



NATURAL RESOURCES DEFENSE COUNCIL

**Comments from the Natural Resources Defense Council to the
Consumer Product Safety Commission on the Proposed Rule:
Prohibition of Children's Toys and Child Care Articles Containing
Specified Phthalates**

ID: CPSC-2014-0033

April 15, 2015

BACKGROUND

The Natural Resources Defense Council ("NRDC") is a national, non-profit environmental organization of lawyers, scientists, and other professionals. NRDC presents these comments on behalf of our 1.4 million members and online activists. NRDC does not have any financial interest in the topic of these comments.

Phthalates are a family of chemicals used mostly as plasticizers in a large number of consumer products including in food contact applications. Many members of the phthalate family are associated with human health effects and have been shown to cause multiple health problems in laboratory animals.

Due to the widespread human exposure and concerns about public safety, especially for young children and the unborn, both European and American governments banned the use of certain phthalates in toys and child care products in the years 2006 and 2008, respectively. Since then, the strength of the evidence supporting those bans has only increased.

RECOMMENDATIONS

We support CPSC in the following:

- Maintain current ban on DBP, BBP, and DEHP.

- Permanently ban four additional phthalates: DIBP, DPENP, DHEXP, and DCHP.
- Make permanent the interim ban on DINP.

Additionally, we recommend the following:

- Extend the permanent ban to include DNOP and DIDP (now subject to an interim ban), due to concerns of the CHAP regarding the developmental toxicity of these two phthalates.
- Permanently ban DIOP.
- Continue to review and monitor DMP, and urge other relevant federal agencies to do the same.
- Recommend that the appropriate agencies take action to reduce exposure to DEP due to reproductive and developmental toxicity including antiandrogenic effects, and evidence of human exposure.
- Continue to collect toxicity and exposure information for DPHP, and urge other relevant federal agencies to do the same.

Maintain current ban on DBP, BBP, and DEHP

We support the CPSC's proposed rules to continue the current ban on DEHP, DBP, BBP, and to extend the ban to DINP based on the findings and conclusions stated in the report of the Chronic Hazard Advisory Panel (CHAP). These proposed rules following the CHAP recommendations, are in line with CPSIA Section 108(b)(2)(B)(iii) which directed the CHAP to "examine the likely levels of children's, pregnant women's, and others' exposure to phthalates based on a reasonable estimation of normal and foreseeable use and abuse of such products." The CHAP's thorough and transparent scientific evaluation was supported by the panel's description of its rationale for methods selection and understanding of its responsibility to draw conclusions about future uses and health effects.

In the US, the permanent ban of di(2-ethylhexyl) phthalate (DEHP), butylbenzyl phthalate (BBP) and di-n-butyl phthalate (DBP) has had a positive impact by greatly reducing people's exposures to these three phthalates.¹ Unfortunately, the banned phthalates have been replaced by others whose exposure in the last 10 years has more than doubled.²

Permanently ban five additional phthalates: DINP, DIBP, DPENP, DHEXP, and DCHP

The Natural Resources Defense Council supports the bans proposed by the CHAP on DINP, DIBP, DPENP, DHEXP, and DCHP (all permanent) and the proposed rules developed by the Consumer Product Safety Commission (CPSC). NRDC believes that strong regulation of these hazardous chemicals will help to protect vulnerable populations.

The addition of permanent bans of DINP, DIBP, DPENP, DHEXP and DCHP – as recommended by the CHAP (CHAP report page 22) - shown to cause adverse health problems, especially in males, for uses in toys and child care products, will contribute to their exposure decline and hopefully promote innovation for safer alternatives.

Extend the permanent ban to include DNOP and DIDP

NRDC also requests the Commission to revise the proposed rule to make the interim bans on DIDP and DNOP permanent. The CHAP reported on developmental and systemic toxic effects caused by these chemicals in animal studies. Given these concerns, the interim bans should be made permanent to protect vulnerable populations, because these phthalates cannot otherwise meet the reasonable certainty of no harm safety standard.

For both DNOP and DIDP the CHAP recognized the concern with systemic and developmental toxicity and therefore recommended that exposures through food and child care products be addressed (CHAP at 95, 104). Developmental toxicants should not be ingredients in children's toys and child care articles.

The CHAP concluded that DNOP is a 'potential developmental toxicant, causing supernumerary ribs, and a potential systematic toxicant, causing adverse effects on the liver, thyroid, immune system, and kidney' (CHAP at 94, 95). The CHAP also recognized that the developmental toxicity dataset was limited and more study was needed.

The CHAP concluded that DIDP was a 'probable toxicant' based on reproductive and developmental effects, and adverse systemic effects on the liver and kidney (CHAP at 104). Scientific studies of DIDP reported developmental effects such as supernumerary ribs, and also multigenerational effects of reduced survival of second generation offspring of exposed rodents (CHAP at 102-103). The CHAP also reported on one study suggesting that DIDP did possess antiandrogenic activity (CHAP at 101).

Consumers are exposed to DIDP through food, food packaging, clothing, and children's vinyl toys. Human exposure to DIDP is measured in the NHANES biomonitoring data and estimated for vulnerable populations by the CHAP (CHAP at 55, 104). The CHAP concluded that most exposure to DNOP for women and children is also from food, but that for infants and toddlers the greatest potential source of exposure was likely child care articles (CHAP at 94).

Unfortunately, the CHAP recommended lifting the current interim bans on both DNOP and DIDP because they did not appear to possess antiandrogenic potential and therefore wouldn't likely contribute to the cumulative risk of antiandrogenic toxicity from phthalates. However, due to evidence of developmental and systemic toxicity, the CHAP also recommended that the government agencies address exposures from food and child care products.

The CHAP used a Margin of Exposure (MoE) method to assess the risk from DIDP and DNOP. Because several of these phthalates have another similar adverse health impact, it is conceivable that there could be a cumulative impact from exposures to a mixture of DINP, DNOP and DIDP, which would enhance the concern about harm.

The CPSC's mandate obligates it "to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals." 15 U.S.C § 2057c(b)(3)(A) . We believe that DIDP and DNOP cannot be assumed to meet the safety standard due to concerns of developmental and systemic toxicity, and exposure to infants, toddlers, and women of reproductive age. Without enough data to conduct a robust risk assessment, NRDC is concerned that lifting the ban on DNOP and DIDP will lead to elevated exposure to these two phthalates as others are banned, posing an uncalculated risk to the population. This raises questions as to whether these chemicals can meet the safety standard of "reasonable certainty of no harm" as defined in Section 108 of the Act.

Permanently ban DIOP

NRDC supports the CHAP recommendation of an interim ban of DIOP due to its isomeric structure that suggests it is “within the range of structure-activity characteristics associated with antiandrogenic activity” (CHAP at 133). Although there is a lack of exposure data for DIOP and human exposure “appears to be negligible” according to the CHAP report, the structure-activity relationships suggest toxicity. NRDC understands that the CPSIA does not provide CPSC a mandate for interim bans. However, we are requesting that the Commission comply with the current statutory mandate “to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals.” 15 U.S.C § 2057c(b)(3)(A) . We believe that DIOP cannot be assumed to meet the safety standard due to the lack of hazard and exposure data necessary to calculate risk to human health.

Continue to review and monitor DMP, and urge other relevant federal agencies to do the same.

NRDC urges CPSC to continue to review and monitor DMP, and urge other relevant federal agencies to do the same. This is consistent with recommendation of the CHAP that identified an incomplete dataset, and some evidence of toxicity liver toxicity and other systemic effects (CHAP at 106).

Recommend that the appropriate agencies take action to reduce exposure to DEP

NRDC urges CPSC to recommend that the appropriate agencies take action to reduce exposure to DEP due to some evidence in humans of reproductive and developmental toxicity including antiandrogenic effects, and evidence of human exposure. This is consistent with the recommendations of the CHAP that identified an, “urgent need to implement measures that lead to reductions in exposures, particularly for pregnant women and women of childbearing age” (CHAP at 109).

Continue to collect toxicity and exposure information for DPHP, and urge other relevant federal agencies to do the same

NRDC urges CPSC to continue to collect toxicity and exposure information for DPHP, and to urge other relevant federal agencies to do the same. The CHAP found that it had very little hazard data, and that its production has rapidly increased in recent years, suggesting that human exposures are also likely to continue to increase as DPHP replaces other linear phthalates as a plasticizer (CHAP at 120-121).

The recommendations of the CHAP, the CPSC proposed rule, and NRDC’s position are summarized in the following table:

Table 1: Summary of recommendations

Current	CHAP (2015)	CPSC (2015)	NRDC
<i>banned</i>			
DBP	ban (antiandrogenic)	ban (no action)	agree
BBP	ban (antiandrogenic)	ban (no action)	agree
DEHP	ban (antiandrogenic)	ban (no action)	agree
<i>interim banned</i>			
DNOP	lift ban (developmental and systemic tox)	lift ban	ban

DINP	ban (antiandrogenic)	ban (make permanent)	agree
DIDP	lift ban (probable syst, repro, dev tox)	lift ban	ban
not banned			
DMP	no action (lack of data)	no action	Continued review and monitoring
DEP	no action (dev and repro tox; antiandrogenic; exposures from non-CPSC products)	no action	Urge appropriate agencies to take action to reduce exposure
DIBP	ban	ban	agree
DPENP	ban	ban	agree
DHEXP	ban	ban	agree
DCHP	ban	ban	agree
DIOP	interim ban (suggestive antiandrogenic)	no action	ban
DPHP	unable to determine (lack of data)	no action	CPSC and other appropriate agencies continue to collect tox and exposure info

ADDITIONAL COMMENTS

The CPSC proposal is consistent with international regulatory actions on phthalates

In 2006, the European commission enacted regulation 1907/2006³ establishing the restriction for six phthalates⁴ used in toys and child care articles⁵ at levels higher than 0.1% by mass of the plasticized material. The restricted phthalates are DEHP, DBP, BBP, DINP, DIDP and DNOP. The regulation also established a re-evaluation of their safety by 2010 “in the light of new scientific information on such substances and their substitutes, and if justified, these measures [restrictions] shall be modified accordingly.” It is worth noting that DEHP, DBP and BBP are also classified as reproductive toxicants category 1B.⁶

The 2010 scientific review concluded that the restrictions then in place for the six restricted phthalates - DEHP,⁷ DBP⁸, BBP⁹, DINP¹⁰, DIDP¹¹ and DNOP¹² - did not need re-examination. However, the report indicated the need for in-depth further assessment to ensure conclusions were based on best available information for each of the latter three chemicals. The 2013 European Chemicals Agency (ECHA) review of DINP and DIDP¹³ concluded a risk from these chemicals “cannot be excluded if the existing restrictions were lifted.” The risk assessment was conducted for each chemical individually. The panel concluded that “DINP has antiandrogenic properties and it could be appropriate to include this substance in a combined risk assessment of phthalates with antiandrogenic properties.”¹⁴

This conclusion is in agreement with the CHAP approach to cumulative risk assessment by grouping DEHP, DBP, BBP, DIBP and DINP based on their antiandrogenic properties.

The CHAP assessment complied with its statutory requirements to consider impacts on children.

Section 108(b)(2) of the CPSIA requires the CHAP to:

“complete an examination of the full range of phthalates that are used in products for children and shall—

- (i) examine all of the potential health effects (including endocrine disrupting effects) of the full range of phthalates;
- (ii) consider the potential health effects of each of these phthalates both in isolation and in combination with other phthalates;
- (iii) examine the likely levels of children’s, pregnant women’s, and others’ exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of such products;
- (iv) consider the cumulative effect of total exposure to phthalates, both from children’s products and from other sources, such as personal care products;
- (v) review all relevant data, including the most recent, best-available, peer-reviewed, scientific studies of these phthalates and phthalate alternatives that employ objective data collection practices or employ other objective methods;
- (vi) consider the health effects of phthalates not only from ingestion but also as a result of dermal, hand-to-mouth, or other exposure;
- (vii) consider the level at which there is a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals and their offspring, considering the best available science, and using sufficient safety factors to account for uncertainties regarding exposure and susceptibility of children, pregnant women, and other potentially susceptible individuals; and
- (viii) consider possible similar health effects of phthalate alternatives used in children’s toys and child care articles.”

The CHAP complied with these directives by:

1) Finding potential health effects:

The CHAP focused its cumulative risk assessment on male developmental toxicity chiefly due to the extent and quality of the animal and human data available compared to other endpoints, consistent with the 2008 National Research Council (NRC) report on phthalates.¹⁵ We support their recommendation and CPSC’s proposed rule to permanently ban DINP, DIBP, DPENP, DHEXP and DCHP (CHAP at 21, 22). The CHAP examined the health effects of each of these phthalates both in isolation and in combination with other phthalates. We appreciate the detailed description of their assessment and descriptive rationale for selection of methods.

Table 2: Phthalates reviewed by CHAP grouped by toxicity effects

Phthalate	Male reproductive toxicity	Other developmental toxicity	Other toxicity endpoints
DBP	Yes	Not described in CHAP report	
BBP	Yes	Fetal growth lethality and teratogenicity. Many developmental abnormality including fused ribs and reduced rib size, cleft palate, exencephalia and spina bifida	
DEHP	Yes	Malformations, intrauterine death and developmental delays	
DINP	Yes	Effects on developing skeletal system and kidney; effect on fetal	Also showed systemic toxicity including effects in liver and

		growth	kidneys, mononuclear cell leukemia
DIBP	Yes	Not described in CHAP report	
DEP	Evidence in humans, not in animals	Increased incidence of skeletal defects (rudimentary ribs)	Also showed reproductive toxicity in females including increase in the age of vaginal opening in F1 offspring; absolute and relative uterus weight in F2 weanlings; shortened gestation length in F1 parental females
DNOP	Unlikely	Increase in the incidence of supernumerary ribs	Also showed systemic toxicity including increase in liver and kidneys weight; irreversible nephropathy; decrease in T4 and increase in T3 hormone levels; reduced thyroid follicle size; altered liver enzymes
DIDP	Unlikely	Increases in fetal skeletal variations including rudimentary or supernumerary cervical and lumbar ribs.	Also showed systemic toxicity including increase in liver and kidneys weight; increase serum triglycerides and cholesterol; histological changes in the liver; multigenerational studies show decreased F1 and F2 pup survival at birth and up to weaning; decrease in body weight in F2 pups.
DPENP ¹	Likely	Unknown ¹	
DHEXP ²	Likely	Unknown	
DCHP	Likely	Unknown	
DIOP	No published studies	Higher incidence of soft tissue abnormalities (intraperitoneal route of exposure considered not relevant)	
DPHP	No published studies. Preliminary industry study showed 25% decreased in sperm velocity	No published studies. Preliminary industry study showed increased incidence of soft tissue variations (dilated renal pelvis)	
DMP	Unlikely	Increase incidence of skeletal defects	
¹ Only two studies; reports of reducing fetal testicular testosterone production. CHAP describes its hazard as “among the most potent phthalates regarding developmental effects.” ² CHAP describes DHEXP as “a reproductive toxicant with a profile similar to DEHP.”			

2) Considering the cumulative effect of total exposure to phthalates and conducting a cumulative risk assessment.

We support the CHAP’s assessment of cumulative effects. The extensive scientific literature and empirical analysis provided by the 2008 NRC report on phthalates¹⁶ clearly documented that for chemicals such as endocrine disrupting phthalates, the health effects of mixtures is greater than the

effect of individual phthalates. It cannot be ruled out that total exposure to all phthalates, or phthalates and other substances, could raise human health concerns.

The NRC report on phthalates and the ECHA Committee on Risk Assessment¹⁷ agree that the risk assessment of phthalates should evaluate and account for chemicals affecting a similar endpoint, in this particular case, male reproductive development due to antiandrogenic effects. It is scientifically sound to calculate the cumulative risk posed by DEHP, DBP, BBP, DIBP and DINP since all cause antiandrogenic effects. The methodology used by the CHAP in its cumulative risk assessment is not new. It is a well understood and science-based approach also used by other regulatory agencies.¹⁸

However, the NRC phthalates report also recommended that cumulative risk assessments should be completed for groups of chemicals that have the “same common adverse outcomes” (NRC phthalates report at 11). For example, phthalates and other chemicals can result in the feminization of a developing male fetus, but have different mechanisms of action; some chemicals mimic estrogen, while others block the androgen hormone receptor; still others affect the levels of androgens (such as testosterone) in the blood. The NRC report discussed the rationale for considering mixtures of chemicals that influence a similar endpoint even if via different mechanisms. “For cumulative risk assessment, the committee strongly recommends that EPA group chemicals that cause common adverse outcomes and not focus exclusively on structural similarity or on similar mechanisms of action.” (NRC phthalate report at 9) NRC’s recommendations pertain to phthalates such as DNOP and DIDP that have liver toxicity or other systemic toxicity by whatever mechanism.

We support the CPSC’s proposed rules to ban DEHP, DBP, BBP, DIBP and DINP based on the best contemporary scientific evidence and methods available. Conducting cumulative risk assessment for chemicals, in general, and those used in consumer products and food, in particular, is overdue as it was stated in the NRC report *Science and Decisions: Advancing Risk Assessment*,¹⁹ Far from being a “novel and unproven” regulatory tool, as alleged by the chemical industry, cumulative risk assessment has been used for over 15 years by the Environmental Protection Agency (EPA)²⁰ in its assessment of pesticides with similar mechanisms of action as mandated by the Food Quality Protection Act of 1996.

3) *Considering whether there is reasonable certainty of no harm to pregnant women and children:*

The CHAP used the hazard index (HI) to identify vulnerable populations at risk of adverse effects due to exposure to phthalates. Simply put, HI is a ratio between exposure (i.e. estimated daily intake) and acceptable dose (i.e. intake deemed acceptable for the same period of time). An HI greater than 1 indicates that there is concern for adverse health effects in the exposed population. In other words, an HI greater than 1 means that there is no longer reasonable certainty of no harm.

In the cumulative risk assessment for DEHP, DBP, BBP, DINP and DIBP, the HI is the sum of each phthalate’s ratio of exposure estimate and acceptable dose (represented by each phthalate’s NOAEL selected from animal studies and uncertainty factors). Because each phthalate exposure to acceptable dose ratio is calculated individually, it takes into consideration differences in potency among the chemicals, as well as individual chemical exposure estimates.

The CHAP concluded that “roughly 10% of pregnant women in the United States” and “roughly 5% of infants” studied have HI values that exceed 1.0. These vulnerable populations must be protected from further harm. While DEHP is a strong contributor to the hazard index, the combined effects of these phthalates together are also driving the higher hazard index. As phthalates replace DEHP their

contribution to the HI will continue to grow – so phthalates that seem “safe” now may not be as their commercial uses increase.

Health effects other than male reproductive toxicity should also be considered

In its review of a large body of scientific evidence, the CHAP also highlighted additional toxicology endpoints affected by phthalates exposures. These included skeletal malformation and toxicity to the liver, kidney and female reproductive system (see Table 2). It is worth noting that this developmental and systemic toxicity was caused by exposure to a) DNOP and DIDP, whose interim ban the CHAP recommended lifting; b) DEP, a chemical the CHAP recommended receive additional study but not a ban; and c) DINP, recommended to be permanently banned due to its antiandrogenic properties. We believe these are serious health concerns that should also be addressed.

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 (Table 2). While not within the scope of the CHAP report, the fact that several of these phthalates have another similar adverse health impact, it is conceivable that there could be a cumulative impact from exposures to a mixture of DINP, DNOP and DIDP, which would enhance the concern about harm. Finally, lifting the ban on DNOP and DIDP, as the proposed rule would, could result in increasing use and exposure, and therefore increasing risks, from the chemicals in the future. The uncertainty about their health effects raises questions as to whether these chemicals can meet the safety standard of “reasonable certainty of no harm” as defined in Section 108 of the Act.

Lack of data does not equal safety – avoid regrettable substitutions

The CHAP’s lack of recommendations for additional regulatory action on phthalates like DIOP, DMP, DEP, DPHP or many of the alternatives evaluated is not an endorsement of their safety. In most cases, the lack of sufficient hazard and exposure information – due to a dearth of scientific studies -- precluded the panel from making a recommendation. We encourage CPSC to follow the CHAP recommendations “that U.S. agencies responsible for dealing with exposures from food and other consumer products conduct the necessary risk assessments with a view to supporting risk management steps.” We recommend that CPSC work with sister agencies to fill data gaps and ensure that the use of these chemicals in food contact materials and other consumer products is truly safe.

Available evidence strongly supports the inclusion of DINP in the assessment

The CHAP inclusion of DINP in its cumulative risk assessment (together with DEHP, DBP, BBP and DIBP), which accounts for the increased use of DINP in consumer products, is consistent with the statutory mandate to consider “foreseeable use” of phthalates.

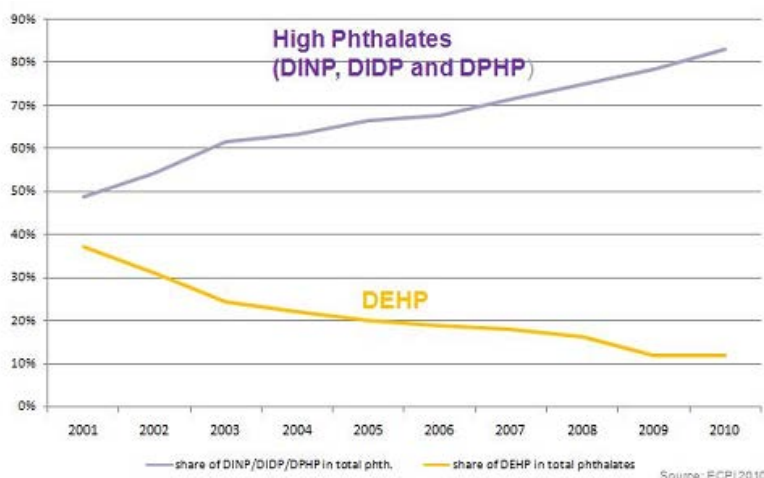
There are two fundamental reasons to include DINP: 1) it has antiandrogenic effects, therefore there is potential for hazard and cumulative risk; and 2) DINP exposure was the highest in infants (0-<1y), toddlers (1-<3y) and children (3-12y) among the eight phthalates measured.²¹ Both potential hazard and exposure estimates are required for risk determination.

The 2014 study of Zota *et al.*²² concluded that, “our analysis of biomonitoring data from a nationally representative sample suggests that US population exposure to phthalates has changed in the last

decade. While exposures to DnBP, BBzP, and DEHP have declined, exposures to replacement phthalates such as DiNP and DiBP have increased.” Regarding DINP, for instance, its urinary metabolite concentration increased more than 100% between 2001 and 2010.

In 2012, the European Chemical Agency reported a steady increase in the global market for DINP.²³ According to ECHA’s 2013 risk assessment of DINP and DIDP²⁴ “[t]he three phthalates DINP, DIDP and DPHP account for the majority of the C9/C10 phthalates both at global and at an EU level,” and “the consumption of DINP, DIDP and DPHP (di-2-propylheptyl phthalate), has increased from representing about 50% of total phthalate sales in Europe in 2001 to approximately 83% of the total sales in 2010.” The report was accompanied by a graph demonstrating the market shift from DEHP towards DINP, DIDP and DPHP since 2001.

Percentage of phthalates sales in Europe compared to other plasticizers²⁵



These market trends correlate with the biomonitoring data by Zota *et al.* which clearly demonstrate that there is more DINP and DIDP entering people’s bodies (Figure 2). Additional market data show that “the overall plasticizers demand is driven by the DOP [more commonly known as DEHP] and DINP/DIDP segment which collectively consumed almost three-fourth of the total global demand in 2013. DOP [DEHP] is the widely consumed low phthalate, whereas DINP/DIDP are the most consumed high phthalates.”²⁶ These data combined indicate that the increased exposure will contribute to increasing public health risk.

The overall scientific evidence supports the CHAP’s reasoning of including DINP in the cumulative risk assessment and its recommendation to permanently ban its use in children’s products.

SUMMARY

In summary, NRDC supports the proposed rule’s banning of the use of DINP, DIBP, DHEXP, DPENP and DCHP in all children’s toys and strongly encourages the Commission to finalize that portion of the rule in its current form. We would, however, urge the Commission to make the interim ban a permanent ban for DIDP and DNOP, and extend it to DIOP, due to concerns about developmental and systemic adverse effects.

NRDC commends the CHAP for producing an excellent report and the Commission for a fair and transparent process and it urges CPSC to move swiftly to finalize a proposed rule that will protect the health of our children.

Respectfully,



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¹ Zota A.R, Calafat A.M, Woodruff T.J. 2014. Temporal Trends in Phthalate Exposures: Findings from the National Health and Nutrition Examination Survey, 2001–2010. *Environ Health Perspect* 122:235–241

² *Ibid*

³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council. December 18, 2006.

⁴ Entries 51 and 52, Annex XVII, EC 1907/2006. Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles.

⁵ A “child care article” was defined as “any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.”

⁶ Annex XIV List of substances subject to authorization. Regulation (EC) No 1907/2006 of the European Parliament and of the Council. December 18, 2006. See <http://www.echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>

⁷ Evaluation Of New Scientific Evidence Concerning The Restrictions Contained In Annex XVII To Regulation (EC) No 1907/2006 (Reach). Review of New Available Information for bis (2-ethylhexyl) phthalate (DEHP). 2010

⁸ Evaluation of New Scientific Evidence Concerning The Restrictions Contained In Annex XVII To Regulation (EC) No 1907/2006 (Reach). Review of New Available Information for dibutyl phthalate (DBP). 2010

⁹ Evaluation of New Scientific Evidence Concerning The Restrictions Contained In Annex XVII To Regulation (EC) No 1907/2006 (Reach). Review of New Available Information for benzyl butyl phthalate (BBP). 2010

¹⁰ Evaluation of New Scientific Evidence Concerning The Restrictions Contained In Annex XVII To Regulation (EC) No 1907/2006 (Reach). Review of New Available Information for di-‘isononyl’ phthalate (DINP). 2010

¹¹ Evaluation of New Scientific Evidence Concerning The Restrictions Contained In Annex XVII To Regulation (EC) No 1907/2006 (Reach). Review of New Available Information for di-‘isodecyl’ phthalate (DIDP). 2010

¹² Evaluation of New Scientific Evidence Concerning The Restrictions Contained In Annex XVII To Regulation (EC) No 1907/2006 (Reach). Review of New Available Information for di-n-octyl phthalate (DNOP). 2010

¹³ Evaluation of new scientific evidence concerning DINP and DIDP. In relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. 2013

¹⁴ *Ibid*

¹⁵ Phthalates and cumulative risk assessment. The task ahead. National Research Council of the National Academy of Sciences. 2008.

¹⁶ Phthalates and cumulative risk assessment. The task ahead. National Research Council of the National Academy of Sciences. 2008.

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- ¹⁷ Evaluation of new scientific evidence concerning DINP and DIDP. In relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. 2013
- ¹⁸ Committee on Risk Assessment (RAC). Opinion on an Annex XV dossier proposing restrictions on four phthalates. 2012.
- ¹⁹ Science and Decisions: Advancing Risk Assessment. National Research Council of the National Academy of Sciences. 2009.
- ²⁰ Assessing Pesticide Cumulative Risk. U.S. Environmental Protection Agency. See <http://www.epa.gov/oppsrrd1/cumulative/>
- ²¹ CHAP report. Table 2.11, page 55; Figure 2.2, page 60
- ²² Zota A.R, Calafat A.M, Woodruff T.J. 2014. Temporal Trends in Phthalate Exposures: Findings from the National Health and Nutrition Examination Survey, 2001–2010. *Environ Health Perspect* 122:235–241
- ²³ Evaluation of new scientific evidence concerning DINP and DIDP. In relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. 2013
- ²⁴ Evaluation of new scientific evidence concerning DINP and DIDP. In relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. 2013
- ²⁵ *Ibid*
- ²⁶ Global Plasticizers (Low Phthalates, High Phthalates, and Non-Phthalates) Market - Trends and Forecasts to 2019. See <http://www.prnewswire.com/news-releases/global-plasticizers-low-phthalates-high-phthalates-and-non-phthalates-market---trends-and-forecasts-to-2019-300025371.html>