

April 15, 2015

Chairman Elliot Kaye  
Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

**Comments on the Notice of Proposed Rulemaking  
Prohibition of Children’s Toys and Child Care Articles Containing Specific Phthalates  
Docket No. CPSC-2014-0033**

The undersigned public health, consumer advocate, environmental health and environmental organizations, representing over 70 million Americans, are writing to comment on the proposed “Prohibition of Children’s Toys and Child Care Articles Containing Specific Phthalates” rule (Phthalates Rule). We strongly support the majority of the provisions within the rule, specifically:

- Making permanent the interim ban on diisononyl phthalate (DINP); and
- Permanently banning 4 additional phthalates – diisobutyl phthalate (DIBP), di-*n*-pentyl phthalate (DPENP), di-*n*-hexyl phthalate (DHEXP) and dicyclohexyl phthalate (DCHP).

However, our organizations urge the Commission to revise the proposed rule to:

- Make permanent the interim bans on diisodecyl phthalate (DIDP) and di-*n*-octyl phthalate (DNOP); and
- Permanently ban diisooctyl phthalate (DIOP).

**Introduction**

Phthalates are chemicals used to make plastic toys like rubber ducks and bath books soft and flexible. They can be found all around us-- in flooring, cosmetics, shower curtains, cars, cleaning products and food packaging. Phthalates have been linked to serious health concerns including reproductive harm in males (poor sperm quality, reduced fertility, testicular cancer, undescended testes, hypospadias, and reduced anogenital distance); neurobehavioral effects in children (reductions in mental and psychomotor development, increases in attention deficits and behavioral symptoms); and liver, kidney thyroid and immune system toxicity.<sup>1</sup>

In response to the large and growing body of scientific evidence illustrating the toxicity of phthalates, the European Union, three states (CA, WA, VT), and ultimately the U.S. Congress enacted legislation banning the use of certain phthalates in children’s toys and child care articles. Section 108 of the Consumer Product Safety Improvement Act (CPSIA), 15 U.S.C. § 2057c, established a permanent ban on di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and butylbenzyl phthalate (BBP), and an interim ban on DINP, DNOP and DIDP pending a review of the scientific evidence on the toxicity of phthalates and phthalate alternatives by a Chronic Hazard Advisory Panel (CHAP).

Congress explicitly directed the CHAP to use the most up-to-date concepts in risk assessment to ensure the CHAP's conclusions were based on the real world use and exposure conditions to phthalates and the resulting risk. Among other provisions, Sec. 108 of the CPSIA required the CHAP to:

- Examine all potential health effects, including endocrine disruption;
- Consider the potential impact of phthalates both in isolation and in combination;
- Take into account vulnerable populations (children, pregnant women, other susceptible individuals);
- Conduct a cumulative risk assessment;
- Consider all exposure routes, including ingestion, dermal, hand-to-mouth and others; and
- Assure a reasonable certainty of no harm from phthalate exposure using sufficient safety factors to account for uncertainty.

Congress directed that within 180 days of receiving the CHAP report, the Consumer Product Safety Commission ("CPSC") must "determine, based on [the CHAP] report, whether to continue in effect the prohibition under paragraph (1) [meaning the interim prohibition on DINP, DIDP and DNOP], *in order to ensure a reasonable certainty of no harm* to children, pregnant women, or other susceptible individuals with *an adequate margin of safety.*" 15 U.S.C § 2057c(b)(3)(A) (emphases added). In addition, for phthalates not covered by the CPSIA's permanent or interim bans, Congress directed the CPSC to consider the findings and recommendations of the CHAP and to ban any phthalate "as the Commission determines necessary to protect the health of children." 15 U.S.C § 2057c(b)(3)(B).

These mandates to the CHAP for how to conduct its risk assessment and the broad authority given to the CPSC to adopt regulations to protect the health of children underscore the clear, health protective intent of Congress when it adopted Sec. 108 CSPIA. These directives and principles should inform CPSC's consideration and final approval of the Phthalates Rule.

### **Sound and Fair Process**

We commend the CHAP and CPSC for conducting the process of the scientific review and subsequent issuing of the proposed rule in an open and transparent manner. All meetings of the CHAP were open to the public. These meetings were well attended by industry where they had ample opportunity to provide data and information and to express their views on the interpretation of the science. Likewise, and as is the practice of the CPSC, all meetings with Commissioners regarding the report and subsequent proposed rule were open to the public, and again well attended by the chemical industry, particularly Exxon-Mobil and the American Chemistry Council.

The seven CHAP members were all nominated by the National Academy of Sciences (NAS) and thoroughly vetted for possible financial conflicts of interest. They represent the worldwide experts in endocrine disrupting chemicals in general and phthalates specifically, and the resulting report reflects that expertise and integrity.

The CHAP process itself constituted an in depth and thorough peer review by the best available scientists of the best available science on the exposure to and health hazard from 14 phthalates and 6 phthalates alternatives. Despite the fact that this process was a peer review in and of itself, and the fact that Congress did not require any further review of the CHAP report, the CHAP members themselves requested an additional peer review through the standard and accepted practice used by scientific journals – the designation of anonymous experts to review and comment on the CHAP report. In fact, the CPSC went to the extraordinary length of publishing those comments and the CHAP report pre- and post- the expert review so the public would have ample opportunity to see the concerns raised and how they were addressed. The peer reviewers were overwhelmingly supportive and validated the integrity and scientific soundness of the process.

We urge the Commission to regard this report as the thorough, credible, independent scientific document that it is, and to act accordingly in keeping with their recommendations and not be swayed by chemical industry pressure as they attempt to undermine and discredit the report and its findings.

### **Solid Science**

The cumulative risk analysis of phthalates performed by the CHAP represents the cutting edge and most current and best available science. It represents a significant improvement over the outdated methodologies currently used for government review of chemical risk, which look at a single exposure of one chemical at a time. This approach of reviewing chemicals in isolation in no way reflects the reality of how humans are exposed to these chemicals in our everyday lives. National biomonitoring data, which was thoroughly reviewed by the CHAP, conclusively show that the American population is continuously exposed to multiple phthalates from multiple sources. To consider those phthalates—which often have similar health impacts—one at a time ignores that reality and seriously underestimates the true exposure and therefore the real impact of these dangerous chemicals on public health.

The cumulative risk analysis performed by the CHAP was specifically required by Congress and follows the recommendation of two reports by the NAS: *Science and Decisions, Advancing Risk Assessment* and *Phthalates and Cumulative Risk Assessment*. The NAS is the gold standard for science in this country – a fact that the chemical industry also recognizes. For example, when industry disagreed with scientific decisions regarding the dangers of formaldehyde and styrene made by the National Toxicology Program, the industry persuaded Congress to require that those decisions be review by NAS panels (the NAS panels confirmed the NTP listings of formaldehyde<sup>2</sup> and styrene<sup>3</sup> as known and reasonably anticipated carcinogens respectively). Successfully conducting a cumulative risk analysis, considering the suite of anti-androgenic phthalates, is a great step forward in risk assessment and an accomplishment for which the CHAP should be highly commended.

Much of the debate around the CHAP report has centered on DINP. Because of its economic value and increasing use in consumer products, the chemical industry has been particularly critical of the CHAP's scientific conclusions about the risks associated with exposure to DINP in the context of the cumulative

risk assessment. We support the CHAP's analysis and recommendation to permanently ban DINP from children's toys. Indeed, since the date at which the CHAP stopped considering new science, the data implicating DINP have only gotten stronger. New epidemiology data associating DINP exposure with reduced anogenital distance in Swedish boys<sup>4</sup> and higher exposure among pre-mature infants<sup>5</sup> continue to heighten concern about the toxicity of this chemical. In fact, the State of California recently listed DINP as a "chemical known to the state to cause cancer" under Prop 65.<sup>6</sup> Clearly, concern about the toxicity of the chemical is on the rise, as is its presence in our bodies.

Biomonitoring data from the National Health and Nutrition Examination Survey (NHANES) has shown that DINP concentrations in the American public are increasing. A recent paper analyzing trends in the NHANES data on exposure to phthalates showed that 89% of the American public is exposed to DINP and that exposure levels have increased 149% from the 2005-2006 to 2009-2010 measurements.<sup>7</sup> A review of the 2011-2012 NHANES data shows the mean concentration of MCOP, a primary metabolite of DINP, increased 71% in adults and 33% in children aged 6-11. Children's exposure is higher overall, as is the case for most phthalates. NHANES data does not include children under 6; however the CHAP report confirmed similarly high levels of exposure to very young children using other biomonitoring data sets.

The NHANES data show a changing suite of phthalate exposure with exposures to some phthalates, such as DINP and DIBP, going up and other phthalates, such as DEHP, DBP and BBP going down (Zota, 2014). Even though some phthalate exposures are going down based on the NHANES results, the 2011-2012 data show consistently higher levels, and sometime substantially so, in children 6-12 as compared to adults. Again, the NHANES data does not provide evidence of trends for children under 6, a key population for consideration in this rulemaking. Additionally, as the use of some phthalates, such as DEHP and DBP, is declining, industry is substituting other phthalates, some of which may not be included in the NHANES biomonitoring study and may have antiandrogenic effects, such as dicyclohexyl phthalate (DCP) and di-*n*-propyl phthalate (DPP)<sup>8</sup>. Clearly, product reformulations are changing the phthalate exposure profiles in children and adults in the US. While the relative contributions of the anti-androgenic phthalates included in the cumulative risk assessment are in flux, in the aggregate they result in exposure levels with a hazard index close to or exceeding one in a significant percentage of women and children.

The CHAP's decision to use the antiandrogenic effects of multiple phthalates on the male reproductive tract as the health endpoint for the cumulative assessment is a sound one based on the scientific evidence available.

### **Health Protective Policy**

In interpreting the CHAP's scientific recommendations and moving forward to finalize the proposed rule, the undersigned organizations urge the Commission to follow Congress's mandates to "ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety," in considering whether to make the interim bans permanent, and to consider what is "necessary to protect the health of children," in considering whether to regulate

phthalates besides those specified by Congress. 15 U.S.C § 2057c(b)(3)(A) & (B). In addition to summarizing the currently available science, the CHAP also consistently called for more information and further scientific assessment of these chemicals. The uncertainties that remain, given the sensitivity of very young children to endocrine disrupting compounds and developmental toxicants, continues to support a precautionary approach to phthalate exposure; erring on the side of protection rather than reintroducing hazardous chemicals into the marketplace.

The undersigned organizations support the proposed rule's banning of DINP, DIBP, DHEXP, DPENP and DCHP in all children's toys and encourage the Commission to finalize that portion of the proposed rule in its current form. Given the evidence in the CHAP report, banning these phthalates is necessary to ensure a reasonable certainty of no harm and to protect the health of children, the legal criteria established by Congress. 15 U.S.C § 2057c(b)(3)(A) & (B).

We would, however, urge the Commission *not* to lift the ban on DIDP and DNOP; but rather to make the interim ban on them permanent. The CHAP did not include DNOP and DIDP in the cumulative assessment because they do not exhibit the same antiandrogenic properties as the other banned phthalates. However, the CHAP report did acknowledge that both are potential developmental and systemic toxicants and called on federal agencies regulating exposures to these chemicals from other sources such as food, "to conduct the necessary risk assessments with a view to supporting risk management steps."<sup>9</sup> The addition of DINP to the cumulative assessment was the basis for the CHAP's recommendation to permanently ban DINP; but the CHAP also noted other concerning health endpoints for DINP, particularly noting that liver toxicity is the most sensitive endpoint. Since they have not been found to be antiandrogenic, DIDP and DNOP were not included in the cumulative assessment. The CHAP used a Margin of Exposure (MoE) method to assess the risk from DIDP and DNOP and recommended lifting the bans based on that analysis despite an acknowledgement that both are potential developmental and systemic toxicants, specifically naming adverse effects on the liver and kidney. While not within the scope of the CHAP report, the fact that several of these phthalates have another similar adverse health impact – liver toxicity – points to the potential cumulative impact from exposures to a mixture of DINP, DNOP and DIDP, which would enhance the concern about harm.

An additional reason not to lift the ban on DNOP and DIDP is that doing so could result in increasing use and exposure, and therefore increasing risks, from the chemicals in the future. DNOP and DIDP have not been used in phthalates in children's toys and child care articles since 2008, and there is no reason to allow their reintroduction into commercial use. Use of these two phthalates remains banned in the European Union and other countries around the world as well as three states – California, Washington and Vermont. Even the Toy Industry Association (TIA) acknowledged that the CHAP recommendations will "have limited practical effects on TIA members, as many of the phthalates deemed unsuitable for use by the CHAP are not widely used in toys and/or remain restricted in other jurisdictions, such as the EU."<sup>10</sup> Additionally, CPSC is required under section 108(b)(3)(A) of CPSIA to "determine, based on such report, whether to continue in effect the prohibition under paragraph (1), in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety." The reintroduction in commerce of DNOP and DIDP does not depend on

whether the CHAP's estimated MoEs are "adequate to protect human health," but rather on whether CPSC must continue their prohibition to "ensure a reasonable certainty of no harm" to susceptible individuals. Given the lack of current use in the market, the uncertainties around the safety of these chemicals, and the Commission's obligations under the statute, we urge the Commission to maintain the current ban.

Finally, we urge the CPSC to implement a permanent ban on DIOP. The CHAP's recommendation is based on sound reasoning and science, given that DIOP has a chemical structure consistent with other antiandrogenic phthalates. Under the CPSIA, the CPSC must evaluate the CHAP's findings on DIOP and ban the chemical "as the Commission determines necessary to protect the health of children." 15 U.S.C § 2057c(b)(3)(B). Given the serious concerns raised by the CHAP's in-depth peer-reviewed study and analysis about the safety of DIOP, including predictive modeling analyzing structure-activity relationships to estimate that antiandrogenic effects are possible from DIOP, we submit that rejecting the CHAP's recommendation for a ban is inconsistent with the Congressional mandate to take the steps necessary to protect the health of children. We urge the Commission to ban the chemical until such time that the science affirmatively shows it to be safe. Far too often in our chemical management system, lack of data is interpreted as a lack of a problem. This is a false premise perpetuated by the chemical industry, which has little incentive to conduct safety testing. We urge the Commission to reject the "no data = no problem" premise and act in the best interests of the health of our children and ban this phthalate.

The proposed rule provides for an effective date that is a very generous 180 days after the publishing of the final rule. Based on the Commission staff analysis of the minimal impact on industry of the new provisions of the rule, we urge the Commission to shorten the implementation period and to ensure that there is no gap in the protections from DINP. We strongly urge the Commission to eliminate the lag time in the implementation of the permanent ban on DINP in toys and child care articles or make clear that the current interim ban will remain in place until the effective date of the final rule. The Commission should not allow a six month gap during which toys currently banned could be legally sold. The APA allows the Commission to shorten the time before the effective date to less than 30 days "for good cause found and published with the rule." 5 USC § 553(d).

### **Summary/Conclusion**

We commend the CHAP for the excellent quality of the Phthalates and Phthalates Alternatives report. We urge the Commission to amend the proposed rule to add DIDP, DNOP and DIOP to the list of phthalates permanently banned in toys and child care products. The resulting final rule will clearly protect the health of our children in this and future generations. They deserve no less.

Sincerely,

Alaska Community Action on Toxics  
Alliance of Nurses for Healthy Environments  
American Academy of Pediatrics

American Public Health Association  
BlueGreen Alliance  
Breast Cancer Fund  
Center for Environmental Health  
Clean and Healthy New York  
Clean Production Action  
Clean Water Action  
Commonweal Biomonitoring Resource Center  
Consumer Federation of America  
Consumers Union  
Earthjustice  
Ecology Center  
Empire State Consumer Project, Inc.  
Environmental Health Strategy Center  
Environmental Working Group  
Green Science Policy Institute  
Greenpeace  
Health Care Without Harm  
Healthy Building Network  
Healthy Legacy, Minnesota  
Informed Green Solutions  
Learning Disabilities Association of America  
MomsRising  
Natural Resources Defense Council  
Science and Environmental Health Network  
TEDX, The Endocrine Disruption Exchange  
U.S. PIRG  
Washington Toxics Coalition  
Women's Voices for the Earth

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<sup>1</sup> U.S. Consumer Product Safety Commission. (2014). Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives. <http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act/Phthalates/Chronic-Hazard-Advisory-Panel-CHAP-on-Phthalates/>

<sup>2</sup> <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=18948>

<sup>3</sup> <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=18725>

<sup>4</sup> Bornehag, C. G., Carlstedt, F., Jönsson, B. A., Lindh, C. H., Jensen, T. K., Bodin, A., ... & Swan, S. H. (2015). Prenatal Phthalate Exposures and Anogenital Distance in Swedish Boys. *Environmental Health Perspectives*, 123(1), 101.

<sup>5</sup> Frederiksen, H., Kuiri-Hänninen, T., Main, K. M., Dunkel, L., & Sankilampi, U. (2014). A longitudinal study of urinary phthalate excretion in 58 full-term and 67 preterm infants from birth through 14 months. *Environmental Health Perspectives*, 122(9), 998.

<sup>6</sup> California Office of Environmental Health Hazard Assessment (OEHHA); (2013). Chemical listed effective December 20, 2013 as known to the State of California to cause cancer: diisononyl phthalate (DINP) [12/12/13]. Available online: [http://oehha.ca.gov/prop65/crnr\\_notices/list\\_changes/122013p65list.html](http://oehha.ca.gov/prop65/crnr_notices/list_changes/122013p65list.html)

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<sup>7</sup> Zota, A.R., Calafat, M., & Woodruff, T.J. (2014). Temporal Trends in Phthalates Exposures: Findings from the National Health and Nutrition Examination Survey, 2001-2010. *Environmental Health Perspectives*. Vol. 122(3).

<sup>8</sup> Dodson, R.E., M. Nishioka, L.J. Standley, L.J. Perovich, J.G. Brody, R.A. Rudel. 2012. Endocrine Disruptors and Asthma-Associated Chemicals in Consumer Products. *Environmental Health Perspectives*, doi:10.1289/ehp.1104052

<sup>9</sup> U.S. Consumer Product Safety Commission. (2014). Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives. <http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act/Phthalates/Chronic-Hazard-Advisory-Panel-CHAP-on-Phthalates/>

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[http://www.toyassociation.org/PressRoom2/News/2014 News/CPSC Releases CHAP Report on Phthalates and Phthalate Alternatives .aspx#.VQERL\\_nF8mQ](http://www.toyassociation.org/PressRoom2/News/2014%20News/CPSC%20Releases%20CHAP%20Report%20on%20Phthalates%20and%20Phthalate%20Alternatives_.aspx#.VQERL_nF8mQ)