



April 15, 2015

Office of the Secretary  
Attn: Todd Stevenson  
US Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

**RE: Comments on the Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates Docket No. CPSC-2014-0033**

The Toy Industry Association, Retail Industry Leaders Association and National Retail Federation (together “Respondents”) respectfully submit the following comments to the U.S. Consumer Product Safety Commission (CPSC or the Commission), regarding the proposed rule on the Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates, Docket No CPSC-2014-0033. We appreciate the opportunity to provide our perspective on the proposed rule, and we ask you to consider our comments carefully as you finalize this rule.

The Toy Industry Association™, Inc. (TIA) represents nearly 850 businesses – toy manufacturers, importers and retailers, as well as toy inventors, designers and testing labs – who are all involved in creating safe and fun toys and games for children. Approximately 3 billion toys are sold in the U.S. each year, totaling \$22 billion at retail; TIA members account for approximately 90% of the market.

Toy safety is the top priority for the industry and TIA and its members have long been leaders in toy safety, dating back to the 1930s. Our efforts include leading the development of the first comprehensive toy safety standard (later adopted as ASTM F963, which in 2008 became a mandatory consumer product safety rule under CPSIA); and the industry continues to provide technical input and actively participate in the ongoing review of this "living" standard today, in order to keep pace with innovation and potential emerging issues. TIA and its members work with government officials, consumer groups, and industry leaders on ongoing programs to ensure safe play. It is very much in this spirit that TIA submits the following comments to the proposed CPSC rule.

**Please note that the toy industry will not be significantly impacted by the proposed rule with regard to needed reformulation of products, as the industry has almost without exception used substitute plasticizers in lieu of any phthalate esters for many years although there will be an added testing cost burden for the industry from the rule as proposed. Our comments**

**are therefore not motivated by a desire to avoid toy industry impacts specifically from this rule, but instead are directed toward what we view as an unprecedented departure from CPSC’s tradition of rulemaking based on sound science, which we believe creates a dangerous and shortsighted precedent.**

The Retail Industry Leaders Association (RILA) is the trade association of the world's largest and most innovative retail companies. RILA members include more than 200 retailers, product manufacturers, and service suppliers, which together account for more than \$1.5 trillion in annual sales, millions of American jobs and more than 100,000 stores, manufacturing facilities and distribution centers domestically and abroad.

RILA members appreciate the Commission’s dedication and efforts to improve the safety of consumer products, particularly children’s products, toys and child care articles and to quickly remove unsafe products from the market. We fully support the Commission’s efforts engage and educate consumers on product safety issues. We share the CPSC’s goal of ensuring that all consumer products sold to U.S. consumers, especially products intended for our most valued customers, children, meet or exceed the highest safety standards.

The National Retail Federation (NRF) is the world’s largest retail trade association, representing discount and department stores, home goods and specialty stores, Main Street merchants, grocers, wholesalers, chain restaurants and Internet retailers from the United States and more than 45 countries. Retail is the nation’s largest private sector employer, supporting one in four U.S. jobs – 42 million working Americans. Contributing \$2.6 trillion to annual GDP, retail is a daily barometer for the nation’s economy. NRF’s [This is Retail](#) campaign highlights the industry’s opportunities for life-long careers, how retailers strengthen communities, and the critical role that retail plays in driving innovation.

## **Background**

In 2008, Congress passed the Consumer Product Safety Improvement Act (CPSIA) which, in Section 108, restricted three phthalates permanently, restricted three others on an interim basis and required the agency to appoint a scientific panel to review these six and other phthalates. This Chronic Hazard Advisory Panel (CHAP) was 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 make recommendations to the CPSC as to which phthalates, or combination(s) of phthalates, should be restricted. CPSIA further directed the CHAP to “review all relevant data, including *the most recent*, best-available, peer-reviewed, scientific studies” (emphasis added).

In July of 2014, the CHAP submitted their findings and recommendations to the CPSC. These included maintaining the permanent ban on the phthalates DEHP, DBP and BBP in toys and child care articles above the 0.1% level outlined in the CPSIA. They recommended lifting the CPSIA ban on DIDP and DnOP and moving DINP from being temporarily banned in mouthable toys and child care articles above 0.1% to permanently banned in all toys and child care articles

above 0.1%. The group also decided four phthalates not restricted by in CPSIA (DIBP, DPenP, DHexP, and DCHP) should be banned in all toys and child care articles at levels above 0.1%.

### **Summary of Comments**

While we appreciate the tremendous efforts evidenced by the CHAP to conduct its review of the voluminous science regarding phthalates in toys and child care articles, as well as the difficulties the CHAP faced in attempting to carry out its complex charge under Section 108 of the CPSIA, we believe that both the recommendations of the CHAP and the CPSC-proposed rule based on that report, are flawed in several respects:

- This rule is, first and foremost, a unique departure from historical precedent at the agency - CPSC has always promulgated regulations that are based on sound science and risk analysis.
- The CHAP used a self-described “novel” cumulative risk methodology to support some of its conclusions, without any clear support for such an approach; in fact, the CHAP itself indicated that urinary phthalate metabolite concentrations are quite variable, but nevertheless proceeded to use them to calculate hazard indices.
- The report and rule are based on obsolete exposure data for phthalates, despite the availability of newer data that show an overall decreased exposure of Americans to phthalates in recent years.
- The CHAP recommendation for a permanent ban on DINP is based solely upon an alleged cumulative antiandrogenic effect with other antiandrogenic phthalates; in fact, the CHAP admits that DINP’s antiandrogenic activity is weak. Moreover, this purported cumulative effect depends on presence of other phthalates (specifically DEHP) with which DINP could act in concert, but these other phthalates are also recommended for permanent bans, thus the possibility of a cumulative risk from the presence of DINP in toys and child care articles does not exist.
- The CHAP report was not publicly peer reviewed as is typically done for scientific studies of this nature, and therefore is of questionable legitimacy for use in rulemaking.
- The recommended expansion of the ban to new phthalates not contemplated in CPSIA and the expansion of the ban of DINP to all toys, not just those that may be mouthed, require ample time for toy and child care article manufacturers, retailers and others in the supply chain to prepare for, whatever changes to existing regulations the final rule may contain.

- Testing costs will increase as a result of the proposed rule, further adding to the testing cost burdens currently borne by manufacturers, retailers and others, despite virtually zero use of any phthalates in toys and child care articles.

### **Precedent Setting Regulation**

This rule is an unfortunate departure from typical analytical and methodical regulations promulgated by the CPSC especially those involving a CHAP report recommendation. For example, in 1998, after receiving a petition from the National Environmental Trust to ban PVC in all toys and other products intended for children under five years of age and issue a national advisory on the health risks presented by PVC, the Commission voted to convene a CHAP to review the effects DINP had on consumers, particularly children. The CHAP reviewed DINP because at that time it was the plasticizer most commonly used in toys to make PVC pliable, and determined that the risk of exposure to children, particularly through toys, was limited and did not present a hazard. CPSC staff agreed with their assessment and recommended that the Commission deny the petition from National Environmental Trust, which it voted to do.<sup>1</sup>

In this instance the 1998 CHAP, and subsequently the Commission, based their decision to regulate – or in this case, not regulate – on sound science. It is our belief that the 1998 CHAP followed the results of the best available science and made informed recommendations, upon which the agency relied in its decision to decline to regulate. This is but one example of how the agency has appropriately relied upon relevant data to support drafting regulations (or not drafting regulations) as deemed necessary. Other examples, such as the promulgation of the small parts regulation,<sup>2</sup> similarly demonstrate this approach.

The CPSC has maintained a long-held practice of letting the science guide the agency's hand in forming regulations and industry guidance, until the promulgation of this rule. It is clear that the CHAP decisions are informed significantly by the precautionary principle (which treats chemicals as "guilty until proven innocent," and which is adhered to by the European Union but up until now has been an anathema to US regulatory practice).

This is not the way the CPSC has typically operated and we are troubled by the precedent the rule sets, not only for the CPSC, but also for any U.S. government agency looking to write regulations related to the safety of chemicals in products. The CPSC prides itself on being an independent regulatory agency that bases its work on science, not politics, but it didn't follow this principle in this rulemaking.

Developing regulations based on sound science has the benefit of providing the greatest benefit to consumers and children's health while resulting in the least burden on the regulated

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<sup>1</sup> CPSC response to Petition HP99-1 Request to ban PVC from Toys and Other Products Intended for Children Five Years and Younger [http://www.ipema.org/news\\_articles/05/CPSC\\_Exec\\_Summary\\_%20PVC.pdf](http://www.ipema.org/news_articles/05/CPSC_Exec_Summary_%20PVC.pdf)

<sup>2</sup> 16 CFR 1501 <http://www.ecfr.gov/cgi-bin/text-idx?SID=50b1b594df5d5f6447f1ffe2d99fab49&node=pt16.2.1501&rgn=div5>

community. Regulations should be developed based on an established need *not* on an unproven concern.

### **“Novel” Scientific Process is Unprecedented and has not Been Validated**

In the CHAP report presented last summer, the group outlined the process they used to identify exposure and risk associated with the phthalates they studied. Instead of using a typical and scientifically accepted method to develop the hazard index (HI) of the cumulative effects of phthalates, the group developed a new and “novel” process not vetted in any other scientific arena.<sup>3</sup> Even the Environmental Protection Agency (EPA), which deals with chemical hazards on a daily basis, has yet to identify and adopt an appropriate cumulative risk model, and indeed is still exploring potential approaches; in 2013, the EPA issued a Request for Information on cumulative risk assessment models.<sup>4</sup>

The CHAP was given a broad charge and it is understandable that some data may not have been available; however, reaching conclusions based on available data and accepted methods, even if some uncertainty exists, is preferable to developing an un-reviewed process just to get to a number – *any* number, regardless of whether that number accurately reflects the risk.

While each step in this novel process has been seriously questioned by scientists in the field of toxicology and public health (and by the CHAP itself<sup>5</sup>), the end result is a public policy recommendation by the CHAP and endorsed in the proposed rule that essentially declares if toys and child care articles contribute even a minute amount to overall phthalates exposure, then products containing those phthalates should be banned. This is a recipe for ineffective regulation – if exposure from toys and child care articles is negligible, as the CHAP report admits,<sup>6</sup> the proposed rule will impose costs on industry while not significantly impacting total population exposures.

Respondents are very concerned about the precedential impact adoption of a rule based on this extreme and untested cumulative risk assessment methodology by the Commission would have, not just for the CPSC but for all U.S. government policy makers and regulators.

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<sup>3</sup> CHAP Report, page 36 <http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf>

<sup>4</sup> EPA Federal Register Notice on RFI for Cumulative Risk Assessments  
<https://www.federalregister.gov/articles/2013/05/01/2013-10296/request-for-information-and-citations-on-methods-for-cumulative-risk-assessment>

<sup>5</sup> For example, the CHAP report notes (p. 73) that “lack of...data from the exposure characterizations completed by the CHAP for phthalates weakens the analyses that couple biomonitoring data to external exposure characterizations to define the percent contribution of children’s toys etc. to cumulative risk.”

<sup>6</sup> The CHAP report states: “Overall, food, beverages, and drugs via direct ingestion, *and not children’s toys and their personal care products*, constituted the highest phthalate exposures to all subpopulations...” (Emphasis in original).

## Data Used Not the Most Recent/Relevant

Another concern with the CHAP process is that the CHAP chose to use data that was not the most up-to-date, nor the most relevant to the issue at hand. Section 108 (2)(B)(v) of the CPSIA requires that the CHAP “review all relevant data, including *the most recent*, best-available, peer-reviewed, scientific studies. In our opinion, the CHAP failed to follow this mandate. Other government agencies, chemical companies, and end users like toy and child care article manufacturers, are constantly studying and reviewing data on exposure from their products. Because of this, studies are also constantly being developed and updated. But it is our understanding that more current data was not included by the CHAP in its analysis even when it was available.

The CHAP began their work in April of 2010 and met several times until their last public meeting held in June of 2012. The group studied CDC National Health and Nutrition Examination Survey (NHANES) data on phthalates from 2005-2006 (publically available February 2010) when more recent and relevant NHANES data was available to the group from 2007-2008 (publicly available October 2010). It is puzzling why the group did not use the most recent data. If more recent data had been used, the group would have noticed a decline in human phthalate exposure which would have impacted the final report’s assessments of cumulative risk.

The CHAP report also relied on lab animal studies of questionable relevance to humans since it has been well demonstrated that lab animals (typically rats) metabolize phthalates very differently than humans. These studies also typically involve extremely high levels of phthalates administered via routes, and at exposure levels, that are unlikely or even impossible to receive from consumers’ use of toys, child care articles, or other consumer products. In fact, dating back to 1998, the CPSC itself has extensively studied the potential absorption by consumers of phthalates from toys and found that mouthing of toys, considered to be the primary route of exposure, causes little exposure to children and that DINP in particular “poses a minimal to non-existent risk of injury.”<sup>7</sup>

Even if the CHAP did not consider the most recent and relevant data, the Commission had the opportunity to do so. Therefore, it is even more unfortunate that the Commission chose not to direct CPSC staff to utilize this more recent data when preparing the staff package and proposed rule for the Commission’s consideration.<sup>8</sup> In fact, the discussion from the Commission’s decisional meeting on the proposed rule seems to indicate that the CPSC staff was directed to not utilize this more recent data in calculating the HI for the phthalates recommended to be banned. We question the rationale behind this decision. Had the more recent NHANES data been utilized, it could well have affected the recommendations regarding

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<sup>7</sup> The CHAP commissioned in 1998, concluded “there may be a DINP risk for any young children who routinely mouth DINP-plasticized toys for 75 minutes/a day or more. For the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury.”

[http://www.ipema.org/news\\_articles/05/CPSC\\_Exec\\_Summary\\_%20PVC.pdf](http://www.ipema.org/news_articles/05/CPSC_Exec_Summary_%20PVC.pdf)

<sup>8</sup> December 17, 2014 Decisional Matter on Phthalates Notice of Proposed Rulemaking

<http://www.cpsc.gov/en/Newsroom/Multimedia/?vid=71311>

banning the phthalates set forth in the proposed rule. Given the significance of this rulemaking, Respondents strongly suggest that the newer data be utilized by the agency in developing and proposing any final rule.

### **DINP Ban is Based on Faulty Reasoning**

The CHAP clearly stated that the main hazard with DINP was a cumulative risk if combined with other antiandrogenic phthalates, most conspicuously DEHP. DEHP has been banned in toys since 2008 and in teething rings, rattles and pacifiers since 1995. Therefore, we found it counterintuitive that the CHAP recommended to permanently restrict DINP (and the rule would codify the restriction).

This CHAP recommendation for a permanent restriction on DINP appears to be based solely upon an alleged cumulative antiandrogenic effect with other antiandrogenic phthalates despite the fact that, as the CHAP admits, DINP's antiandrogenic activity is weak<sup>9</sup>. This purported cumulative effect also depends on presence of other phthalates with which DINP could act in concert, but these other phthalates are also recommended for permanent bans so the possibility of a cumulative risk from toys and child care articles does not exist. If the concern with regard to DINP is its interaction and combination with already banned phthalates, where could the exposure come from with those substances already eliminated from the marketplace? Additionally, the CPSC science staff confirmed that DINP would not present a hazard on its own to consumers because the margin of exposure is minimal, at best, and does not represent a safety hazard.<sup>10</sup>

### **Lack of Openness in Process**

In addition to what Respondents believe to be the use of flawed scientific methodology, the CHAP process itself, especially with regard to the peer review of the draft CHAP report, was also deficient and not in keeping with established procedures for governmental science reviews. The peer review process was essentially conducted in secret, and without the benefit of public review of, or input on, the peer reviewers' comments.

Typically when CHAPs, or any other scientific body of this nature, are formed to develop findings for the U.S. government, they are required to adhere to the 2004 Office of Budget and Management's (OMB) Final Information Quality Bulletin for Peer Review.<sup>11</sup> That bulletin outlines a process which requires openness and transparency in the development of scientific findings. This includes a peer-review period where other scientists, not involved in the CHAP

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<sup>9</sup> Section 5.3.2.5 Page 99 of the CHAP report <http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf>

<sup>10</sup> Staff Briefing Package, page 43

<http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2015/ProposedRule-Phthalates-112514.pdf>

<sup>11</sup> OMB's Final Information Quality Bulletin for Peer Review

<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf>

process, review the group’s findings, while at the same time allowing members of the public to review them. In part, the OMB bulletin states:

Peer review should not be confused with public comment and other stakeholder processes. The selection of participants in a peer review is based on expertise, with due consideration of independence and conflict of interest. Furthermore, notice-and comment procedures for agency rulemaking do not provide an adequate substitute for peer review, as some experts - especially those most knowledgeable in a field - may not file public comments with federal agencies. The critique provided by a peer review often suggests ways to clarify assumptions, findings, and conclusions. For instance, peer reviews can filter out biases and identify oversights, omissions, and inconsistencies. Peer review also may encourage authors to more fully acknowledge limitations and uncertainties. In some cases, reviewers might recommend major changes to the draft, such as refinement of hypotheses, reconsideration of research design, modifications of data collection or analysis methods, or alternative conclusions.

We believe that if this process had been followed, issues related to the timeliness and relevance of the data would have been raised and corrected, and as a result, the CHAP and the CPSC may very well have come to different conclusions from considering timely and relevant data. Members of the scientific community and industry can provide a wealth of knowledge in their fields of expertise and give necessary perspective and review. The CHAP report would have benefited from this type of review process and might have avoided the lack of confidence its final report has engendered, absent such review.

Some members of the scientific community have also voiced concerns with the report, despite the fact that their input has not been formally solicited under peer review. As reported in The Hill, Christopher Borgert, president and principal scientist at Applied Pharmacology & Toxicology Inc. has said of the report, “For myself personally, I would say while I’m not weighing in on regulation or policy, I find a weak scientific basis for doing anything from this report.”<sup>12</sup> If public and peer-review had been conducted, Mr. Borgert and others would have been given the opportunity to review the data before the CPSC embarked on rulemaking, and this NPR would likely have looked very different.

### **Expansion of the Rule/Effective Date**

The proposed rule would expand the current ban on DINP from only accessible components of “toys that can be placed in a child’s mouth”<sup>13</sup> (determined to be those with any physical dimension of less than five centimeters) to *all toys and child care articles*, and would likewise extend the new ban on four additional phthalates to *all toys and child care articles, both regardless of mouthability*. If the Commission’s final rule is in fact intended to be based on risk

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<sup>12</sup> The Hill news story <http://thehill.com/regulation/233154-report-being-used-to-draft-plastics-rule-is-flawed-scientists-say>

<sup>13</sup> CPSIA Section 108 (b)(1) <http://www.cpsc.gov//PageFiles/129663/cpsia.pdf>



of exposure to phthalates from toys and child care articles, then there exists no real basis to expand the ban beyond only mouthable toys and child care articles, which Congress clearly intended the ban to be limited to with respect at least to the interim-banned phthalates, including DINP.

With regard to the effective date of any final rule on phthalates (and associated testing requirements), Respondents urge the Commission to give regulated entities ample time to respond to the rule by providing an effective date of at least one year from finalization of the rule.<sup>14</sup> This not only would be fair, but is consistent with past CPSC practice. While it is true that manufacturers, retailers and other in the supply chain now typically test for the presence of regulated phthalates in toys and child care articles, there are testing and other issues with regard to the identification and differentiation of phthalates that industry should be given time to address prior to being held liable for any violations of the new, final rule.<sup>15</sup>

### **Testing Impact**

According to the information we have received from our members, which include several CPSC accredited testing labs, the changes to this rule will not have a large financial impact on testing costs, however any increase could be detrimental to small toy companies. Phthalate testing can be done once to determine which phthalates are present. Nevertheless, testing to determine the exact formulation of the phthalates present, or not present, in the material tested will increase costs.

Most toy and child care manufacturers and retailers have already phased out use of or have never used the banned phthalates listed in the rule. Nevertheless, at this time while we wait for the Commission to grant material exclusions for the phthalate standard, testing to determine their absence is still required even for materials known to not contain phthalates. The NPR deregulates two phthalates, but does however add four new phthalate alternatives that will now require testing, and this will increase the cost of testing. Any increase, especially for small companies, could be significant for an industry already burdened heavily by testing and compliance costs.

We therefore again call on the Commission, in addition to its considerations of the comments raised on this phthalates NPR, to issue determinations for materials that are known not to contain the regulated phthalates so that industry does not have to test these materials unnecessarily.

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<sup>14</sup> We would also note that Section 5(c) of Public Law 112-28 (CPSIA amendments) could be interpreted to provide for a retroactive application (back to 2011) of any final phthalates rule, which would of course be an absurd result. Therefore, we urge the Commission to clarify this in the final rule.

<sup>15</sup> Note in this regard that Respondents understand that DIDP and DINP are sometimes difficult to differentiate when undertaking phthalates testing, which is not presently a significant issue since both are banned under law. If the ban on DIDP were to be lifted and the ban on DINP maintained, this may become a barrier to full compliance, one that laboratories will need time to address before the final effective date of the rule.

## Conclusion

We would urge the agency to use caution when moving forward with a rule that is not based on scientifically sound methods, uses data that is obsolete or of questionable relevance, and did not employ transparent review procedures required for major government scientific studies of this kind.

It is unfortunate that toys and child care articles have been caught in the net of being considered “high risk products” for exposure to phthalates when evidence has not supported this label. Even the CHAP agreed that toys and child care articles do not present a risk of exposure for phthalates.<sup>16</sup> Despite this, manufacturers and retailers have and will continue to take all necessary steps to ensure that all toys and child care articles sold to U.S. consumers are safe for children.

We understand the agency’s mandate from Congress to promulgate a rule based on the CHAP’s findings within a short timeframe, but we urge the CPSC to be prudent when regulating chemicals in toys or other consumer products where the science has proven little, to no actual risk is present.

Thank you again for the opportunity to provide comments. If you have any additional questions, comments or concerns, please contact any of the undersigned or Autumn Moore at [amoore@toyassociation.org](mailto:amoore@toyassociation.org) or 202.459.0350.

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<sup>16</sup> CHAP report Executive Summary, Page 3 <http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf>