



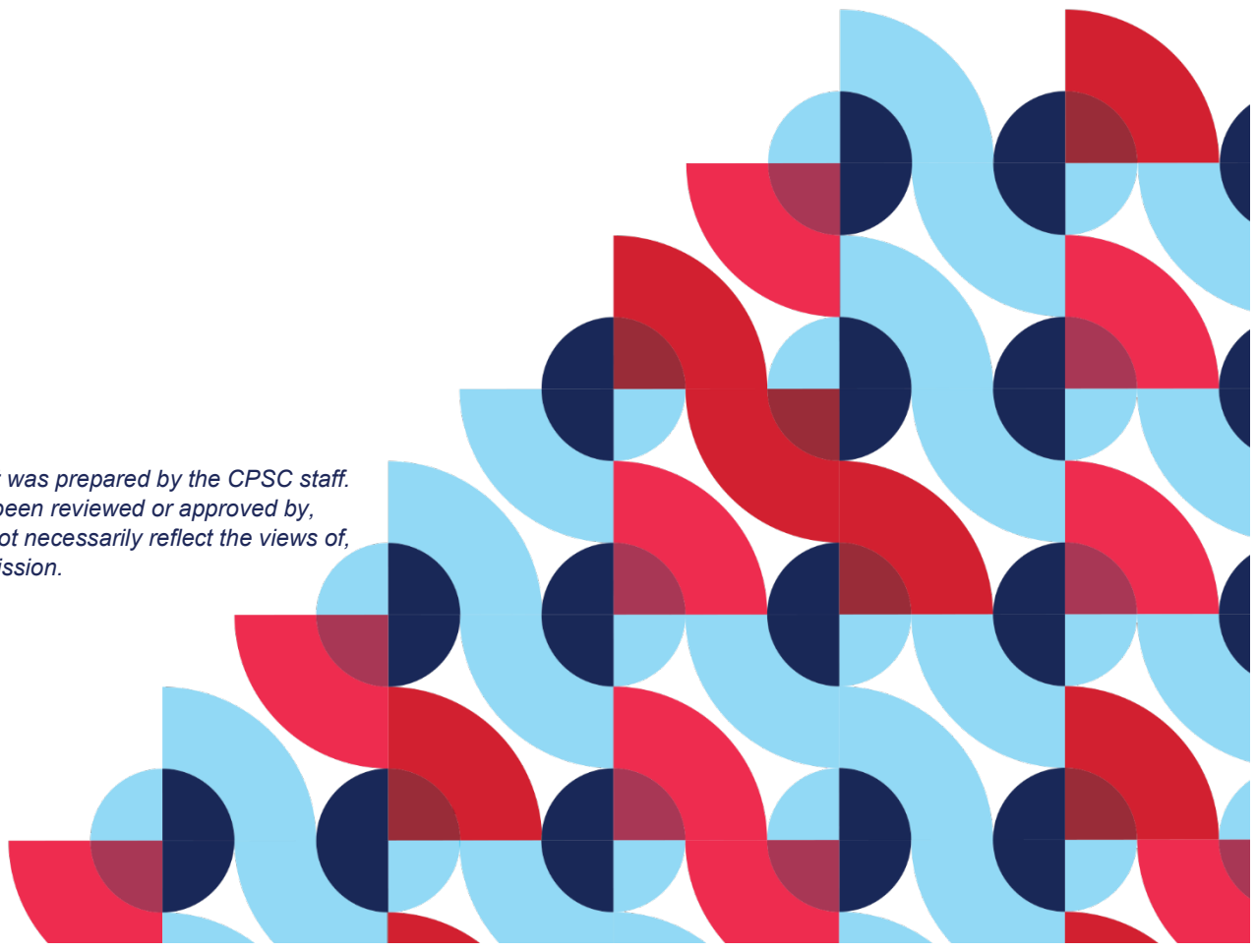
United States

Consumer Product Safety Commission

Cost-Benefit Analysis of Continuing the Interim DINP Prohibition in the Final Rule: 16 CFR Part 1307 “Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates”

February 2022

This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.



I. Executive Summary

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. The CPSIA also directed the U.S. Consumer Product Safety Commission (CPSC or Commission) 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 should be prohibited in addition to those already permanently prohibited. The CPSIA required the Commission to promulgate a final rule after receiving the final CHAP report.

The Commission published the final rule on October 27, 2017 (82 FR 49938) with an effective date of April 25, 2018. The final rule made the interim prohibition of diisononyl phthalate (DINP) permanent and expanded the scope of covered products to which the DINP prohibition 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 final rule prohibits the manufacture and sale of any children's toys and child care articles that contain concentrations of more than 0.1 percent of DINP. The final rule also prohibits concentrations of more than 0.1 percent of diisobutyl phthalate (DIBP), di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), and dicyclohexyl phthalate (DCHP) in children's toys and child care articles, and ended the interim prohibitions on diisodecyl phthalate (DIDP) and di-n-octyl phthalate (DNOP). The preambles to the notice of proposed rulemaking (NPR) and final rule provide more detailed discussions of the CHAP report and CPSC staff's technical analysis and findings in support of the rule. (*See* NPR 79 FR 78324, December 30, 2014, and final rule 82 FR 49938, October 27, 2017, as amended at 83 FR 34764, July 23, 2018.)

In December 2017, the Texas Association of Manufacturers, and others, petitioned the U.S. Court of Appeals for the Fifth Circuit to review the CPSC's final phthalates rule (82 FR 49938)¹. In March 2021, the court remanded the rule to the CPSC to reconsider its final rule, by addressing two procedural issues the court found. The appeals court held, among other things, that the final rule had failed to consider the costs of continuing Congress's interim prohibition on DINP and remanded the rule to the CPSC to consider the costs of continuing the interim DINP prohibition in the final rule to determine whether the rule is "reasonably necessary" to protect from harm². This document provides CPSC staff's analysis of the costs and benefits of continuing the interim prohibition on DINP, to address the deficiency the court found.

The final rule made permanent an interim prohibition on DINP content that had been in place since 2009 for mouthable toys and child care articles, and expanded the scope from mouthable toys to all toys. (This document uses CPSIA's definition of a "toy that can be placed in a child's mouth" as the definition of a "mouthable toy.") Thus, the cost of the final rule as compared to the alternative of ending the interim prohibition on DINP in mouthable toys and child care

¹ Texas Association of Manufacturers, et al., v. U.S. Consumer Product Safety Commission, 989 F.3d 368 (5th Cir. 2021)).

² CPSC's response to the other procedural issue found by the Court is included in the *Federal Register* notice seeking comment on this document.

articles is the cost of testing those products to demonstrate compliance, and the cost of any necessary reformulation to comply with the regulated level of DINP. CPSC staff estimates the total cost for DINP testing of products subject to the final rule is no more than \$934,000 annually to the entire U.S. toy and child care products industry as a whole, including both importers and manufacturers, plus an unknown small cost for replacing DINP with other plasticizers. The cost for related businesses, such as toy stores and general retailers, was zero because items had already been subject to the interim prohibition for almost 10 years. Therefore, retailers should not have had any mouthable toys or child care articles with prohibited DINP content in stock by the time the final rule became effective. The cost impact on related U.S. businesses, such as U.S. chemical manufacturers, was minimal, because most toys and child care articles sold in the United States were imported when the CPSIA passed, and also when the Commission promulgated the final rule. Toys were, and still are, a very small portion of the market for DINP worldwide, and the rule thus had no observable impact on the price of DINP. Finally, because the U.S. regulations were consistent with existing regulations on DINP in many other countries, consumer product suppliers to the world market had already phased out DINP in children's products intended for the North American and European markets, as well as smaller markets with similar regulatory restrictions.

Congress directed the Commission to determine whether to continue the interim prohibition as 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 extend the prohibition as "necessary to protect the health of children." 15 U.S.C. § 2057c(b)(3). After reviewing relevant studies, the CHAP found that certain phthalates including DINP (which the CHAP called active or anti-androgenic) cause adverse effects on the developing male reproductive tract. The CHAP focused on testicular dysgenesis syndrome (TDS) as the toxicity endpoint for phthalate exposure, which results in poor semen quality, reduced fertility, testicular cancer, cryptorchidism (undescended testes), and hypospadias (a type of male genital deformity). The essential benefit of this final rule is avoiding the costs to individuals and society of male reproductive harm caused by exposure to phthalates in children's toys and child care items. Staff analysis in this cost-benefit analysis (CBA) based on peer-reviewed literature estimates the direct, indirect, and quality of life costs per case of TDS to be between \$92,000 and \$300,000. Estimates from peer-reviewed literature of the total cost to society of harm from endocrine-disrupting chemicals, including phthalates, range from tens of millions to hundreds of billions of dollars per year, as discussed in detail in the Benefits section of this document. CPSC staff estimates that if the final rule prevents just 4 to 10 cases of TDS per year, which would represent less than 0.1 percent of TDS cases annually in the U.S., then the lowest estimate of benefits would outweigh the highest estimate of costs. In fact, the actual benefits of this rule associated with direct reduction of TDS are likely far greater than this "break-even" threshold. The rule also benefits the public by reducing additional health impacts where DINP exposure would contribute to cumulative harm from multiple endocrine-disrupting chemicals.

II. Market for DINP

a. DINP in Mouthable Children’s Toys and Child Care Articles

DINP is an ingredient used to make plastic soft and flexible. It is one of many competing phthalate and non-phthalate³ chemicals and chemical mixtures known as plasticizers. It is used in a variety of consumer and industrial products, particularly products made with polyvinyl chloride (PVC), including construction materials, electrical cords, vinyl flooring, automotive interiors and undercoating, tubing, food packaging, gloves, shoe soles, raincoats, and hoses. It can also be used in inks, adhesives, sealants, paints, pool liners, wall coverings, coated fabrics, and soft plastic dip coatings, such as the soft handle grips on metal hand tools. DINP was the most commonly used phthalate in flexible plastic toys in 2007, just before Congress passed the CPSIA⁴.

Section 108(g)((2)(B) of the CPSIA defines the phrase “toy that can be placed in a child’s mouth” as follows: “. . . 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.” This document uses the CPSIA’s definition of “toy that can be placed in a child’s mouth” as the definition of a “mouthable toy.” The CPSIA also defined a “child care article” as a “consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.”

Child care product suppliers voluntarily removed DINP from teething rings, bottle nipples, and pacifiers from the U.S. market beginning in 1999. By 2007, Canada and Europe had similar voluntary removals from the market of children’s products containing phthalates or mandatory prohibitions on phthalates in items small enough to be mouthed. Although phthalates were commonly used in mouthable soft plastic toys before passage of the CPSIA, toy manufacturing was not a major market sector for DINP, or any other plasticizer in the United States. Most toys sold in the United States in 2008, when Congress passed the CPSIA, were imported.⁵ When the Commission promulgated the final rule in 2017, most toys sold in the U.S. market (more than 92 percent by dollar value) were imported, primarily from China.⁶

Mouthable children’s toys and child care articles were not previously, and are not currently, a major market sector for DINP, or for other plasticizers, in the United States or in the world market. In 2010, CPSC staff estimated that children’s toys and child care articles were less than 1 percent of the total market for DINP, based in part on information provided by U.S. DINP manufacturers.⁷ This is consistent with more recent information from parties to a U.S.

³ The term “phthalate” is commonly used to refer to ortho-phthalates, including DINP. Consumer products marketed as “phthalate free” typically do not contain phthalate esters but may contain terephthalates such as DOTP.

⁴ Phthalate Esters Panel of the American Chemistry Council website from August 2007, via internet archive ([Phthalates Information Center -- Phthalates and Your Health -- Children’s Toys \(archive.org\)](https://www.webcitation.org/1011111111))

⁵ U.S. Department of Commerce, International Trade Administration, Global Patterns of U.S. Merchandise Trade, NAICS code 33993, Dolls, Toys, and Games, shows imports of more than \$22.8 billion in 2008, of which \$20.7 billion were from China.

⁶ U.S. Department of Commerce data, same NAICS code, shows imports of more than \$20.1 billion in 2017, of which \$17.7 billion were from China.

⁷ <https://cpsc.gov/s3fs-public/ToxicityReviewOfDINP.pdf>, pages 16 and 100 of the PDF file.

International Trade Commission investigation (ITC, 2017) of dioctyl terephthalate (DOTP) imports from South Korea. DOTP is a terephthalate plasticizer that is commonly used as a functional alternative to DINP. One of the parties characterized the toy manufacturing share of the DOTP market as “single digit on the low end.” Multiple private sector analyses of the global DINP market, as well as U.S. chemical industry market information provided to EPA in the recent request for a review of DINP’s status under the Toxic Substances Control Act, consistently list construction materials, electrical cords, vinyl flooring, automotive interiors and undercoating, tubing, and food packaging as the major uses. Data from 2015 reported to EPA by manufacturers and importers of DINP show that only two of 28 U.S. suppliers of DINP used it in children’s products that were not covered by the CPSIA prohibition.

The market for DINP is mostly affected by the prices of raw inputs, and production and demand in Asia, rather than the demand for toys and child care articles in the United States. Manufacturers’ contract prices for plasticizers are often indexed to the prices of the raw inputs. Declines in the prices for raw inputs from 2014 to 2016 coincided with the decline of U.S. prices for DOTP, DINP, and other plasticizers during the same period. In 2017, the U.S. ITC determined that the U.S. chemicals industry had been materially injured by imports from South Korea of DOTP, a competing substitute for DINP, which had been sold at less than fair value in the immediately prior years (ITC, 2017). These two factors of declining input prices and underpriced functional substitutes materially impacted the entire U.S. market for plasticizers. Comparatively, the interim ban on DINP in mouthable children’s toys and child care articles applied to items that represented less than 1 percent of the world market for DINP. CPSC staff analysis finds that the continuation of the ban on DINP in mouthable children’s toys and child care articles in the United States did not have a significant impact on price or on quantity produced, because the DINP market is largely affected by worldwide supply and demand for other uses, particularly construction, wiring, and automotive. Staff found no evidence that DINP prices or production were impacted by the CPSIA interim prohibition, or by the final rule. CPSC staff concludes that continuation of the final rule would not have a significant impact on prices or on quantity produced.

Other plasticizers in toys and child care articles that are not prohibited by CPSC’s final rule are available to provide a similar functionality to DINP, at a comparable price. There are also multiple plastics available that do not use a plasticizer, some of which are exempted from phthalate testing by CPSC’s rule 16 CFR part 1308 “Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics.” There are many plastics other than PVC available for toy manufacturing. The non-PVC plastics commonly used in toys include ABS, polystyrene, polypropylene, polyethylene, polyester, and silicone. Toy manufacturers thus have many cost-effective functional alternatives to PVC that provide utility like a PVC with DINP. In addition, some of these plastics do not require third party testing for phthalates, thereby reducing testing costs for manufacturers. Therefore, there is no evidence that the initial interim prohibition on DINP caused any significant loss of utility for mouthable toy and child care article manufacturers, or that the continuation of that prohibition in the final rule reduced utility for those manufacturers.

The price of DINP is now, and has been in the past, highly correlated with its raw inputs and the prices of competing phthalates and non-phthalate functional substitutes. In recent years, prices

for DINP, di-(2-ethylhexyl) phthalate (DEHP), and DOTP typically have been within 5 percent to 10 percent of each other, subject to temporary shipping and production issues for each plasticizer in various countries, and the specific terms of any individual contract. At times, DINP has been *more* expensive than the functional alternatives that provide similar utility for similar quantities. In the U.S. ITC case, all 19 respondents providing pricing information indicated that they used contracts or transaction-by-transaction negotiations; none reported using a set price list. As noted in the general market analysis below, Asia dominates the world market in both production and consumption of plasticizers, so the U.S. price is strongly influenced by both supply and demand issues outside the United States. Parties to the U.S. ITC dispute did not agree on whether DOTP prices were higher than DINP prices, or vice versa, during 2014-2016, although they generally agreed both prices were declining. In the decade between passage of the CPSIA and promulgation of the final rule, DINP production worldwide increased as DINP replaced DEHP in some applications. In the past several years, DINP has been replaced in some applications in the United States with a terephthalate substitute, often DOTP. In summary, the prohibition on DINP content in mouthable toys and child care articles did not impact the general market for plasticizers in the United States. It is extremely unlikely, given the number of functional substitutes available at comparable prices, and that the constant dollar price of children's toys in the United States has fallen in the past decade, that the prohibition on DINP caused increases, to any quantifiable extent, in materials costs for the mouthable children's toy and child care articles industry.

b. Market Factors – Additional General Background on Market for DINP and Plasticizers

CPSC staff research found that the market for DINP and other plasticizers is dominated by factors other than the mouthable children's toy and child care article market in the United States.

As noted, DINP is used in a variety of consumer and industrial products, particularly products made with polyvinyl chloride (PVC), including construction materials, electrical cords, vinyl flooring, automotive interiors and undercoating, tubing, food packaging, gloves, shoe soles, raincoats, and hoses. Other ortho-phthalates, terephthalates, and non-phthalate substitutes can also be used for these purposes; DINP is a commodity input material.⁸ The suitability of DINP, compared to other plasticizers, depends on the specific requirements of a particular application, such as durability or exposure to high temperatures, as well as cost. Global production of all plasticizers is estimated at more than 9 million metric tons annually, with phthalates accounting for more than half of that production, and DINP accounting for about 1.7 million metric tons. Asia, particularly China, accounts for about two-thirds of world production and consumption of plasticizers, while the U.S. accounts for less than 10 percent. According to the EPA Chemical Data Reporting tool, DINP consumption in the United States was roughly stable from 2011 to 2015, at between 200 and 500 million pounds of DINP imported or manufactured per year. This range is consistent with independent private sector estimates of U.S. consumption of DINP. U.S. DINP consumption grew at a steady, but modest rate, from 2008 to 2018, at roughly 2 percent per year.

⁸ As discussed in more detail later in this document, the CHAP analyzed the impacts of multiple common phthalate and non-phthalate substitutes. The CHAP did not find evidence that any of the non-phthalate substitutes had anti-androgenic health effects that would justify including them in the cumulative risk assessment or in the prohibition on use in mouthable children's toys and child care articles.

Exact prices for plasticizers depend on the specifics of an individual contract or individual transaction negotiations between buyers and sellers, including exchange rate adjustments, shipping costs, order size, forward pricing, and indexing, among other factors. Asia dominates the market in both production and consumption of plasticizers, so the U.S. price is influenced by demand and supply issues outside the United States. When the final rule was published in 2017, U.S. prices for DINP, DOTP, and several competing non-prohibited plasticizers ranged from about \$1,700 to \$2,000 per metric ton, subject to freight costs and the terms of any specific contract. Before COVID-related supply chain issues impacted prices in 2020 to 2021, phthalate prices, in general, had decreased slightly over the past 15 years, because production capacity worldwide has expanded and prices of raw materials have fallen. Demand growth for phthalates has been positive since the CPSIA passed, but slower than for non-phthalate plasticizers. Prices were unusually high and volatile in 2020 and 2021, due to COVID-19-related supply chain issues impacting demand and supply, which are slow to resolve.

Phthalates are still commonly used in many flexible plastic applications, including wire and cabling, hoses and other flexible piping, wall coverings, automotive interiors and undercoating, roofing, and other construction and industrial uses. DINP is often the phthalate of choice, based on price and performance, particularly for wiring and automotive uses. Demand for plasticizers depends upon demand in the construction, wiring, and automotive sectors, which are major market sectors for soft PVC, and thus, for plasticizers.

There have been voluntary shifts in uses of various plasticizers for economic reasons over the past 20 years, as manufacturers have chosen cheaper phthalates, plasticizers with different functional capacities, or phased out certain phthalates for products where consumers demand “phthalate free” products, independent of regulatory requirements. In 2010, before the NPR was published, a major flooring supplier announced that their products in the United States would be phthalate-free; other suppliers and major retailers followed their example. Thus, CPSC staff found no evidence that the final rule’s restriction on DINP in mouthable toys and child care articles in 2017 discouraged the use of phthalates in consumer products in general, other than in toys or child care articles. DINP world production has continued to grow. The voluntary phase-out of phthalates in general (not DINP specifically) in consumer products other than toys began before the NPR published, and in many countries, not just in the United States.

Regulatory restrictions on phthalates in other countries, as discussed in more detail later in this document, generally only apply to toys and children’s products. (As noted earlier, consumer products marketed as “phthalate free” typically do not contain phthalate esters but may contain terephthalates such as DOTP.) World consumption of phthalate plasticizers decreased from more than 85 percent of the world plasticizer market in 2008, to approximately 55 percent in 2020. The move to non-phthalate plasticizers began before the passage of the CPSIA and continued after promulgation of the final rule. CPSC staff found no evidence that continuing the interim prohibition on DINP in mouthable toys caused or accelerated this trend. In the 2017 US ITC DOTP investigation hearings, industry experts disagreed on the extent to which DINP and DOTP are functional substitutes. They also did not agree whether the regulatory status of DINP was an important factor in competition with DOTP, or whether the main deciding factor for plasticizer purchasers was price. They also disagreed if end users of DINP and DOTP

commonly switched between phthalate and non-phthalate plasticizers, or if once a switch was made away from phthalates in consumer products, that switch tended to be permanent.

In summary, the market for DINP in the United States is dominated by factors other than the continuation of the interim ban on DINP in mouthable toys, including, but not limited to, production and demand for plasticizers in Asia, prices of raw inputs, growth of the construction and automotive sectors, and the availability of suitable phthalate and non-phthalate functional substitutes. Pricing is subject to negotiated contracts that may include exchange rate adjustments, shipping costs, volume discounts, forward pricing, and indexing to raw materials prices. Regulatory restrictions in other countries are limited largely to toys and children's products, although consumer demand for "phthalate-free" products has led to voluntary substitution in some other consumer sectors. The availability of suitable substitutes is subject to supply and demand conditions in other countries for plasticizers and their raw materials, production capacities overseas, and freight shipping availability.

III. Regulation of DINP in U.S. and Foreign Countries

a. U.S. Regulation

In the United States, in addition to the CPSC regulation on DINP content in children's toys and child care articles, DINP is subject to regulation by EPA,⁹ FDA,¹⁰ and the U.S. Coast Guard.¹¹

Many U.S. states also have regulations requiring additional warning labels or reporting for articles containing DINP and other phthalates, and some restrict phthalate content. California passed a law in 2007, before the enactment of the CPSIA or the promulgation of the final rule, banning the manufacture, sale, and distribution of any toy or child care product that contained more than 0.1% of DEHP, dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). California's law also banned content of more than 0.1% of DINP, diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP) in toys and child care articles, if that product can be placed in the child's mouth.

Some state regulations have a lower content threshold for reporting or labeling than the CPSC final rule, and in some cases, provide a wider scope. For example, Vermont's threshold for reporting of DINP content in children's products is 50 ppm, which is 0.005 percent, as compared to 0.1 percent in the CPSC final rule, and Vermont's regulation covers all children's articles, including apparel, cosmetics, jewelry, and car seats.¹² Oregon has reporting requirements similar to Vermont's for phthalate content in children's products above 50 ppm, and it has a new law going into effect in 2022 prohibiting such content. Maine has current reporting requirements for chemicals of concern in children's products and a new law going into effect in 2022 prohibiting

⁹ The Toxic Substances Control Act (Pub. L. No. 94-469, 15 U.S.C. 53) requires manufacturers and importers to provide information to EPA every 4 years on certain chemicals they manufacture or import into the United States, including DINP.

¹⁰ See 21 CFR section 178.3740 "Plasticizers in polymeric substances."

¹¹ See 46 CFR part 150 "Compatibility of Cargoes."

¹² <https://www.healthvermont.gov/environment/children/chemicals-childrens-products>.

phthalates in food packaging.¹³ Washington state requires reporting of any DINP content, including below 100 ppm for individual phthalates if the total phthalate content is above 0.1 percent (1000 ppm), and prohibits the manufacturing or sale of children's products with a total phthalate content of more than 0.1 percent by weight.¹⁴ California currently requires warning labels¹⁵ on all products containing DINP, not just consumer or children's products, stating that the product may expose the consumer to a chemical that is known by the state of California to cause cancer.

b. Foreign Regulations

DINP is subject to regulatory restrictions in many other countries, primarily in toys and children's products. In the European Union (EU), DINP content is restricted to less than 0.1 percent in toys and child care articles that can be placed in the mouth. The threshold for the regulated amount in other countries is typically the same as in the CPSC regulation – 0.1 percent. However, the scope of prohibited products varies slightly between some countries. For example, in Canada, the prohibition applies to child care articles intended for children up to 4 years of age, and toys for children up to age 14, rather than 3 years and 12 years, respectively, in the CPSIA and in CPSC's final rule. But in general, the relative consistency in various countries' regulations creates economies of scale for toy and child care product manufacturers and suppliers that can manufacture and sell a product that is compliant with the phthalate content regulations for multiple countries.

Many prohibitions on phthalates in children's toys and child care articles in other countries were implemented before passage of the CPSIA. In the EU, DINP was temporarily banned from mouthable children's products in 1999, with a permanent prohibition beginning in 2005, while Brazil's regulatory prohibition on DINP and other phthalates in children's toys began in 2007. Japan prohibited DINP in toys intended to be mouthed beginning in 2002.

In summary, many other countries, and an increasing number of U.S. states, have regulatory restrictions on DINP content in children's products. The United States was neither the first, nor the most recent country to promulgate such restrictions. In the United States, California's regulation pre-dated the CPSIA. Although retailers and manufacturers have voluntarily removed phthalates in general (not specifically DINP) from other consumer products, the legal restrictions on DINP in consumer products in other countries are largely limited to children's products. The CPSC's final rule continuing the interim prohibition on DINP is consistent with phthalate regulations in other countries, allowing for economies of scale for suppliers of children's toys and child care articles to sell products to a world market. Given the economies of scale for products compliant with DINP regulatory restrictions in multiple countries, it would likely not be profitable for toy suppliers to the U.S. market to reintroduce DINP for toys manufactured in large volumes and sold worldwide, absent CPSC's final rule.

¹³ <https://www.maine.gov/dep/safechem/packaging/index.html>, and <https://www.maine.gov/dep/safechem/childrens-products/index.html>.

¹⁴ <https://ecology.wa.gov/Regulations-Permits/Reporting-requirements/Reporting-for-Childrens-Safe-Products-Act/Chemicals-of-high-concern-to-children>.

¹⁵ <https://www.p65warnings.ca.gov/fact-sheets/diisononyl-phthalate-dinp>.

IV- Cost Analysis from Final Rule Briefing Package Relevant to this Cost-Benefit Analysis

CPSC staff's analysis in support of the final rule included a brief analysis of the cost impact of the rule to comply with the Regulatory Flexibility Act (RFA) (5 U.S.C. §605) certification that the rule would have no significant impact on a substantial number of small businesses. This section summarizes the portions of that analysis that are relevant to this CBA.

The Commission certified under the RFA that the final rule would not have a significant impact on a substantial number of small entities. The analysis to support that certification¹⁶ assessed the impact of the final rule on small businesses. Benefits were not considered or analyzed as part of that certification. This CBA uses two findings from the RFA certification for the final rule.

These findings are:

- The cost of reformulation to manufacturers would be minimal because many functional alternatives to DINP exist and DINP had already been phased out of many toys and child care articles; and
- The increase in costs for testing products is minimal because manufacturers would still have to test for certain other prohibited phthalates in the absence of the rule and the additional cost of testing for DINP in the final rule is not significant, given the typical bundled pricing for testing phthalates.

CPSC staff's analysis found that the additional cost of testing toys for DINP would be minimal because these products already required phthalate testing for the three phthalates Congress permanently prohibited under the CPSIA. CPSC staff estimated the additional cost of testing to be roughly 35 cents per test, reflecting mostly the additional cost of the chemical standards required for the tests. Testing laboratories generally offer phthalate testing as a bundled price of about \$300 per test, with a range of \$125 to \$350, depending on volume discounts and where the tests are performed. The marginal cost of adding or subtracting one phthalate from the test bundle is minimal.

V. Cost Estimate of Continuing the Interim Prohibition on DINP as Compared to Ending the Interim Prohibition on DINP

This section considers the cost of continuing the interim prohibition on DINP, as compared to ending the interim prohibition on DINP. The total cost for compliance testing is estimated at no more than \$934,000 annually to the entire U.S. toy industry, including manufacturers and importers. There is also a small, but unquantified, cost impact for switching to a different plasticizer, or to a plastic that does not require a plasticizer. Any such reformulation costs were a one-time cost that would largely not be borne by U.S. businesses, because most toys (more than 92 percent) are imported. In addition, CPSC staff found no evidence that reformulation or testing costs raised the retail prices of toys for consumers, or the availability of any particular type of toy. U.S. Bureau of Labor Statistics data show prices of toys in the United States have declined steadily in constant dollars, seasonally adjusted, since 1997.

¹⁶ [https://www.cpsc.gov/s3fs-public/Final Rule - Phthalates - September 13 2017.pdf](https://www.cpsc.gov/s3fs-public/Final%20Rule%20-%20Phthalates%20-%20September%2013%202017.pdf), see Tab C "Impact on Small Business."

If the CPSC did not prohibit DINP content above 0.1 percent in mouthable children’s toys and child care articles, suppliers would no longer be required to third party test for DINP content to comply with the CPSC final rule. However, suppliers would still be required to test for the presence of other prohibited phthalates, including the three CPSIA statutorily-prohibited phthalates. Since the cost of testing for phthalates is commonly bundled, CPSC staff expects the incremental cost reduction of removing DINP from the testing requirements will be small. In addition, state prohibitions and labeling laws would still apply, and any suppliers selling to the U.S. market would have to test for and limit DINP content to comply with those laws. Therefore, even if the interim DINP prohibition had ended, children’s toy and child care article suppliers would likely have continued obligations to restrict DINP content to comply with state prohibitions and to sell to an international market.

a. Cost of Testing for Children’s Toy and Child Care Article Suppliers

The relevant cost of compliance with the final rule, compared to ending the interim prohibition on DINP, is the cost of testing for DINP in mouthable toys and child care articles that are subject to the final rule. However, not all mouthable toys and child care articles are made of plastic or require testing for phthalates. Recent estimates (Aurisano, 2021) indicate that roughly 55 percent of toys sold contain some type of plastic. CPSC staff’s analysis in 2010 found that only about 30 percent of sampled soft plastic toys and child care articles were made of PVC (Dreyfus, 2010). In addition, not all plastic toys or child care articles must be tested for phthalates. In February 2013, the Commission published a rule (codified at 16 CFR part 1199 “Children’s Toys and Child Care Articles Containing Phthalates: Guidance on Inaccessible Component Parts”), clarifying that the permanent and interim restrictions on phthalate content specified in the CPSIA do not apply to component parts of toys or child care articles that are inaccessible to the child through normal and reasonably foreseeable use and abuse of the product. In 2017, the Commission promulgated a rule specifying plastics that are not required to be third party tested for phthalates. That regulation is codified at 16 CFR part 1308, “Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics.” The exempted plastics are polyethylene (PE), polypropylene (PP), acrylonitrile butadiene styrene (ABS), general purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), high-impact polystyrene (HIPS), and super high-impact polystyrene (SHIPS). The Commission determined that certain plastics would not contain the phthalates prohibited in concentrations above 0.1 percent content in children’s toys and child care articles. Some of these plastics are particularly common in plastic toys; CPSC staff estimated in the Regulatory Flexibility Act (RFA) analysis for the determinations rule that polypropylene and high-density polyethylene are used in 38 percent and 25 percent, respectively, of injection-molded toys.

The potential cost of testing to demonstrate compliance with the phthalates final rule was substantially reduced by the rules that exempted inaccessible component parts and many plastics commonly used in toys from third party testing for phthalates. Additionally, any negative impacts on chemical companies selling plastics or plasticizers to toy manufacturers was likely mitigated by these two rules, which were promulgated in 2013 and 2017, which was after passage of the CPSIA, but before the phthalates final rule went into effect.

In 2017, when CPSC promulgated the final rule, the United States imported more than \$20.1 billion dolls, toys, and games, according to U.S. Census data. According to U.S. Census data,

U.S. manufacturing in the relevant NAICS¹⁷ category in 2017, was \$1.6 billion, which means imports represented 92.6 percent of the total \$21.7 billion market. Using Toy Association data, the average toy cost about \$10 in 2017.¹⁸ That would represent about 2.17 billion units. Assuming that about 55 percent of toys sold contain plastic (Aurisano, 2021), and about 25 percent of those are made of an exempt plastic (from the RFA analysis for the 2017 exempt plastics rule cited earlier), then roughly 41 percent of toys sold would need to be tested for phthalates, and specifically for DINP. If 41 percent of 2.17 billion units require reformulation and additional testing to comply with this rule, that is about 890 million toys per year. Assuming each model of toy sells 1,000 units,¹⁹ that is 890,000 models to test. At 35 cents per test,²⁰ and 3 samples per model, the annual cost for DINP testing to the entire U.S. toy industry could be as high as \$934,500. It is likely much lower, as CPSC staff analysis (Dreyfus, 2010) found that only about 30 percent of soft plastic toys were made of PVC. Also, as noted in this document, and as explained in more detail in the final rule briefing package, phthalate testing services are normally sold in a bundle of tests for various regulated phthalates, costing about \$300 for the bundle. If only the DINP interim prohibition were ended, while the prohibitions on other phthalates specified in the CPSIA were continued, the annual compliance testing cost for the entire U.S. toy industry might decline much less than \$934,000, if at all.

It is difficult to estimate the number of child care article suppliers impacted by the continuation of the interim ban on DINP in mouthable toys and child care articles, as consumer products “to facilitate sleep or the feeding of children age 3 and younger” might fit into a number of different NAICS categories, and are often sold by the same suppliers that sell toys. Many of these items are not made of soft plastic, but rather, are made of hard plastic, wood, fabric, or metal. Child care articles are similarly subject to the materials determinations rule for certain types of plastics, and the rule exempting inaccessible component parts. In addition, many of these items are manufactured in accordance with product-specific voluntary or mandatory standards that specifically include limits on phthalate content in accessible components. As with toys, most of these items are imported. It is unlikely that the compliance testing burden from child care articles intended for use by children age 3 or younger would add significantly to the estimated total cost of the continuation of the interim ban on DINP in mouthable toys and child care articles.

b. Cost of Reformulation for Toy Suppliers

Reformulation was a one-time cost incurred at the time of the CPSIA (and in response to restrictions in other countries), that was largely not borne directly by U.S. businesses because most toys (more than 92 percent) are imported. The cost of reformulation to use a different plasticizer than DINP was likely minimal. CPSC staff cannot estimate the precise cost with the

¹⁷ NAICS is the system used by federal statistical agencies to classify business establishments to collect, analyze, and publish statistical data. For more information, see: <https://www.census.gov/naics/>.

¹⁸ https://www.toyassociation.org/PressRoom2/News/2017_News/toy-industry-economic-impact-in-the-us-reaches-107-5-billion.aspx.

¹⁹ In the absence of specific data, CPSC staff made a conservative assumption of 1,000 units per toy model to avoid underestimating the cost of the DINP prohibition in mouthable toys and child care articles, particularly to smaller businesses. Economies of scale and volume discounts listed on toy supplier wholesale sites suggest the average number of units per model may be much greater, which would tend to reduce the total testing cost to the industry as a whole.

²⁰ The cost of testing is from the analysis done to support the RFA certification in the final rule.

available information, although given that the plasticizer market is highly competitive, the incremental cost of substituting another plasticizer would have been minimal.

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. In countries that do not prohibit phthalates in children’s toys, or limit the scope of the prohibition, DEHP or DIDP, rather than DINP, is often the most common phthalate used in children’s toys. However, DINP is often the second- or third-most common phthalate used in mouthable toys, which suggests it is a cost-effective material in children’s toys and child care articles, where allowed, but other plasticizers are used in those places as well. For example, researchers in New Zealand found that 28.6 percent of sampled toys contained DINP above 0.1 percent, and 40.8 percent had concentrations of above 0.1 percent of DIDP (Ashworth, 2018). Researchers in India found DEHP in 96 percent of sampled toys, and DINP and DIDP in 42 percent of toys (Johnson, 2011). DINP and other phthalates are still commonly used in larger toys sold in foreign markets that have a prohibition on phthalates only in mouthable toys. For example, in 2012, researchers in Japan, where phthalates have been prohibited in mouthable toys since 2002, found functional levels of DEHP in 42 percent and DINP in 25 percent of sampled “non-designated” toys, such as large balls and inflatable beach toys. (Abe, 2012). As Table 1 illustrates, CPSC regulators continue to intercept more than a hundred imported toys a year with phthalates that exceed regulated levels. European regulators similarly continue to intercept hundreds of imported toys each year with phthalates that exceed regulated levels in the European Union.

Table 1: Number of Samples with Phthalate Violations Intercepted by CPSC

FY 2017	FY 2018	FY 2019
108	98	113

U.S. states that have reporting requirements for DINP in children’s products at a lower concentration level than the prohibition in the final rule have hundreds of reported items listed in their state registries. Thus, although it cannot be quantified with the available information, the evidence suggests that DINP can be a less costly plasticizer option than the non-prohibited substitutes because it is still being used in toy manufacturing outside the United States. Thus, although the one-time impact to children’s product manufacturers of reformulation has been minimal on a per-item basis, it may not have been zero for foreign manufacturers selling to U.S. importers.

c. Costs to Large, Foreign and Peripherally Related Businesses

The scope of the CPSC staff economic analysis for the final rule was the analysis required by the RFA to support the certification that the rule would not have a significant impact on a substantial number of small U.S. entities. The economic analysis supporting the final rule did not consider cost impacts on large businesses, foreign businesses, or businesses of any size not directly involved in manufacturing or importing mouthable toys or child care articles. CPSC staff analysis finds the cost impact from the continuation of the interim prohibition on DINP in mouthable toys and child care articles to foreign, large, or peripherally involved businesses, such as chemical manufacturers and toy retailers, to be minimal.

Large and foreign toy and child care articles businesses faced the same or lesser impact as small businesses in this sector—few items need to be reformulated, and any testing cost increases would have been minimal. Due to economies of scale, larger toy and child care article suppliers typically have a lower cost per model for third party testing costs because they sell more units per model and can sometimes use component part testing to spread the testing costs across multiple models. DINP was typically an insignificant cost of production for toy manufacturers as a percentage of the retail price of the toy, and the incremental cost of replacing DINP with a different plasticizer should not have substantially raised input costs, if costs increased at all. Switching from one plasticizer to another, or to a material that did not require a plasticizer, should not have required new capital or equipment expenses for toy manufacturers. The CPSC materials determinations rule for plastics (16 CFR Part 1308 “Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics”) does not require phthalates testing for certain plastics that are commonly used in injection-molded plastic toys. Toy suppliers had already begun voluntarily to phase-out PVC from soft plastic toys before the NPR was published—CPSC staff analysis in 2010 found that only about 30 percent of soft plastic toys and child care articles tested were made of PVC (Dreyfus, 2010). By the time the final rule was published, due to the interim prohibition, DINP had not been allowed in mouthable toys and child care articles sold in the United States for nearly 10 years, so retailers would not have had any stock to sell down. Thus, the impact to retailers was zero for the continuation of the prohibition on DINP in mouthable toys and child care articles

Because of the interim prohibition, manufacturers of DINP had not been selling large volumes of DINP to manufacturers of children’s toys and child care articles, either in the United States or to manufacturers in other countries making items for export to the United States. Although the shift by mouthable toy and child care article manufacturers from DINP to other phthalates or non-phthalate plasticizers may have shifted plasticizer market share among large chemical suppliers, these shifts would have been very small because toys and child care articles were a very small share of end use for DINP, compared to other uses (*e.g.*, wiring insulation, construction, and automotive uses). When CPSC’s proposed rule published, DINP was competing with imported DOTP from South Korea that was being sold in the United States at less than fair market value, as determined by the U.S. International Trade Commission (ITC, 2017). If the DINP prohibition had been lifted, manufacturers of DINP could have witnessed increased sales of DINP to toy manufacturers, but toy manufacturing likely would have remained a tiny share of the total plasticizer market, particularly in the United States. Also, because the CPSC continuation of the interim ban on DINP in mouthable toys and child care articles was consistent with existing regulations in many other countries, consumer product suppliers to the world market had already phased out DINP in children’s products intended for the Canadian and European markets, as well as to smaller markets with similar regulatory restrictions.

d. Cost of Continuing the Interim Prohibition on DINP for Consumers

Although the prohibition of DINP may have slightly increased the cost of manufacturing children’s toys and child care articles, there is no evidence of such impact on the retail prices or availability of children’s toys or child care articles. The price differential between DINP and alternative plasticizers that provide similar functionality with similar quantities is typically a few

hundred dollars per metric ton (thus, a few cents per pound of plasticizer), often less than \$100. Moreover, the cost of any plasticizer would be a small fraction of the retail price of a toy, even in a toy like a novelty pencil eraser or a squishy bath toy, where the plasticizer might be more than 40 percent of the item by weight. Even for those toys, the *incremental* cost of using a more expensive plasticizer, rather than DINP, would be only a few cents per item, often less than 1 cent per item. A review of toy prices provides no evidence that the prohibition on DINP increased the retail prices of toys. U.S. Bureau of Labor Statistics data show prices of toys in the United States have declined steadily in constant dollars, seasonally adjusted, since 1997. In addition, the overall U.S. market for traditional toys (*i.e.*, not video games) declined slightly in constant dollar terms between 2007 and 2017. Overall, both prices and demand for the traditional types of toys, where soft plastic could represent a significant portion of the retail price or manufacturing cost, fell. There is also no evidence that soft plastic toys, such as bathing toys or action figures, were removed from the market due to the costs of testing or product reformulation. Such items are still widely available from a wide variety of suppliers. This does not mean that prohibition of DINP had no impact on the prices or supplies of children's toys or child care articles, but rather, that the impact was minor, both in absolute terms and compared to other impacts on the market.

e. Summary of Costs for Continuing the Interim Prohibition on DINP Compared to Ending the Interim Prohibition on DINP

The cost of the DINP prohibition to manufacturers of mouthable toy and child care articles is the difference between the costs they incur with the interim prohibition made permanent, and what their costs would have been if the interim prohibition on DINP were lifted. There is evidence that the manufacturing costs with the interim DINP prohibition in effect may be slightly higher for some items than they would be in the absence of a prohibition. However, CPSC staff research found no evidence that either testing or reformulation costs have impacted the prices or availability of mouthable toys and child care articles. The cost of reformulation was likely minimal, based on the similar cost of competing plasticizers, and the need for similar formulations to sell to other international markets. Competing plasticizers with similar functionality were and are readily available at a similar price, thus, ensuring that minimal utility was lost by mouthable toy manufacturers from continuing the interim prohibition on DINP. As for testing costs, the final rule required products to be tested for other permanently prohibited phthalates, and the additional testing costs per unit for DINP were minimal, about 35 cents per test, as part of a testing bundle for other phthalates, which is typically around \$300. The total cost for DINP testing of products subject to the final rule would be no more than \$934,000 annually to the entire U.S. toy industry as a whole, including both importers and manufacturers.

The direct impact on related businesses, such as toy stores and general retailers, was zero because items had already been subject to the interim prohibition for almost 10 years and non-phthalate substitutes for the prohibited substances are available to enable the production of commercially marketable toys. Therefore, retailers should not have had any mouthable toys or child care articles with prohibited DINP content in stock. The direct impact on related U.S. businesses, such as U.S. chemical manufacturers, was minimal, because most toys and child care articles sold in the United States were imported, when the CPSIA passed, and when the Commission promulgated the final rule. Finally, because the U.S. regulations were consistent with existing regulations on DINP in many other countries, consumer product suppliers to the

world market had already phased out DINP in children's products intended for the North American and European markets, as well as smaller markets with similar regulatory restrictions.

VI. Benefits of Continuing the Interim Prohibition on DINP

The intended outcome of the final rule regarding the interim prohibition on DINP, as mandated by the CPSIA, was the assurance of a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety. Section 108 of the CPSIA did not require CPSC to find that the benefits of the rule exceeded the costs, but rather, that the rule was needed to "ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety."

The chief benefit of continuing the interim prohibition on DINP is avoiding the costs to individuals and society of cases of testicular dysgenesis syndrome (TDS) caused by exposure to phthalates in mouthable children's toys and child care articles. This benefits section discusses in detail the costs per case and the costs to society, of TDS caused by phthalates, including DINP. The beneficial impact of continuing the interim prohibition on DINP that is addressed here is specifically the reduced harm from the reduced exposure to DINP in mouthable children's toys and child care articles.

Given the prevalence of mouthable children's toys with DINP content above 0.1 percent available in foreign markets, and the number of items intercepted by CPSC import surveillance each year, it is likely that if the final rule had lifted the prohibition on DINP, the exposure to DINP from mouthable children's toys and child care articles in the United States would increase, and the benefits, compared to continuing the interim ban, would be reduced. The Commission determined that lifting the interim prohibition on DINP would not "ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety." Although the exact benefits of continuing the prohibition on DINP cannot be quantified, CPSC staff estimates that the benefits exceed the estimated costs if 4 to 10 cases of TDS per year would be prevented by continuing the interim ban on DINP in mouthable toys and child care articles, which would represent far less than 0.1 percent of TDS cases. However, as discussed below, staff estimates that the likely number TDS cases actually prevented by continuation of the DINP ban is substantially higher than this.

The CHAP did not estimate etiological causality rates for TDS attributable to phthalate exposure, nor did CPSC staff in the briefing package for the final rule make such an estimate. Similarly, neither the CHAP nor subsequent staff analysis of NHANES data estimated how many women of reproductive age in the U.S. as a whole had a hazard index above 1.0. Thus, staff cannot estimate precisely how many cases are prevented by the rule. In the peer-reviewed literature discussed in more detail below, the lowest fraction of TDS cases attributed to exposure to endocrine-disrupting chemicals, including DINP, is 2 percent, with estimates as high as 40 percent. Based on the CHAP's exposure assessment, up to 29 percent of infants' potential DINP exposure is from toys and child care articles. Thus, the recommended prohibition on DINP

would address up to 29 percent of infants' exposure to anti-androgenic phthalates²¹, which represent a major category of endocrine-disrupting chemicals (Attina et al. 2016).

Two percent of TDS cases in the U.S. would represent hundreds of cases per year for cryptorchidism, hypospadias, and testicular cancer together. The number of infertility cases from specifically poor semen quality is more difficult to estimate, but would add to the total. Forty percent of TDS cases in the U.S. would represent more than 15,000 cases per year for cryptorchidism, hypospadias, and testicular cancer. Thus, the “break-even” threshold of this rule preventing 4 to 10 cases per year is a small fraction of the estimates in peer-reviewed literature of TDS cases attributable to endocrine-disrupting chemicals. Staff believes the prohibition of DINP is likely to prevent far more than 4 to 10 cases per year and that benefits of this rule likely exceed the costs by an order of magnitude.

a. Background to Benefits Estimates

The CHAP focused on TDS as the toxicity endpoint for phthalate exposure, which results in poor semen quality, reduced fertility, testicular cancer, cryptorchidism (undescended testes), and hypospadias (a type of male genital deformity). The CHAP did consider other toxicity endpoints for phthalate exposure, including other types of cancers, ADHD, and longer-term mortality impacts. However, the CHAP's recommendation for the permanent prohibition on DINP, and the justification for the final rule, was based on the adverse effects of DINP on male reproductive development. Given the strong evidence from peer-reviewed literature linking TDS to phthalate exposure, the CHAP recommended making the interim prohibition on DINP permanent. 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. 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.” The CHAP concluded that certain phthalates cause effects on the male reproductive system, and that these effects may occur from phthalate exposures at any life stage from the fetus through adulthood. The CHAP's conclusion is based primarily on studies in animals (CHAP 2014; pp. 13-14) and supported by epidemiological (human) studies (CHAP 2014, pp. 27-33, Appendix C). While adverse effects may occur at any life stage, the CHAP further concluded that the fetus is the most sensitive population, followed by neonates, children, and adults. Therefore, the CHAP derived toxicological values (potency estimates for anti-androgenicity) from animal studies involving prenatal exposures. The CHAP reasoned that a toxicological value that protects the most sensitive population (the fetus) will also protect infants, children, and other sensitive populations (CPSC 2017, TAB B, pp. 8-9 and 19). The practice of selecting the most protective endpoints and potency estimates is consistent with the statutory mandate to provide a reasonable certainty of no harm with an adequate margin of safety, and is also consistent with CPSC Chronic Hazard Guidelines (CPSC 2017, TAB B, p. 19).

The CHAP assessed exposure and risks for pregnant women (as a surrogate for the fetus) and infants, in part because these are the most sensitive populations, and also to satisfy the CPSIA's charge to “examine the likely levels of children's, pregnant women's, and others' exposure to

²¹ In the CHAP, Table E1-21 “Sources of phthalate ester exposure (percent of total exposure) for infants” shows that for infants, 12.8 percent of total DINP exposure is from toys, and 16.5 percent is from child care articles, for the population mean exposure.

phthalates . . .” CPSIA §108 (b)(2)(B)(iii). (CHAP 2014, p. 12). Prohibiting toys and child care articles containing more than 0.1 percent of certain phthalates would not directly reduce risks to pregnant women and their fetuses (CPSC 2017, TAB B, p. 20). However, other sensitive groups (i.e., infants, toddlers, and children who are more likely to be exposed through contact with toys and child care articles) are also considered in the CHAP’s analysis and recommendations. In addition, the CPSIA required the CHAP and the Commission to consider whether to prohibit toys and child care articles containing certain phthalates, not to prohibit products that directly affect pregnant women. CPSIA §108 (b)(2)(C).

The CHAP did not find that children’s toys and child care articles were the main or only source of DINP exposure for infants, children, and women of reproductive age, but rather, that the estimated exposure was sufficient that the prohibition was needed to ensure a reasonable certainty of no harm, which was the threshold for regulation set by Congress in section 108 of the CPSIA. Based primarily on studies in animals, there is empirical evidence that male fetuses, infants, and children are more sensitive to the reproductive tract effects of phthalates than adults. Other recent studies have reinforced and added detail to the concerns expressed in the CHAP report regarding phthalates, specifically DINP, in children’s toys and child care articles. A recent analysis of “chemicals of concern” in children’s toys (Aurisano, 2021) estimated that the average child in Western countries receives 18.3 kilograms of plastic toys per year. Given that some households have more than one child, the potential exposure from plastic toys in some households would be higher for both children and adults. Pregnant women in families with more than one child would be exposed to plastic toys from the younger children, thus exposing the fetus of subsequent children to phthalates. While adults do not typically mouth toys, exposure to phthalates can occur from handling toys and child care articles, from subsequent hand to mouth transfer. Mouthable toys manufactured and sold before the final rule went into effect, which could contain prohibited phthalates above the currently permitted levels, may still be in use.

The CHAP analyzed human biomonitoring data and potency estimates for anti-androgenicity to estimate exposures and cumulative risk assessments. CPSC staff analysis of National Health and Nutrition Examination Study (NHANES) data sets published since the CHAP analysis in the CHAP report have found that the exposure to DINP for women of reproductive age (WORA) is now greater than exposure to DEHP, BBP, DBP, or DIDP. CPSC staff analyzed NHANES data sets subsequent to the CHAP report from 2007/2008, 2009/2010, and 2011/2012, using the methodology from the CHAP, and published the results. Data from 2013/14 were added after they became available. For the cumulative risk assessment, the CHAP and subsequent CPSC staff analysis used a Hazard Index (HI) approach, which is widely used in cumulative risk assessments of chemical mixtures. Individuals with HIs greater than 1.0, a level that indicates adverse impacts may be expected, were observed in every NHANES data cycle analyzed. The exposure to various phthalates shifted over time, as DEHP exposure decreased, while DINP became the predominant source of exposure to phthalates for women of reproductive age.

The TDS harm alone was sufficient to justify the permanent prohibition on DINP in the final rule. However, the CHAP, and this cost-benefit analysis, likely underestimate the benefits of continuing the interim ban on DINP in mouthable toys and child care articles, by not quantifying the impact of other negative health impacts of phthalate exposure from children’s toys and child care articles, where the quantified extent of the impact was not as well documented at the time

the CHAP report was written. Recent peer-reviewed research (Engel, 2021) summarizes the current evidence of other toxic effects of phthalates on women of reproductive age, infants, and children. The CHAP, and this cost-benefit analysis, did not quantify the negative health impacts where the DINP exposure contributes to the cumulative harm from multiple endocrine-disrupting chemicals other than the specific phthalates analyzed by the CHAP. The CHAP did consider DINP's contribution to cumulative exposure from multiple phthalates analyzed by the CHAP.

The CHAP found that roughly 10 percent of pregnant women in the U.S. population have HI values that exceed 1.0, depending on which set of PEAAs (potency estimates for anti-androgenicity) was used. After publication of the NPR, CPSC staff analyzed NHANES data sets for WORA from 2007/08 through 2013/14. CPSC staff's analysis shows that the risk to WORA, as indicated by HI, has decreased since 2005/06, the data analyzed by the CHAP²², but that there were individuals with an HI greater than 1.0 in every year of data. In the 2013/14 data, out of a sample of 538 WORA, for PEEA Case 1, three WORA had an HI greater than 1.0; for PEEA Case 2, nine WORA had an HI greater than 1.0; and for PEEA Case 3, two WORA had an HI greater than 1.0. In percentage terms, 99.5 percent of WORA in the 2013/14 sample had an HI less than or equal to 1.0 when considering PEEA Case 1 and 99.6 percent when considering Case 3. For PEEA Case 2, an estimated 98.85 percent of WORA had an HI less than or equal to 1.0 in the same cycle. Thus, between 0.4 percent and 1.2 percent of WORA had an HI of greater than 1.0, using the most recent data set, and there were WORA with an HI greater than 1.0 in every exposure scenario.

The CHAP did not estimate etiological causality rates for TDS attributable to phthalate exposure, nor did CPSC staff in the briefing package for the final rule make such an estimate. Given that between 0.4 percent and 1.2 percent of the individuals in the study sample of 538 women had an HI greater than 1.0 in the 2013/14 data set, hundreds of thousands of individuals each year in the United States could be impacted by phthalate exposure, and the impacts of fetal exposure can persist into adulthood. Exposure during childhood can also impact infertility. The beneficial impact of continuing the interim prohibition on DINP is specifically the reduced harm from the reduced exposure to DINP in mouthable children's toys and child care articles.

b. Benefits Analysis that Provides a Quantitative and Qualitative Estimate of Averted Costs

It is possible to estimate the cost per case of TDS, but as noted, neither the CHAP, nor CPSC staff analysis to support the final rule, estimated how many cases of TDS would be prevented or reduced in severity because of the final rule. This section provides a range of estimates of cost per case of TDS, and qualitative comparison to conditions with similar disease burden.

The costs for a nonfatal injury or disease, both to the individual and to society, include direct medical costs of treatment; indirect costs, such as lost productivity from missing work to recover from surgery, or to care for a child recovering from surgery; and quality of life or intangible losses. A recent study in the United States of endocrine-disrupting chemicals (Attina, 2016) estimated the direct and indirect cost of cryptorchidism at \$8,300 per case, in 2010 dollars, testicular cancer at more than \$22,000 per case, and male infertility at \$10,400 per case, but the study did not provide an estimate for hypospadias. (Phthalates are one type of endocrine-

²² Following sample collection, it takes years to perform chemical analyses and quality control checks before the data are published.

disrupting chemicals.) A recent study conducted in Nordic countries estimating the burden on society of TDS caused by endocrine-disrupting chemicals (Olsson, 2014) estimated the net present value (NPV) discounted direct and indirect costs of testicular cancer at 4,240 EUR per case, which would be about \$5,100, using an exchange rate of \$1.20 per EUR, cryptorchidism at EUR 5474 per case (approx. \$6,600), hypospadias at 11,540 EUR per case (approx. \$13,850), and male infertility at 3,480 EUR per case (approx. \$4,175). These estimates reflect medical costs in the European Union; costs in the United States might be different or have more regional variation. U.S. Medicare estimates of the national average costs at a hospital outpatient center for “Repair of hypospadias complications (*i.e.*, fistula, stricture, diverticula); by closure, incision, or excision, simple: Code: 54340” total \$3,656, including the patient’s cost and Medicare’s cost. A more complicated “Repair of hypospadias cripple requiring extensive dissection Code: 54352” has an estimated cost of \$5,850. U.S. Department of Health and Human Services (HHS) data on hospitalization costs show a median cost of \$8,647 in 2014 for in-patient treatment of hypospadias, and \$9,578 for in-patient treatment of undescended testes. A recent study (Ward, 2020) estimates the direct cost to U.S. private insurers for hypospadias at \$5,431 per case, which is comparable to Medicare’s estimate. Another U.S. study from 2009 estimated the cost of repairing cryptorchidism at \$7,500 to \$10,298 per patient, depending on whether the correction was done in infancy or later in life (Hsieh, 2009). Thus, the approximate direct and indirect costs for treating TDS symptoms range from \$3,650 to more than \$22,000 per case, depending on severity and location of treatment (outpatient vs in-patient). However, the Attina study did not appear to discount costs of future disease burden that could be attributed to current exposures, such as the cost of treating testicular cancer that occurs decades after fetal exposure. The purpose of that study was to document current costs of harm from past and current exposure. Therefore, the partially undiscounted source (Attina, 2016) is not considered to be the top end of the range for this analysis, and the discounted net present direct and indirect medical costs are estimated at \$3,650 to \$13,850.

Intangible costs or qualitative disease burden are more complicated to estimate, but standard methodologies exist that are widely accepted. A standard metric used by the World Health Organization (WHO) and health researchers in many countries to estimate the societal burden of nonfatal diseases and injuries is DALYs, or Disability-Adjusted Life Years. A DALY represents the loss to society of the years of life lost to a disease or injury and the years lived with the disability. One DALY is equal to one lost year of healthy life. Estimating a DALY requires weighting the severity of the health outcome for the years lived with disability with a disability weight, ranging from 0, representing perfect health, to 1, representing a state of health near death. Using this measure allows researchers to compare the burden to society of different diseases, and compare the cost-effectiveness to society of different treatments, across time and across different countries, with different health care environments. The disability weights and Global Burden of Disease estimates (IMHE, 2019) initially were developed in the 1990s, as part of a large WHO-funded study, and they have been updated each decade to reflect recent data from researchers in more than 100 countries.

The Global Burden of Disease estimates (IMHE, 2019) provide disability weights for relatively common conditions that do not include the TDS symptoms. Other researchers have built on the Global Burden of Disease model and methodology to develop estimates of disease burden for less common diseases and chronic conditions. The disability weights for the congenital male

reproductive anomalies discussed in the CHAP are 0.07 for undescended testes, 0.2 for mild hypospadias, and 0.6 for severe hypospadias, based on a recent peer-reviewed study (Poenaru, 2017). The Poenaru study found that these weights were consistent between surgical professionals and community members, and between people in Kenya and Canada, illustrating the methodological robustness of DALY estimates in public health policy research. Another recent study (Jentink, 2012) assigned a disability weight of 0.8 to hypospadias; CPSC staff has used the lower estimate of 0.6 in this analysis. Conditions with comparable Global Burden of Disease disability weights from the most recent version are a moderate stroke or heart failure (0.07), profound developmental intellectual disability (0.2), or end-stage renal disorder on dialysis (0.6). The severity of comparable disability burden estimates reflects that while some outward symptoms of TDS can be addressed surgically in infancy, other anti-androgenic effects can persist into adulthood, particularly reduced fertility and increased risk of testicular cancers, even in the absence of continued phthalate exposure. CPSC staff did not find literature estimating the DALY for the TDS conditions, which would multiply the disability weight by the number of years in which the disability impacts the individual.

The chief benefit of continuing the interim prohibition on DINP is reducing the risk of harm, specifically male reproductive congenital symptoms and cancer risk caused by prenatal exposure to phthalates, including DINP, as well as infertility problems caused by both prenatal and childhood exposures. Each case of male reproductive congenital conditions has a disability weight of 0.07 to 0.6, as discussed earlier, reflecting lifetime impacts, such as increased risk of testicular cancer and reduced fertility, as well as the costs and intangible impacts of surgical treatment. A case of cryptorchidism that is treated successfully with surgery is reflected with the lower disability weight, comparable to a moderate stroke, while the higher disability weight for a severe case of hypospadias reflects longer term and more severe impacts, comparable to end-stage renal failure treated with dialysis. The disability for any individual case of hypospadias and cryptorchidism depends on the severity and response to treatment. Surgical treatments are not successful or require further surgery in many cases; and even with successful surgical treatment, these conditions can cause urologic and fertility disabilities later in life, as well as being correlated with an increased risk of male reproductive system cancers.

Many public health studies in the United States and European Union use QALYs (Quality Adjusted Life Years) to evaluate and compare health policies and treatments. The concept is similar to DALYs, with the numerical scale reversed, so that 1 is a state of perfect health, and 0 is a near-death state. In a recent study conducted in Nordic countries estimating the burden on society of TDS caused by endocrine-disrupting chemicals (Olsson, 2014), the QALY value losses for hypospadias and cryptorchidism were estimated at 0.4 and 0.42, respectively. This is consistent with the disability weights in Poenaru, given the reverse numerical scale for DALYs versus QALYs. The advantage of using DALYs or QALYS allows comparisons of conditions and treatments without monetizing costs of intangibles, such as pain, or loss of ability to have children. Monetized estimates of QALYS do exist, however. Using 2014 U.S. ranges of estimated values for QALYs (HHS RIA Guidance, 2016) and a 3 percent discount rate for future disabilities, the values for hypospadias and cryptorchidism would reflect a cost to society of approximately \$92,000 to \$300,000 per case (multiplying 0.4 times the estimated value per QALY of \$230,000 to \$750,000); the benefit of avoiding that disability would be the same. However, the HHS guidance for value-per-QALY assumes that the person is 40 years old, and

that the disability impacts them for the rest of their life. The monetized QALY value for a disability that requires pediatric surgery but may or may not have effects later in life, such as reduced fertility or testicular cancer, might be higher or lower. On one hand, the immediate impacts that require surgery in the first year of life should not be discounted, and thus, the value per QALY could be even higher; but the other impacts might occur later in a lifetime of 75+ years, and thus, should be discounted over more years.

In summary, using U.S. values for QALYs, the monetized impact of TDS on quality of life (the intangible costs) could be about \$92,000 to \$300,000 per case. The discounted direct and indirect costs of medical treatment and lost productivity would range from \$3,650 to \$13,850 per case. Using disability weights (IMHE, 2019, Poenaru, 2017), the qualitative severity of TDS would be comparable to a moderate stroke, or to end-stage renal failure treated with dialysis. The quantitative monetary value of this benefit at the national level cannot be estimated because CPSC staff is unable to estimate the percentage of WORA with an HI greater than 1.0 in the population of approximately 60 million WORA in the United States, nor predict the number of TDS cases that would result from that exposure.

Using the low end of the U.S. range value for QALYs of \$92,000 per case, and adding in a rough estimate of discounted direct and indirect medical costs of \$6,000 per case, the benefits of the continuation of the interim ban on DINP in mouthable toys and child care articles would exceed the upper range of estimated costs (\$934,000) for testing if 10 cases of TDS disabilities per year were prevented by continuing the interim prohibition on DINP. Using the high end of the U.S. range value for QALYs of \$300,000 per case of TDS, plus \$6,000 for discounted direct and indirect costs, the benefits of continuing the interim prohibition on DINP would exceed the high end of the estimated cost range if 4 TDS cases per year were prevented.

The TDS diseases and symptoms are relatively common in the United States, so 4 to 10 cases per year would represent far fewer than 0.1 percent of such cases, which is lower by an order of magnitude or more than the etiological factor for endocrine-disrupting chemicals in any of the peer-reviewed literature discussed in the next section. For example, hypospadias occurs in approximately 1 in 200 male births, or about 10,000 cases per year in the United States.²³ Cryptorchidism cases that are severe enough to require medical treatment occur in about 1 percent of male births,²⁴ or about 19,000 cases per year in the United States. Testicular cancer is less common, occurring in about 0.4 percent of males during their lifetime, or about 9,500 cases per year.²⁵ Infertility is extremely common, impacting at least 10 percent of couples in the U.S., but any individual case may have multiple causal factors, so it is difficult to estimate the number of cases that are specifically due to low semen quality or other TDS disabilities. In about 8 percent of infertility cases, male infertility is the only identified cause.²⁶ The lowest estimate in the literature reviewed by CPSC staff of the etiological factor for endocrine disrupting chemicals on TDS was 2 percent, which would represent hundreds of cases per year in the United States. Based on the CHAP's exposure assessment, up to 29 percent of infants' potential DINP exposure is from toys and child care articles. Thus, the recommended continuation of the prohibition on

²³ <https://www.cdc.gov/ncbddd/birthdefects/hypospadias.html>.

²⁴ <https://www.ncbi.nlm.nih.gov/books/NBK470270/>.

²⁵ <https://seer.cancer.gov/statfacts/html/testis.html>.

²⁶ <https://www.cdc.gov/reproductivehealth/infertility/index.htm>.

DINP would address up to 29 percent of infants' exposure to anti-androgenic phthalates, which represent a major category of endocrine-disrupting chemicals.

c. – Range of Benefits (Costs Avoided) from Comprehensive Cost Effectiveness Analysis of Impact on Society

The CHAP analysis of data and interpretation of existing research only considered information available by the end of 2012. Since the NPR was published in 2014, various health economics studies, particularly in the EU, have estimated the total cost to society of exposure to endocrine-disrupting chemicals, and the corresponding economic benefits of reducing that exposure. A 2018 Organisation for Economic Co-Operation and Development (OECD) working paper on the socio-economic costs of phthalates (Holland, 2018) summarizes multiple relevant studies, most published since 2014. The estimated total costs to society, and equivalent benefits of averting such costs, range from hundreds of millions of EUR to billions of EUR per year. Studies in the United States are of similar magnitude in dollar terms. The large range reflects that different studies considered different chemicals and different impacts as toxicity endpoints. However, none of the available peer-reviewed studies specifically estimate the cost of TDS to society caused by exposure to DINP in mouthable children's toys and child care articles. The total benefit of reduced cases of TDS in the United States from continuing the interim prohibition of DINP in mouthable toys and child care articles would be some unknown, perhaps small, fraction of the estimates in these studies. This section discusses the ranges of those estimates, but CPSC staff cannot determine what fraction of the total societal impact of endocrine-disrupting disease burden would be prevented or reduced in severity by continuing the interim prohibition on DINP.

Perhaps the most narrowly focused, and thus, directly relevant of the recent studies was one conducted for the Nordic Council of Ministers (Olsson, 2014), analyzing specifically the cost of TDS to society from exposure to endocrine-disrupting chemicals, particularly phthalates. The Olsson study is relevant because it breaks out direct and indirect costs and provides a range of estimates using alternative assumptions about etiology (what portion of TDS cases are caused by exposure to endocrine-disrupting chemicals). It also discounts costs and benefits (net present value or NPV) to reflect the discounted future costs of treating TDS disabilities that do not occur until decades after exposure. While other U.S. and EU studies have considered the costs of multiple possible impacts of endocrine-disrupting chemicals, the Olsson study focused specifically on TDS. However, the Olsson study did not estimate the impact specifically from exposure to DINP in mouthable children's toys and child care articles.

The Olsson study considered direct, indirect, and intangible costs. The Olsson study provided different estimates of the total cost to EU society, based on the assumptions that 2 percent, 20 percent, or 40 percent of TDS cases were caused by endocrine-disrupting chemicals. Using the lowest 2 percent etiological estimate and prevalence of TDS disabilities in the (pre-Brexit) EU, the total cost to EU society would be about 59 million EUR annually. The EU population of 506 million in 2014 (pre-Brexit) was larger than the U.S. population of about 318 million in 2014, so a proportional impact number for the United States would be 37 million EUR annually. The middle etiologic estimate of 20 percent yielded a cost to the European Union of 592 million EUR, equivalent to 370 million EUR for a population the size of the United States. These are discounted estimates, reflecting the NPV of costs between exposure and incidence of disability.

Undiscounted costs would be more than twice as high, reflecting that exposure to phthalates before birth could result in disabilities decades later.

Based on the Olsson study, if the prevalence of TDS caused by endocrine disrupters is roughly equivalent in the United States to its prevalence in the European Union, which appears to be the case, the cost of all TDS caused by endocrine disrupters per year of exposure (and thus, the benefit of removing endocrine-disrupting chemicals) would be approximately 370 million EUR annually for a population the size of the United States. That is approximately \$444 million, using the middle etiologic estimate, which assumes that 20 percent of TDS cases are caused by phthalates, and an exchange rate of \$1.20 per EUR. If the lowest etiological estimate of 2 percent is used, the benefit is approximately \$44 million. The CPSC final rule did not prohibit all phthalates from all consumer products; the recommended prohibition on DINP would address up to 29 percent of infants' exposure to anti-androgenic phthalates. Thus, the benefit of the continuation of the interim ban on DINP in mouthable toys and child care articles would be some material fraction of the Olsson estimate of total societal impact, considering only DINP exposure specifically from mouthable children's toys and child care articles, and considering primarily the impact on women of reproductive age.

Other recent studies have looked at the cost impacts of endocrine disrupting chemicals, which include phthalates. Some recent estimates (Trasande, 2016) of the total cost impact on EU society of endocrine-disrupting chemicals exceed 1.28 percent of GDP as the median estimate. However, that study includes the direct and indirect costs for IQ loss and associated intellectual disability, autism, attention deficit hyperactivity disorder, endometriosis, fibroids, obesity, diabetes, cryptorchidism, male infertility, and mortality associated with reduced testosterone, which is a much larger scope of impacts than the CHAP considered for DINP. The European Health and Environment Alliance (HEAL, 2014) report on endocrine disrupting chemicals estimated current annual health costs in the EU resulting from past and current exposure to such chemicals at approximately 31 billion EUR, or roughly 0.2 percent of pre-Brexit EU GDP, using an etiological estimate of 2 to 5 percent for the medical conditions considered. The HEAL report attributed slightly less than 1 percent of that 31 billion EUR cost to male reproductive harm. The HEAL report considered only current direct and indirect costs, not intangible quality of life costs, nor net present value discounted costs of future treatments.

A different study (Attina, 2016) considered the cost of endocrine-disrupting chemicals to U.S. society. Unlike the Olsson, HEAL, and Trasande studies of EU costs, based on EU disease burden, the Attina study considered U.S. medical costs and U.S. exposures to phthalates and other endocrine-disrupting chemicals. However, the scope was all endocrine-disrupting chemicals and toxicity endpoints including but not limited to TDS, so it would be difficult to isolate from this estimate only the specific impact of CPSC's continuation of the interim ban on DINP in mouthable children's toys and child care articles. It is notable that the Attina study median estimate of the cost burden to U.S. society of endocrine-disrupting chemicals of \$340 billion exceeds 2.3 percent of GDP. The upper end of the range was more than \$500 billion per year. In contrast, the Olsson study of only TDS costs at the median 20 percent etiologic estimate would be the equivalent of \$444 million U.S. per year for the United States, or about 0.05 percent of U.S. GDP, which was similar to the HEAL estimate of specifically male reproductive harm costs, considering that the HEAL estimate did not consider intangible costs.

In summary, the recent literature on total societal economic burden of endocrine disrupting chemicals has a large range of cost estimates, from under \$100 million for TDS impacts only to over \$500 billion for a larger set of health impacts on the United States or an EU population equivalent to the size of the United States. It is not possible to determine what fraction of those estimates would be attributable specifically to exposure to DINP in mouthable children's toys and child care articles, but the available evidence indicates that such DINP exposure would constitute a material additional risk.

d. Other Factors that Could Impact Benefits Amount or Distribution

Within U.S. society, the harm from phthalate exposure may disproportionately impact infants, children, and women from vulnerable populations. Thus, the benefits of continuing the interim ban on DINP in mouthable toys and child care articles in reducing phthalate exposure may disproportionately benefit certain populations within the United States. EPA analysis of NHANES data from 2011 to 2014 (ACE, 2017) found that Black, non-Hispanic women of child-bearing age had higher median concentrations of the phthalate metabolites of di-2-ethylhexyl phthalate (DEHP), dibutyl phthalate (DBP), and butyl benzyl phthalate (BBzP) than women of other races. Also, the EPA analysis found that women living below the poverty level had higher concentrations of phthalate metabolites in their urine than women living at or above the poverty level. Similarly, Black, non-Hispanic children had higher levels of phthalate metabolites than children of other races, and children living in poverty had higher levels of phthalate metabolites than children living at or above the poverty level.

It has been suggested that the prohibitions on phthalates, including DINP, have merely led to a shift to "regrettable substitutes" that might have equally bad or worse health impacts that are not yet documented. If that were true, the benefits of continuing the interim prohibition on DINP in mouthable children's toys and child care articles would be limited. As required by the CPSIA, the CHAP analyzed the impacts of multiple common phthalate and non-phthalate substitutes. The CHAP did not find evidence that any of the substitutes had anti-androgenic health effects that would justify including them in the cumulative risk assessment or in the prohibition on use in mouthable children's toys and child care articles. The CHAP also considered possible health effects from the substitutes, other than anti-androgenic effects, and concluded that available information did not support CPSC action against those substitutes, although the CHAP recommended additional research on some of the substitutes to identify any hazard or exposure concerns.

Recent peer-reviewed analysis of functional substitutes (van Vugt-Lussenburg, 2020) found that some common, bio-based, non-phthalate substitutes "are not only technically viable alternatives to phthalates, but also offer significant toxicological benefits, which supports a non-regrettable substitution." In addition, CPSC staff analysis found evidence (Dreyfus, 2010) that a substantial portion of manufacturers of soft toys had already voluntarily switched to plastics that did not require a phthalate or non-phthalate plasticizer before the NPR was published.

The EU has developed extensive guidelines on using benefit/risk analysis to assess the trade-offs of using phthalates in certain medical devices versus alternative substances, designs, or treatments (SCHEER, 2019). For some medical devices, such analysis may find that the benefits

of continuing to use a phthalate outweigh the potential harm, such as where the risks of a particular phthalate are extremely well documented and understood, as compared to the unknown risks of a substitute, and where the phthalate has medically relevant functional benefits, such as stabilizing red blood cells in blood bags. In that case, the medical benefit of the continued use of phthalates in a medical device could outweigh the risks. However, in the case of the CPSC final rule, it is highly unlikely there are any important life-saving functional benefits of continued use of DINP in a mouthable children's toy or child care article, instead of a non-phthalate substitute without known anti-androgenic effects, or a plastic that does not require a plasticizer.

VII. Conclusion

Based on this analysis, CPSC staff concludes that the rule is a cost-beneficial solution that achieves the statutorily required safety purpose of ensuring a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety by continuing the interim prohibition on DINP. By "cost-beneficial," CPSC staff means that the ratio of benefits to costs is greater than 1. CPSC staff estimates that costs are small, while the benefits are potentially very large, but cannot be fully quantified. From the cost side, the compliance costs of continuing the interim ban on DINP in mouthable toys and child care articles are no more than \$934,000 annually to the entire U.S. toy and child care article industry for testing, likely much less, and reformulation costs were minimal, if any. The cost of prohibiting DINP content in mouthable children's toys and child care articles, and third party testing to ensure compliance, is balanced against—and likely greatly outweighed by—the benefits of averting male reproductive disabilities that include genital deformities that require pediatric surgical treatment, infertility, and cancers of the male reproductive system.

Continuing the statutory interim prohibition on DINP in the final rule had no observable impact on the price of mouthable children's toys or child care articles. It has had no observable impact on the market for DINP, primarily because mouthable children's toys and child care articles are a very small share of the market for DINP. It likely did not reduce utility for mouthable toy and child care article manufacturers, because many functional substitutes for DINP exist at similar prices. On the benefits side, the reduction in exposure to DINP, a commonly used anti-androgenic phthalate, is expected to continue to reduce the instances of TDS and reduce the associated costs to individuals and society, including direct medical costs, lost productivity, and intangible pain and suffering. The costs of the health effects on society of phthalates, including DINP, and other endocrine disruptors are very high, and thus, the benefits of reducing those impacts are also high. CPSC staff cannot quantify the specific amount of the benefits derived from prohibiting DINP in mouthable children's toys and child care articles. However, the lowest estimates in the peer-reviewed literature of the fraction of TDS cases that are caused by endocrine-disrupting chemicals are around 2 percent, which would represent hundreds of cases per year in the United States, with the upper end of the range around 40 percent, which would represent more than 15,000 cases. If even just 0.1 percent of such cases were prevented by continuing the interim ban on DINP in mouthable toys and child care articles, a percentage that likely is substantially lower than the actual prevention, the lowest estimate of benefits from the continuing rule would greatly outweigh the highest estimate of costs.

References:

Abe, Yutaka, et al. "Survey of Plasticizers in Polyvinyl Chloride Toys." *Shokuhin Eiseigaku Zasshi*. vol. 53, no. 1, (2012) pp.19-27.

Ashworth, Matthew James, et al., "Analysis and Assessment of Exposure to Selected Phthalates Found in Children's Toys in Christchurch, New Zealand." *International Journal of Environmental Research and Public Health*. 15,2 200. 25 Jan. 2018.

Attina, Teresa M et al. "Exposure to endocrine-disrupting chemicals in the USA: a population-based disease burden and cost analysis." *The Lancet. Diabetes & endocrinology* vol. 4,12 (2016) 996-1003.

Aurisano, Nicolo et al. "Chemicals of concern in plastic toys." *Environment International*, vol. 146, (2021), 106194.

Bizzari, Sebastian et al., "CEH Marketing Research Report: Plasticizers." *SRI Consulting*, January 2009.

Bizzari, Sebastian et al., "Chemical Economics Handbook: Plasticizers." *IHS Chemical*, January 2013.

Chronic Hazard Advisory Panel "Final Report to the CPSC on Phthalates and Phthalate Alternatives," CPSC, 2014.

CPSC (2017) Responses to Public Comments on the Notice of Proposed Rulemaking on the Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates. In, Staff Briefing Package, Draft Final Rule: Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, TAB B. U.S. Consumer Product Safety Commission. September 13, 2017. <https://www.cpsc.gov/s3fs-public/Final%20Rule%20-%20Phthalates%20-%20September%2013%202017.pdf>

Dreyfus M. "Phthalates and Phthalate Substitutes in Children's Toys." Consumer Product Safety Commission, Bethesda, MD, March 2010.
<http://www.cpsc.gov/PageFiles/126545/phthallab.pdf>.

Engel, Stephanie M et al., "Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children." *American Journal of Public Health* vol. 111,4 (2021): 687-695.

Greene M. "Mouthing Times Among Young Children from Observational Data." U.S. CPSC, Bethesda, MD 20814. June 17, 2002.

"Guidelines on the benefit-risk assessment of the presence of CMR/ED phthalates in certain medical devices." European Union Scientific Committee on Health, Environmental and Emerging Risks, 2019 (SCHEER).

Hammel, Stephanie C et al., “Children's exposure to phthalates and non-phthalate plasticizers in the home: The TESIE study.” *Environment international* vol. 132 (2019): 105061.

Hauser, Russ et al., “Male reproductive disorders, diseases, and costs of exposure to endocrine-disrupting chemicals in the European Union.” *The Journal of Clinical Endocrinology and Metabolism* vol. 100,4 (2015): 1267-77.

Holland, Mike. “Socio-economic assessment of phthalates.” OECD ENV/WKP (2018)7.

Hsieh, Michael H et al., “Economic analysis of infant vs. postpubertal orchiopexy to prevent testicular cancer.” *Urology* vol. 73,4 (2009): 776-81.

Jentink, Janneke et al., “Economic evaluation of anti-epileptic drug therapies with specific focus on teratogenic outcomes.” *Journal of Medical Economics* vol. 15,5 (2012): 862-8.

Johnson, Sapna et al., “Phthalates in toys available in Indian market.” *Bulletin of environmental contamination and toxicology* vol. 86,6 (2011): 621-6.

Kiss C. “A Mouthing Observation Study of Children Under 6 Years.” U.S. CPSC, Bethesda, MD 20814. June 14, 2002.

Malveda, Mike, et al., “Chemical Economics Handbook: Plasticizers.” *IHS Markit*, May 2021.

Olsson, Ing-Marie et al., “The Cost of Inaction: A Socioeconomic Analysis of Costs Linked to Effects of Endocrine Disrupting Substances on Male Reproductive Health.” *Nordic Council of Ministers*, TemaNord 2014:557.

“Peer Review of the CHAP Draft Report on Phthalates and Phthalate Substances.” *Toxicology Excellence for Risk Assessment*, 2015.

<https://www.cpsc.gov/s3fs-public/pdfs/TERAREportPhthalates.pdf>.

Poenaru, D et al., “Establishing disability weights for congenital pediatric surgical conditions: a multi-modal approach.” *Population health metrics* vol. 15,1 8. 4 Mar. 2017.

Trasande, L et al., “Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis.” *Andrology* vol. 4,4 (2016): 565-72.

U.S. Department of Health and Human Services. “Guidelines for Regulatory Impact Analysis: 2016.

U.S. Environmental Protection Agency. “America’s Children and the Environment,” third edition, updated 2017 (ACE).

U.S. International Trade Commission (ITC). “Dioctyl Terephthalate (DOTP) from Korea.” Investigation No. 731-TA-1330, hearing transcripts and final report (Publication 4713), 2017.

Van Vugt-Lussenburg B et al., “Endocrine activities of phthalate alternatives; assessing the safety profile of furan dicarboxylic acid esters using a panel of human cell-based reporter gene assays.” *Green Chem*, 2020, 22, 1873-1883.

Ward et al., “Burden, Treatment, and Cost of Hypospadias in the United States: Findings from the Urologic Diseases in America Project.” *Journal of Urology*, April 2020.

Other Sources:

Centers for Disease Control and Prevention [CDC], National Center on Birth Defects and Developmental Disabilities website “Facts About Hypospadias.”

<https://www.cdc.gov/ncbddd/birthdefects/hypospadias.html>.

Euromonitor International, prices and trends in retail prices of toys.

European Chemicals Agency, Annex XVII to REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) – Conditions of Restriction.

Government of Canada Phthalates Regulations (SOR/ 2016-188).

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2016-188/index.html>.

Independent Commodity Intelligence Services (ICIS).

Institute for Health Metrics and Evaluation [IMHE], Global Burden of Disease Study (2019).

<http://ghdx.healthdata.org/record/ihme-data/gbd-2019-disability-weights>.

Medicare.gov, Procedure Price Lookup tool for Outpatient Procedures.

<https://www.medicare.gov/procedure-price-lookup/>.

Phthalate Esters Panel of the American Chemistry Council website from August 2007, via internet archive.

(https://web.archive.org/web/20070819033220/http://www.phthalates.org/yourhealth/childrens_t_oys.asp).

Toy Industry Association

https://www.toyassociation.org/PressRoom2/News/2017_News/toy-industry-economic-impact-in-the-us-reaches-107-5-billion.aspx.

U.S. Department of Commerce, Census Bureau, U.S. manufacturing data for NAICS code 33993.

(<https://data.census.gov/cedsci/table?y=2017&n=33993&tid=ECNSIZE2017.EC1700SIZEREVEST>).

U.S. Department of Commerce, International Trade Administration, Global Patterns of U.S. Merchandise Trade, NAICS code 33993.

U.S. Department of Health and Human Services, Healthcare Cost and Utilization Project (HCUP) HCUPnet

(<https://hcupnet.ahrq.gov/#setup>)

U.S. Environmental Protection Agency, Docket EPA-HQ-OPPT-2018-0436, Manufacturer- Requested Risk Evaluation of DINP and Toy Association comments on Draft Scope Documents

for DINP and DIDP Issued Under Section 6 of TSCA; EPA-HQ-OPPT-2018-0436 and EPA-HQ-OPPT-2018-0435.

U.S. Environmental Protection Agency Chemview (<https://chemview.epa.gov/chemview>), including data for both CASRN 28553-12-0 and CASRN 68515-48-0.

U.S. Department of Labor, Bureau of Labor Statistics. Prices of toys. <https://beta.bls.gov/dataViewer/view/timeseries/CWSR0000SERE01>. See also <https://www.in2013dollars.com/Toys/price-inflation> for a graphical representation of the data.