweigh the costs, likely by an order of magnitude." NRDC et al. also noted that while they agreed with the conclusions of the CBA that the rule is "cost beneficial" and meets a break-even criteria, the legal requirement is only that the costs are "reasonably related to expected benefits," and that the CBA met both the standard of case law and the standard set by the court in the remand. Harding commented that "the rule would significantly decrease the exposure of medically vulnerable people like children and pregnant women to the dangerous phthalate without impacting the economy."

Two commenters, ACC and an individual (Maranda), generally found the benefits estimates unpersuasive. The ACC asserted that the benefits analysis was incorrect based on data outside of that provided in the CHAP, and ACC provided details of other data that should be considered. Specifically, ACC generally asserted that the benefits analysis was incorrect because the benefits analysis was based on what they assert to be incorrect scientific assumptions about the extent of the hazards to society from DINP, rather than an incorrect quantification of the monetary benefits to society of preventing cases of testicular dysgenesis syndrome (TDS). Maranda had concerns

about the safety of DINP substitutes, which staff discusses in Section II.A of this document.

Response: Staff addresses ACC's argument for using other data in detail in Section II.A, above. CPSC based its benefits analysis in the CBA on the avoided costs to society and to individuals for TDS caused by exposure to DINP. The CHAP focused on TDS as the toxicity endpoint for phthalate exposure. The CHAP's recommendation for the permanent prohibition on DINP was based on evidence of adverse effects of DINP on male reproductive development. CPSC focused its benefits analysis on the scientific findings from the CHAP. No commenters provided new data on benefits that was in scope, such as different data about the medical costs of treating TDS.

Topic: Data and Models

Comment: The ACC asserted that the CPSC should have used different data and models to estimate benefits. They stated that the CHAP report was "dated" and should not have been used as the basis for the CBA, nor should CPSC have used the 2013-14 NHANES data when more recent 2017-18 data is available. NRDC et al. pointed out that the court stated that the CPSC's decision to use the 2013-14 data, or to protect the 99th percentile from harm, are consistent with CPSC's mandate to "ensure a reasonable certainty of no harm."

Response: CPSC based its benefits estimate on the CHAP, as required by the CPSIA, and the data available at the time of the final rule. Data on phthalate exposure after the rule was published are not relevant to the analysis of harm caused by the phthalate exposure that the rule was intended to address, as explained in detail in the data justification portion of this memo and in the staff comment response. The CHAP focused on TDS as the toxicity endpoint for phthalate exposure, therefore the benefits analysis focused on the benefits of reducing the incidence of TDS. The CBA did discuss in detail other peer reviewed literature that quantified the harm of other toxicity endpoints for phthalate exposure. As noted by NRDC et al., the court remand did not order CPSC to consider different data, but rather to collect comments on the changed justification for the final rule. In addition, NHANES data collected since the promulgation of the rule, as cited by the ACC, shows less exposure to DINP, which demonstrates that the rule and voluntary actions to reduce phthalate content in other products have in fact been effective at reducing exposure as discussed in previous responses to comments.

Topic: Impacts Other than Reduction in Testicular Dysgenesis Syndrome

Comment: NRDC et al. agreed that reduced cases of TDS are the "essential benefit" of making the interim prohibition permanent, so it was appropriate that the CBA benefits section focuses on the estimated the cost per case of TDS and the costs to society of

TDS caused by phthalate exposure from mouthable children's toys and child care articles. However, they also agreed with staff analysis in the CBA that the quantified estimate of TDS cases likely understate the benefits of the rule, particularly where DINP exposure could contribute to cumulative harm from multiple other endocrine-disrupting chemicals.

The ACC noted that the CBA referenced various peer reviewed journal articles that discussed other potential adverse health effects, in addition to TDS, from phthalate exposure. They urged CPSC to quantify these effects, rather than allegedly just suggesting that these unquantified impacts provide further evidence that the benefits exceed the costs of the final rule.

An individual (Harding) found the exposure data used to justify the final rule "weak and insufficient," but also noted that "the rule would significantly decrease the exposure of medically vulnerable people like children and pregnant women to the dangerous phthalate without impacting the economy."

An individual (Maranda) stated that "because the evidence found is not substantial enough the Commission should reject this proposed rule." This commenter also stated that "the CHAP has proven DINP to be safe again and again."

Response: None of these comments presented new, in-scope data that was relevant to the estimated benefits of the final rule, such as a quantitative estimate of the contribution of DINP to the cumulative impact of other endocrine-disrupting chemicals, a quantitative estimate of other negative health impacts of DINP exposure, the number of cases of TDS caused by DINP exposure, or different estimates of the cost per case. Despite the statement by Maranda, the CHAP did not find DINP to be "safe." The CHAP found that DINP causes male reproductive development toxicity and specifically recommended that the interim prohibition on DINP be continued. The CBA discussed in detail other peer reviewed literature that presented evidence of other adverse health impacts of phthalate exposure, and the costs of those other adverse impacts. It also discussed the specific dollar value of that harm, as estimated by those studies. For example, the European Health and Environment Alliance report from 2014 (HEAL 2014) estimated annual health costs in the E.U. from endocrine-disrupting chemicals at approximately 31 billion Euros per year. The Attina study (Attina 2016) had a median estimate of the cost burden to U.S. society of endocrine-disrupting chemicals of $340 billion per year. The CBA cited multiple other peer reviewed studies with specific monetary estimates of the harm from phthalates and other endocrine-disrupting chemicals.

Topic: Environmental Justice

Comment: NRDC et al. commented that while the CBA discussed disparate impacts in the benefits analysis, CPSC should "explicitly consider the environmental justice benefits of addressing these historic and continuing disproportionate impacts when weighing the benefits and costs of continuing the DINP ban."

Response: The commenter did not provide additional data to analyze environmental justice benefits. As noted by the commenter, the CBA did discuss disparate impacts of exposure to phthalates, citing EPA analyses of NHANES data (EPA 2017). Subsequent EPA data analysis of data from 2013 to 2016[14], immediately prior to the publication of the final rule, continues to show these disparate impacts. As noted in the CBA, because phthalate exposures appear to be higher in infants, children, and women from Black, non-Hispanic populations, and populations in living poverty than in other groups, the rule may disproportionately benefit persons from vulnerable populations. As for environmental justice, the regulation offers the same protection from DINP exposure from new toys and child care articles to all consumers. There are no exceptions to the rule for small suppliers or for inexpensive items.

Staff is aware of many peer reviewed studies regarding the disparate exposure to phthalates (including James-Todd et al, 2017; Wenzel et al. 2018). These were not discussed in detail in the CBA because of the narrow scope of the court's remand, but staff notes that these studies are generally consistent with the EPA findings discussed above. For example, Wenzel's study of women in South Carolina found that "[s]ociodemographic characteristics associated with elevated phthalate concentrations included being unmarried, less educated, having a low income, high body mass index (BMI), and/or being African American." James-Todd found that pregnant non-Hispanic Black and Hispanic women in Massachusetts had higher levels of phthalate metabolites than white women.

Topic: Exposure to the Hazard Through Household Dust

Comment: The ACC commented that the primary exposure to DINP from toys and childcare articles may be from exposure to phthalates in household dust, rather than through mouthing, and that the CBA should have analyzed the benefits from reducing this type of exposure.

Response: The CBA based the analysis of benefits on the findings of the CHAP. The CHAP did analyze household dust as a source of phthalate exposure for women, infants, and children. It found that while dust contributed more than 10 percent of the exposure for some phthalates, particularly DEHP, DBP, and BBP,[15] dust was not a

[14] https://www.epa.gov/americaschildrenenvironment/biomonitoring-phthalates.
[15] DEHP: di(2-ethylhexyl) phthalate; DBP: dibutyl phthalate; BBP: butyl benzyl phthalate.

major source of DINP exposure. See Table E1-24 of the CHAP report (CHAP 2014). The ACC did not provide data on household dust contribution from DINP exposure. Regardless, this would not affect the benefit analysis that is based on number of TDS cases and cost per case because the exposure to DINP from toys and child care articles would have a negative impact on infants, children, and women of reproductive age, whether from mouthing or from dust.

C. Out of Scope Issues

The following points made by commenters are outside the scope of the court's remand and CPSC's request for public input. They categorically are not relevant to the questions at issue. Nevertheless, for the sake of completeness, CPSC staff briefly discusses them in this section.

Out of Scope Comments on Data Justification

Issue: PEAAs (Potency Estimates for Anti-Androgenicity)

Comment: ACC provided detailed comments on the PEAAs used by the CHAP, and alternatives to those PEAAs. ACC commented that CPSC's PEAAs have been superseded by "more robust" data, citing a 2017 National Academies report (NASEM 2017) on low-dose toxicity from endocrine active chemicals, which ACC describes as a "follow-up" study to the 2008 NRC report on phthalates cumulative risk (NRC 2008).

Response: The court directed the Commission to request comment regarding a change in the primary justification from the proposed rule to the final rule, that is, the change in the percentage of the population with a HI greater than 1. Therefore, the PEAAs raised by the commenter are out of scope. Furthermore, ACC did not raise the issue of NASEM's "more robust" data in their comments on the proposed rule.

However, CPSC staff reviewed the NASEM report (NASEM 2017), as explained in the staff's final rule briefing package (CPSC 2017c; pp. 197-204).[16] Staff notes that the NASEM report had a different purpose than the CHAP report, used different methods, and did not review all of the same studies. Finally, the NASEM report is not a "follow-up" to the 2008 National Research Council (NRC) report on phthalates cumulative risk (NRC 2008). The 2017 NASEM report had a different purpose and scope.

[16] See Briefing Memorandum, Part III.B, NAS Report on Endocrine Disruptors.

Topic: PEAAs Used

Comment: ACC included their own "PEAAs" in Table 2 of Attachment One of their comment. ACC's values are derived from the 2017 NASEM report on low-dose toxicity from endocrine disruptors at low doses (NASEM 2017). ACC's "PEAAs" are labeled "NAS $BMDL_5$," which means the NASEM's calculations of the lower statistical confidence limit of the benchmark dose (statistical estimate of the dose) at which fetal testosterone levels are reduced 5 percent compared to the control value.

Response: The "PEAAs" submitted by ACC are out of scope as they do not address the change in justification from the proposed rule to the final rule. CPSC staff notes the following regarding ACC's comment: First, the ACC values are roughly comparable to the CHAP's values and staff determined that using them instead of the CHAP's values would not have changed the findings that formed the basis of the CHAP's conclusions. Second, ACC ranked the "reliability" of some of the PEAAs. CPSC staff notes that ACC ranked their own PEAAs highest, but did not include the CHAP's Case 2, in which DINP is estimated to be more potent than in the other cases. CPSC staff also notes that the CHAP did not rank their cases; they simply stated that they used three different approaches and obtained roughly comparable results.

CPSC staff considers that the values derived from the NASEM report are not truly PEAAs as defined by the CHAP. The CHAP defined PEAAs as "potency estimates for anti-androgenicity;" that is, toxicological values that are specific for antiandrogenic or phthalate-syndrome endpoints. The CHAP's Cases 1 and 3 were based on all health endpoints associated with the phthalate syndrome, whereas the ACC values were based on a single endpoint: testosterone concentrations in blood. The CHAP's Case 2 was based on the rate of testosterone production, which is thought to be a key early step in the biological process leading to the phthalate syndrome. Thus, the CHAP selected endpoints that were representative of the phthalate syndrome. In contrast, the ACC values were based on testosterone concentrations, which represent only one characteristic of the phthalate syndrome. Furthermore, the rate of testosterone production, rather than testosterone concentrations, is considered a better biomarker for phthalate syndrome effects (Hannas et al. 2011b).

Finally, NASEM performed benchmark dose analysis of testosterone levels and other phthalate syndrome effects for the purpose of evaluating the dose response; that is, to study the magnitude of health effects associated with low doses (NASEM 2017; Appendix C). Although benchmark dose analysis is the first step in the process of deriving PEAAs or acceptable daily intakes, the NASEM committee did not complete the process by deriving PEAAs or acceptable daily intakes.

Topic: Use of Benchmark Doses to Develop PEAAs

Comment: ACC stated that the CHAP should have used the benchmark dose (BMD) approach to develop PEAAs, because the BMD approach is the US Environmental Protection Agency's (EPA) preferred approach to estimating more precise safe doses from a dose-response curve, compared to the traditional approach that is based on the no-observed-adverse-effect-level (NOAEL) or lowest-observed-adverse-effect level (LOAEL).

Response: This comment is out of scope because it does not address the data justification for the final rule, but rather repeats comments made on the data justification for the proposed rule. ACC previously commented on the CHAP's use of the NOAEL/LOAEL approach instead of the BMD approach (CPSC 2017c; TAB B, Staff Response to Public Comments, p. 72). Although there can be advantages to the BMD approach, NOAEL/LOAEL-based methods have been used for decades and are still used, such as when data are inadequate to support BMD methods. In practice, in many cases, there is little difference between the dose-response estimates from NOAEL/LOAEL and BMD approaches. Significant differences may occur in cases where a NOAEL has not been established, which does not apply to the CHAP's PEAAs (Barnes et al. 1995; Crump K.S. et al. 1997). In fact, the BMD method was originally developed to give results that are approximately equal to the already identified NOAEL (Barnes et al. 1995; Crump K.S. et al. 1997).

Topic: PEAA Case 2

Comment: ACC notes that the CHAP used three different approaches (Cases) to estimate PEAAs for the cumulative risk assessment data (ACC 1, pp 4-5). ACC criticized Case 2, which used a relative potency method, because it "ignored" the in vivo data used for Case 1 and Case 3.

Response: This comment is out of scope because it does not address the data justification for the final rule, but rather repeats comments made on the data justification for the proposed rule. Staff responded to similar comments in the briefing package on the final rule (CPSC 2014; TAB B. Staff Responses to Public Comments, pp. 64-81). Case 2 was based on a study in which several phthalates were tested side-by-side in the same assay. This side-by-side approach is ideal for comparing the relative potency of related chemicals. Previous studies tested phthalates separately in different laboratories using different protocols. Although the ACC comment described this study

as an in vitro assay, the research involved studying laboratory animals, and subsequently performing biochemical analyses, similar to many other phthalate studies.

Topic: Newer Data

Comment: ACC stated that the Commission established a precedent for reviewing the latest data when it reviewed newer NHANES data not available to the CHAP, so CPSC should have considered subsequent data published after the final rule, including particularly the 2017/18 NHANES data and the 2017 NAS report.

Response: This comment is out of scope because it suggests reviewing data that were not available at the time of the final rule, rather than commenting on the justification for the final rule. However, staff did review the 2017 NAS report, as discussed in this memo (see below) and in the final rule briefing package. As directed by the Commission, staff analyzed the most recent NHANES data available at the time (2013/14) and sought public comment before the Commission issued the final rule (82 FR 11348). That analysis did not set a precedent to review data from after promulgation of the final rule. Finally, the decline in phthalate levels since the final rule is not at issue in the court's remand. The court directed the Commission to request comment on the change in the justification from the proposed rule to the final rule, that is, the change in the percentage of the population with a HI greater than 1 between the data analyzed for the proposed rule and some of the data analyzed for the final rule.

Topic: Accuracy of Spot Sampling

Comment: ACC objected to the use of "spot sampling" to estimate human exposure to phthalates, and to estimates of the percentage of the population exceeding an HI of one.

Response: This comment is out of scope because it does not comment on the justification for the final rule or the CBA. Staff responded to similar comments on the proposed rule in the briefing package on the final rule (CPSC 2017. Staff Briefing Package). The NHANES biomonitoring study is a large, statistically-based sample to measure chemical exposures in the population. In this case, spot urine samples were collected at different sites and at various times of the day and days of the week. Because participants are randomly selected according to a probability-based complex, multistage sample design, the estimated daily intakes are representative of the U.S. population.

Topic: Whether Other Studies Show DINP Is Safe

Comment: ACC states that since 2017, several regulatory agencies (EC 2020, European Chemicals Agency 2018, NICNAS 2015) and a systematic review by the National Academy of Sciences (NASEM 2017) have concluded that DINP is not a reproductive/developmental toxicant in humans. ACC states that NASEM conclusions on reproductive/developmental studies on DINP do not align with those of the CPSC. ACC describes the National Academy of Sciences study as a "follow-up" to the 2008 study on phthalates by the National Research Council (NRC 2008)

Response: This comment is out of scope because it does not address the data justification for the final rule. ACC repeats the comments on the NASEM report that they made in response to the proposed rule. ACC did not mention the 2015 NICNAS report in their previous comments, although the report was available at the time the proposed rule was open for comments. The 2018 ECHA and 2020 EC reports are new assessments that were published after the final rule, but do not address the data justification for the proposed rule.

Nonetheless, the staff responds to this comment for the sake of completeness. CPSC staff disagrees with ACC's characterization of the four reports cited in their comment. The commenter's characterization that any of these reports found DINP to be "safe" is inaccurate. CPSC staff's understanding of the findings of each report cited is as follows:

1. Environment Canada (EC)

The report by Environment Canada (EC 2020a) concluded that current exposures to DINP in Canada – after Canada restricted DINP beginning in 2010 – are not a concern. The EC report cited by the commenter summarized a screening-level risk assessment of multiple phthalates (EC 2020b). It appears that EC focused on a few key studies in its review (Lee and Koo 2007; Li et al. 2015). In contrast, the CHAP (CHAP 2014, Appendix A, pp. 24-25) reviewed nine studies, including key publications (Gray et al. 2000; Hannas et al. 2011b). Nonetheless, EC concluded that DINP causes male reproductive effects (EC 2020b, p. 126) and has a similar mode of action to other medium chain phthalates, such as diisobutyl phthalate (DIBP) and di-(2-ethylhexyl) phthalate (DEHP). EC (2020b, p. 131) performed a cumulative risk assessment (CRA) that included DEHP, DIBP, dibutyl phthalate (DBP), butyl benzyl phthalate (BBP), and DINP, which are the same phthalates in the CHAP's CRA. Based on the CRA, EC (2020b, p. 133) concluded that current upper-bound exposures to phthalates

lead to HIs between 0.34 and 0.83, which are below the level of concern (HI>1). The contribution of DINP to the HI was small.

Overall, EC (2020b, p. 123) concluded that "…this conservative, lower-tiered HI approach indicated no concern for human health from potential cumulative exposure to medium-chain phthalates for the general Canadian population, specifically the more sensitive subpopulations (pregnant women/women of childbearing age, infants, and children), at current levels of exposure."

EC's (2020b) findings are consistent with current exposures in the U.S. They indicate that voluntary and mandatory actions have led to reduced exposures to phthalates and reduced the risk of adverse effects. CPSC staff notes that Canada has restrictions on DINP in toys and child care articles that can be placed in a child's mouth, which have been in place since 2010[17] and were updated in 2016. [18]

2. National Academies of Science, Engineering, and Medicine (NASEM)

The National Academies' report (NASEM 2017) did *not* conclude that DINP is not a reproductive/developmental toxicant in humans, as explained in CPSC staff's final rule briefing package (CPSC 2017c; pp. 197-204).[19] Also, the NASEM report is not a "follow-up" to the 2008 National Research Council (NRC) report on phthalates cumulative risk (NRC 2008), as inaccurately described by ACC. The 2017 NASEM report had a different purpose and scope.

The CHAP evaluated the potential health risks of phthalates, including DINP. NASEM focused on endocrine disruption at low doses. Thus, the CHAP reviewed all available data, while the NASEM committee selected only studies that included low-dose exposures. Furthermore, NASEM focused its attention on certain individual characteristics of the phthalate syndrome, including fetal testosterone, anogenital distance (AGD), and hypospadias. In contrast, the CHAP considered all endpoints associated with the phthalate syndrome which, by definition, is a group of signs or symptoms that, when considered together, characterize a disease. Phthalate symptom effects include reduced testosterone synthesis, reduced 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, and genital malformations (hypospadias)

[17] https://www.canlii.org/en/ca/laws/regu/sor-2010-298/latest/sor-2010-298.html
[18] https://canadagazette.gc.ca/rp-pr/p2/2016/2016-07-13/html/sor-dors188-eng.html
[19] See Briefing Memorandum, Part III.B, NAS Report on Endocrine Disruptors.

(Barlow and Foster 2003; Foster 2006; Foster et al. 2001; Gray et al. 2009; see also Howdeshell et al. 2017; Howdeshell et al. 2008). Thus, the CHAP did not evaluate the body of evidence for fetal testosterone or other specific effects individually, but considered the overall body of evidence for phthalate syndrome-related effects.

The NASEM committee concluded that DINP is a presumed human hazard based on effects on fetal testosterone (NASEM 2017, Table 3-30). The NASEM committee concluded that there is a high level of evidence that fetal exposure to DINP is associated with decreased fetal testosterone in male rats, but that there was an inadequate level of evidence to assess whether exposure to DINP is associated with decreased fetal testosterone in human studies. Having sufficient evidence in animals and limited evidence in humans leads to the conclusion that DINP is "probably toxic in humans" (CPSC, 1992). CPSC staff also note that a reduced rate of testosterone production (Hannas et al. 2011b) and concomitant reduced insl3 gene expression, rather than blood testosterone concentration, are considered the key events leading to the phthalates syndrome (Foster 2006; Howdeshell et al. 2017; Wilson et al. 2004).

The NASEM committee concluded that DINP is not classifiable as to whether it is a reproductive hazard to humans based on anogenital distance (AGD) (NASEM 2017, Table 3-29). The NASEM committee concluded that there is very low confidence in the body of evidence for DINP and AGD in animal studies, based on unexplained inconsistency and imprecision in the results of the four studies evaluated, and for a probably high risk of bias rating in key areas involving two of the four studies (NASEM 2017, pp. 88-89). The committee considered that only one of the four studies found evidence of decreased AGD (Boberg et al. 2011), and based on its evaluation, the committee concluded that there is an inadequate level of evidence to assess whether fetal exposure to DINP is associated with a decrease in AGD in male rats. The committee reported moderate confidence in the evidence for DINP and AGD in human studies, but determined that there was an inadequate level of evidence to assess whether fetal exposure to these phthalates is associated with a decrease in AGD in male infants. CPSC staff agree that there are inconsistencies in the data on AGD. The CHAP came to a different conclusion mainly because they considered *all* the available studies, not just the four studies in the NASEM report. Further, the NASEM committee did *not* evaluate DINP for hypospadias.

Overall, the conclusions of the NASEM committee are generally consistent with those of the CHAP. The differences can be explained by differences in methodology and different goals of the two studies.

3. European Chemical Agency (ECHA)

The European Chemicals Agency (ECHA) report (ECHA 2018, pp. 9-12) enumerated twelve studies showing the male developmental effects of DINP, including the studies reviewed by the CHAP (CHAP 2014, Appendix A, pp. 24-25). ECHA found evidence that perinatal exposure to DINP leads to effects associated with the phthalate syndrome in rats, including: increased incidence of areolas and malformations (Gray et al. 2000); decreased test weights with histological changes in adulthood (Masutomi et al. 2003); decreased testosterone levels (Borch et al. 2004; Clewell et al. 2013a); reduced AGD (Boberg et al. 2011; Lee et al. 2006); reduced rate of testis production (Borch et al. 2004; Hannas et al. 2011b); increased incidence of mononuclear gonocytes (Clewell et al. 2013a; Clewell et al. 2013b; Li et al. 2015); the presence of Leydig cell aggregates (Clewell et al. 2013b; Li et al. 2015); reduction of absolute weight of levator ani/bulbocavernosus muscles (LABC) (Clewell et al. 2013b); and reduced Insl and steroidogenesis mRNA levels (Li et al. 2015).

ECHA concluded that the incidence of malformations in Gray et al. 2000 was not statistically significant, despite Gray et al. reporting a probability of <0.04, which is generally considered statistically significant. ECHA also noted that the reduced AGD and increased nipple retention reported by Boberg et al. (2011) were not present at postnatal day 90, which Boberg et al. attributed to the lower potency of DINP, as compared to other phthalates. ECHA also cited alterations in female behavior (masculinization) and changes in hypothalamic gene expression (Boberg et al. 2011; Lee et al. 2006) listed effects on the behavior and brains of offspring following perinatal exposure. Although studies in humans are not conclusive, they are consistent with the results of animal studies.

ECHA concluded that “that there is clear evidence of an adverse effect on development.” ECHA also concluded that “the available data indicate toxicity of DINP to reproductive organs and on sperm count and sperm motility potentially leading to fertility effects (ECHA 2018, p. 20). However, ECHA received 52 public comments, including 27 from industry stakeholders (ECHA 2018, p. 21). After considering the public comments, ECHA changed its conclusions on reproductive and male developmental effects. ECHA concluded that “DINP warrants no classification for developmental toxicity (ECHA 2018, p. 32) and “that overall there is insufficient evidence for effects on sexual function and fertility in

experimental animals, citing 'inconsistencies in the data" and lack of information on histopathology in some studies (ECHA 2018, p. 27).

The conclusions in ECHA's final report are in stark contrast to the conclusions of the CHAP (CHAP 2014) and two reports from the National Academy of Sciences (NASEM 2017; NRC 2008). Furthermore, CPSC staff considers that there is ample evidence that phthalate syndrome effects persist into adulthood and lead to reduced, or absent, reproductive ability (Barlow et al. 2004; Foster 2006; Foster et al. 2001; Howdeshell et al. 2017). 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 (Hannas et al. 2011a). Although studies in humans are not conclusive, they are consistent with the results of animal studies. The CPSC staff disagrees with ECHA's final conclusions and concludes that the available data support the conclusions of the National Academy of Sciences and the CHAP that DINP causes developmental and reproductive effects in male animals.

4. Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)[20]

The Australian NICNAS report (2015) concluded that DINP affects reproductive development in males and identified a NOAEL of 50 mg/kg-d in animal studies. However, NICNAS also concluded that the effects appeared to be reversible and, therefore, additional information was needed to confirm the potential hazard. The NICNAS report did not identify specific studies to support their conclusions. In contrast, the CHAP report (CHAP 2014) and two reports from the National Academy of Sciences (NASEM 2017; NRC 2008) reached different conclusions. Furthermore, CPSC staff considers that there is ample evidence that phthalate syndrome effects persist into adulthood and lead to reduced, or absent, reproductive ability (Barlow et al. 2004; Foster 2006; Foster et al. 2001; Howdeshell et al. 2017). 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 (Hannas et al. 2011a).

[20] Now known as the Australian Industrial Chemicals Introduction Scheme (AICIS). AICIS is Australia's chemical regulatory agency.

EPA is in the process of evaluating the potential health risk from DINP exposure (EPA 2021). In addition, EPA issued a Supplemental Notice of Proposed Rulemaking in August 2022 (Docket EPA–HQ–TRI–2022–0262) to add DINP to the list of toxic chemicals subject to reporting requirements under the Emergency Planning and Community Right to Know Act (EPCRA) (EPA 2022). EPA based their action, in part, on evidence from recent peer reviewed research showing that DINP "is reasonably anticipated to cause cancer and serious or irreversible chronic health effects including developmental, kidney, and liver toxicity." A recent review article from the University of Illinois supports the conclusion that DINP causes male developmental toxicity (Yang et al. 2021). Finally, a recent study found that occupational exposure to DINP caused decreased testosterone levels in workers (Henrotin et al. 2020). Overall, CPSC staff concludes that DINP is antiandrogenic, causes the phthalate syndrome in animals, and probably causes related effects in humans.

Topic: Developmental effects of DINP

Comment: One commenter (ACC) cited a publication that reported no developmental effects of DINP (van den Driesche et al. 2020).

Response: This comment is out of scope because it does not specifically address the data justification for the final rule. The paper by van den Driesche et al. is one of numerous papers on the male developmental effects of DINP. ECHA (2018, pp. 9-12) reviewed 12 relevant reproductive developmental studies, all of which showed evidence of DINP's antiandrogenic effects. The CHAP (2014, Appendix A, pp. 24-25) reviewed nine animal studies, many of the same studies reviewed by ECHA, all of which showed evidence of DINP's antiandrogenic effects. Staff notes that not all of the antiandrogenic effects of DINP are expected to be seen in all studies. The phthalate syndrome is, by definition, a collection of health endpoints that, taken together, constitute the syndrome.

Potential reasons why van den Driesche et al. obtained different results from other studies include differences in study design, such as the number of animals/litters tested, the duration of exposure, and when measurements were made. These parameters differed from, for example, the study by Gray et al. (2000). Gray et al. looked at more animals and litters, and the duration of exposure was longer. In addition, van den Driesche focused on effects in adult offspring. Perinatal exposures 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.

Overall, the weight of evidence demonstrates that DINP causes permanent effects on male reproduction, including malformations, testicular pathology changes, and loss of reproductive function. Furthermore, the animal studies, which involve short term exposures, do not reflect the continuous exposures that occur in humans.

Out of Scope Comments on the CBA of Continuing the Interim Prohibition on DINP

Topic: Indirect Impact on Flooring Market

Comment: ACC commented that if CPSC rescinded the rule, manufacturers could sell flooring with phthalates in the United States. ACC assumed that this would lower costs for flooring, and that the lower cost would benefit manufacturers and consumers. These costs and benefits should have been considered in the CBA.

Response: This comment is out of scope of the request for comments and the court remand. Flooring is out of the scope of the phthalates rule. The final rule does not prevent manufacturers from selling flooring with phthalate content. However, the manufacturers that removed phthalates from flooring in the U.S. also sell phthalate-free flooring in other major markets, as well as phthalate-free vinyl inputs for other uses, in response to world-wide consumer demand for phthalate-free products. This was done voluntarily.

Topic: Toys Larger Than Mouthable Size

Comment: The ACC commented that the cost of the scope expansion between the interim prohibition and the final rule to include larger than mouthable toys and child care articles was substantial, and should have been considered in the CBA.

Response: This comment is outside the scope of the request for comments and the court remand. The scope of the CBA, as required by the court remand, was specifically the continuation of the interim prohibition in DINP in mouthable toys and child care articles. The impact of the final rule on the market for larger toys is out of scope, and not required by the court remand. However, the cost impact of the scope expansion was very small. This was explained in the briefing package for the notice of proposed rulemaking (NPR) as part of the supporting information for the certification of no significant impact on a substantial number of small businesses (CPSC 2014 NPR Staff Briefing Package, Tab A). A review of samples tested by CPSC staff at the time of the NPR indicated that of 725 samples that were found to contain phthalates through infrared screening techniques, fewer than five samples (or less than 1 percent) contained DINP but were also probably too large to be placed in a child's mouth (CPSC 2014 NPR Staff Briefing Package, Tab B). Child care articles of any size were in the

scope of both the interim prohibition and the final rule; the final rule did not change the scope for child care articles.

The Commission's decision to include toys larger than mouthable size in the scope of the proposed and final rules was consistent with the CHAP's recommendation, and consistent with the scope of the CPSIA's permanent prohibitions on other phthalates.

Topic: WTO Trade Barriers

Individual commenter Maranda commented that the World Trade Organization thinks "the removal of DINP may bring some unnecessary barriers."

Response: The commenter provided no information to substantiate this comment, and we received no such comments about DINP from the WTO, or any country through their WTO representative, on this rule. Article 2.2 of the WTO Agreement on Technical Barriers to Trade specifically includes national standards for "protection of human health or safety" as a "legitimate objective" for national technical regulations, unless, as specified in article 2.4, there are relevant international standards.[21] There is no ISO standard for an acceptable level of phthalates in toys and child care articles, although there is one for testing for phthalate content (ISO 8124-6). The consistency between the United States, EU, Canada, Japan, China, and other nations on restrictions on phthalates in children's toys and child care articles help remove, rather than create, trade barriers. A supplier can make a toy that is consistent with DINP restrictions in multiple countries, contributing to economies of scale. As discussed in detail in the CBA, the vast majority of imported toys in the U.S. are imported from China, which has a national mandatory standard restricting phthalate content in toys that became effective before the CPSC final rule was published.

III. Conclusions

The court's remand specified that "The Commission must allow industry to comment and consider the new justification for the Final Rule. Further, it must consider the costs of continuing Congress's interim prohibition on DINP to determine whether the rule is "reasonably necessary" to protect from harm." (989 F.3d at 389-390.) CPSC's March 2022 *Federal Register* notice addressed the remand by giving the public the opportunity to comment on the justification for the final rule, and by providing the opportunity to comment on the staff CBA of the continuation of the interim prohibition on DINP.

CPSC staff reviewed and considered the comments submitted to the RFC and responded to them accordingly. CPSC staff has even responded to comments that are not being given weight because they are out of scope. Based on staff's review and

[21] See https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm.

consideration of the issues raised in the comments submitted, CPSC staff recommends that further rulemaking to revise the final rule is unnecessary. CPSC staff recommends publishing a *Federal Register* notice providing the public with access to the staff's responses to the comments.

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