

# MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION

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**IN RE: CITIZEN PETITION TO DESIGNATE  
FOUR MEMBERS OF THE CHEMICAL CLASS  
PHTHALATES AS PRIORITY CHEMICALS**

*Filed by*

**2,071 VOTERS REGISTERED IN  
THE STATE OF MAINE,  
INCLUDING 125 STATE LEGISLATORS**

*and the*

**ALLIANCE FOR A CLEAN & HEALTHY MAINE,  
ENVIRONMENTAL HEALTH STRATEGY CENTER,  
ENVIRONMENT MAINE RESEARCH AND  
POLICY CENTER,  
MAINE HEALTHY CHILDREN'S PROJECT OF THE  
LEARNING DISABILITIES ASSOC. OF MAINE,  
MAINE LABOR GROUP ON HEALTH,  
MAINE ORGANIC FARMERS &  
GARDENERS ASSOCIATION,  
MAINE PEOPLE'S RESOURCE CENTER,  
MAINE WOMEN'S POLICY CENTER,  
PHYSICIANS FOR SOCIAL RESPONSIBILITY  
MAINE CHAPTER,  
PLANNED PARENTHOOD OF NORTHERN  
NEW ENGLAND, and the  
TOXICS ACTION CENTER.**

**CITIZEN PETITION TO  
INITIATE RULEMAKING  
TO DESIGNATE FOUR  
MEMBERS OF THE  
CHEMICAL CLASS  
PHTHALATES AS  
PRIORITY CHEMICALS**

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Filed May 14, 2014

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**PETITION FOR RULEMAKING TO DESIGNATE  
FOUR MEMBERS OF THE CHEMICAL CLASS  
PHTHALATES AS PRIORITY CHEMICALS.**

NOW COME 2,071 registered voters of the state of Maine, including a bipartisan group of 123 State Senators and State Representatives, together with the Alliance for a Clean and Healthy Maine, the Environmental Health Strategy Center, Environment Maine Research and Policy Center, Maine Healthy Children's Project of the Learning Disabilities Association of Maine, Maine Labor Group on Health, Maine Organic Farmers and Gardeners Association, Maine People's Resource Center, Maine Women's Policy Center, Physicians for Social Responsibility/Maine Chapter, Planned Parenthood of Northern New England and the Toxics Action Center, (together as "Petitioners") to petition the Commissioner of the Maine Department of Environmental Protection ("Department") pursuant to 5 M.R.S.A. § 8055 to initiate rulemaking to enact the state regulation entitled "*DESIGNATION OF FOUR MEMBERS OF THE CHEMICAL CLASS PHTHALATES AS PRIORITY CHEMICALS,*" 06-096 CMR ch. 888, to:

1. Designate four members of the chemical class phthalates as priority chemicals, including di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), and diethyl phthalate (DEP) (together as the "regulated phthalates");
2. Require manufacturers of certain consumer product categories that contain more than *de minimis* amounts of intentionally-added regulated phthalates to submit information to the department regarding which products contain regulated phthalates, the amount of and function of regulated phthalates in these products, and, if known, the availability of safer alternatives; and
3. Establish deadlines for reporting that are staggered by size of manufacturer based on the manufacturer's annual sales: 12 months for the largest manufacturers, 18 months for large manufacturers, 24 months for medium manufacturers and a date to be set by the Department, based on review of materials previously submitted, for small manufacturers.

The text of the proposed rule modification and signed petition, as verified and certified pursuant to 21-A M.R.S.A. § 354(7), have been submitted to the Department simultaneously with this Petition, with materials circulated during the petition drive attached as Appendix A.

## **I. SUMMARY**

The four phthalates nominated for designation as priority chemicals in this Petition are hormone-disrupting compounds that have been demonstrated by credible scientific evidence in more than one hundred peer-reviewed scientific studies to produce a constellation of severe and permanent adverse health effects, particularly during fetal development and early childhood. Each of these four chemicals is widely used in children's and consumer products sold in Maine. Each has have been found in the dust and the air in the home, work and school environments. And each has been found in human bodily fluids at high levels among the vast majority of participants sampled in Maine and throughout the country.

In light of the growing scientific consensus that high levels of exposure to these four phthalates are causing ongoing and present harm to children, there is a corresponding emerging consensus among regulators on the need to act. The European Union is preparing to phase out all use of three of these chemicals within the next 10 months; the U.S. Congress has banned them in certain toys and child care products; the U.S. Environmental Protection Agency (EPA) and the State of California have red-flagged these phthalates as chemicals of concern; and Washington State has required disclosure of use of these four phthalates in certain children's products.

Yet, despite these actions – which in the U.S. narrowly focus on phthalate restrictions in toys and child care products – very little is known about more significant sources of daily and higher-level exposure of our children to these chemicals from other common household products, furniture and building materials. Without disclosure of this information, Maine

consumers and retailers are without the knowledge necessary to protect their health and the Department is without the information to determine whether additional chemical management is necessary.

The proposed rule would provide unique information that is critical to advance research and protect our families' health, at very low cost to industry and to the state government. The proposed rule is crafted to exempt products for which phthalate content disclosures are currently available in the public domain. For other products, the proposed reporting rule would be phased in over two years, starting with the largest manufacturers. Reporting requirements are limited to information already known by and readily available to manufacturers. A one-time compliance fee will cover the minimal cost of administering this rule. Oversight of phthalate reporting can be easily integrated into the Department's existing priority chemical reporting procedures.

## **II. THE PETITIONERS**

This petition is brought by 2,071 registered Maine voters, including 125 State Senators and State Representatives who are Republicans, Democrats, and Independents that make up two-thirds of the Maine Legislature. The Petitioners reside in 168 cities and towns covering the breadth of Maine, from Kittery to Presque Isle, and from Farmington to Deer Isle. Petitioners reside in all 16 Maine counties from Aroostook to York.<sup>1</sup>

This petition is also brought by the following organizations:

The Alliance for a Clean and Healthy Maine ("ACHM") is a diverse coalition of Maine-based organizations working to protect human health by phasing out toxic chemicals that build up in the food web and our bodies. The Alliance believes that all Maine people have a right to a

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<sup>1</sup> See Appendix A. The signed petitions, as verified and certified pursuant to 21-A M.R.S.A. § 354(7), have been provided to the Department simultaneously with this petition.

healthy environment where they live, work and play; envisions a future free of exposure to harmful chemicals in air, water or food; and seeks to build a healthy economy that provides good jobs producing clean products and services. Since 2002, the Alliance has campaigned to replace dangerous chemicals (such as arsenic, mercury, lead, brominated flame retardants, and BPA) used in everyday consumer products with safer alternatives, and ensure the responsible collection and disposal of consumer products containing toxic chemicals. The Alliance actively supported passage and implementation of the Kid-Safe Products Act in 2008. Earlier this year, the Alliance tested 25 Mainers for exposure to phthalates and published a biomonitoring survey report, *Hormones Disrupted: Toxic Phthalates in Maine People*, which documented widespread exposure. A copy of the report can be found in Appendix F to this Petition.

Environmental Health Strategy Center (“EHSC”) is a nonprofit Maine corporation founded in 2002 with the purpose of promoting human health and safer chemicals in a sustainable economy. EHSC has 10,000 members and supporters and uses science-based research and advocacy to improve health through safer chemical policy reform at the federal and state levels. EHSC has worked for more than 10 years to support Maine policies and programs to replace dangerous chemicals - such as lead, mercury, brominated flame retardants, PVC, BPA, and others - in everyday consumer products with safer chemicals. EHSC led the campaigns in 2008 and 2011 to enact and defend Maine’s Kid-Safe Products Act, and is a founding member of the Alliance for a Clean and Healthy Maine. EHSC’s “Sustainable Economy” program promotes the design and manufacture of safer chemicals and products using "green chemistry" and supports economic development based on the sustainable production of renewable chemicals and bioplastics from Maine wood chips, potato waste, and other biomass.

Environment Maine Research and Policy Center is a nonprofit, membership organization dedicated to preserving Maine's wild places and natural beauty, improving air and water quality, reducing toxic threats in the environment and everyday products, and building a clean energy future. Environment Maine works on behalf of its more than 13,000 members and activists, including many who are deeply concerned about the health and environmental threats of toxic chemicals in everyday products. Environment Maine also is part of Environment America, a national federation of state-based environmental advocacy organizations, and joined the Steering Committee of the Alliance for a Clean & Healthy Maine in 2011. Environment Maine helped pass the 2012 Maine ban on BPA in baby food packaging, has worked at the state level to reduce the threat of pesticides, and has a long history of working to improve federal policy to protect the public and environment from toxic threats.

Maine Healthy Children's Project is a program of the Learning Disabilities Association of Maine (LDA-ME), a statewide nonprofit family organization founded in 1980 whose mission is to provide support, education and advocacy to individuals with learning and attention disabilities, their families and the professionals who work with them. LDA-ME seeks to reduce the incidence of these disabilities in future generations. According to a 2011 report issued by the U.S. Centers for Disease Control and Prevention, nearly 1 in 6 American children were diagnosed with a learning or developmental disability in 2008. The National Academy of Sciences estimates that environmental factors, including toxic chemicals, cause or contribute to at least a quarter of learning and developmental disabilities in American children. For more than 10 years, LDA-ME has strongly supported efforts to eliminate environmental factors that contribute to preventable disabling conditions, such as exposure to unnecessary toxic chemicals in everyday consumer products. The rapidly developing brain of the fetus, infant and young



child is much more susceptible to toxic substances than the adult brain and exposure to priority chemicals can have profound neurodevelopmental effects with lifelong consequences.

Maine Labor Group on Health (“MLGH”) is a statewide occupational safety and health organization that was founded in 1977. MLGH’s goal is to prevent harm to the health of Maine’s people where they work, live and play. According to the National Institute for Occupational Safety and Health (NIOSH), 4% to 10% of U.S. cancers (48,000 incident cases annually) are caused by occupational exposures.<sup>2</sup> Hazardous chemicals used in everyday consumer products expose workers and their families both at work and at home. Phasing out dangerous chemicals protects workers throughout the manufacturing and supply chain, and will help protect children and families at home. MLGH has played a role in passing Maine’s Right-to-Know law, Toxics Use Reduction Act, and the Kid-Safe Products Act.

Maine Organic Farmers and Gardeners Association (MOFGA), formed in 1971, is the oldest and largest state organic food organization in the country. MOFGA has members in more than 6,500 households and businesses in Maine and beyond. Its mission is to help farmers and gardeners grow organic food, fiber and other crops; protect the environment; recycle natural resources; increase local food production; support rural communities; and illuminate for consumers the connection between healthful food and environmentally sound farming practices. MOFGA tracks emerging science and public awareness about exposure to toxic chemicals through the food system. Through public policy initiatives, MOFGA focuses on human exposure to chemicals from the ubiquitous presence of chemicals in the water, air and soil; from the presence of chemicals in food packaging and distribution; and from the chemicals in food cultivation and processing.

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<sup>2</sup> See <http://www.cdc.gov/niosh/topics/cancer/>.

Maine People's Resource Center, (“MPRC”), along with its sister organization Maine People’s Alliance (“MPA”), has more than 33,000 members, and is Maine's largest grassroots community action organization and is dedicated to social, racial and environmental justice. MPRC’s/MPA's purpose is to bring individuals and organizations together to realize shared goals. MPRC/MPA focuses on leadership development to promote positive social change and is known for grassroots organizing and education. MPRC/MPA, through its civic campaigns, makes personal contact with more than 100,000 Mainers every year. MPRC/MPA advocates for responsible stewardship of our natural resources and a clean, toxic-free environment. MPRC/MPA has long led the fight to stop the spread of mercury pollution at the former HoltraChem plant in Orrington and to hold corporate polluters responsible across the state, and has also worked to make sure the products used by Maine people every day are safe for themselves, their children and the environment.

Maine Women’s Policy Center (“MWPC”) has worked since 1978 to advance women’s economic, social, and political equality – to the benefit of all Maine women and families. The MWPC has developed cutting-edge state policies around equal pay, domestic violence prevention, employment security, and more, while training women leaders to be active citizens in their communities. The Maine Women’s Policy Center partners with our sister organization, the Maine Women’s Lobby, to deepen the understanding of lawmakers, the media, and the public, of the issues facing women and girls in Maine. Our work in partnership with the Environmental Health Strategy Center and the Alliance for a Clean and Healthy Maine since 2006 has helped to bring an important population to the discussion about safe chemicals policy reform – women who care deeply about creating a safe home for their families, one free of harmful chemicals.

Physicians for Social Responsibility – Maine Chapter, (“PSR ME”) is a nonprofit advocacy organization that is the medical and public health voice for education and policies to prevent toxic degradation of the environment, to mitigate and adapt to climate change, and to prevent nuclear proliferation. PSR ME uses science-based medical research and advocacy to protect human health through education and policy reform at the federal and state levels. PSR ME has worked with the Alliance for a Clean and Healthy Maine to support policies and programs that protect human and environmental health. Through work with our Pediatric Toolkit and Toxic Teas, PSR ME has trained medical professionals throughout Maine to educate patients about toxics in everyday household products like baby bottles, food cans, personal products, and even medical supplies. PSR ME also reaches into the community with similar educational opportunities.

Planned Parenthood of Northern New England (“PPNNE”) educates young women about the threats of toxicants and brings young women’s voices to the environmental health movement. Last year, 78% of PPNNE’s 11,600 patients in Maine were under 30 year old. The goal of PPNNE’s environmental health program – and its participation in the Alliance for a Clean and Healthy Maine – is to improve and protect the health and fertility of the women and families of northern New England by decreasing their exposure to harmful contaminants in our environment.

Toxics Action Center works side by side with community groups and leaders who are facing a toxic pollution problem or threat at the local level. Many of the community members the Center works with are very concerned about their family's exposure to chemicals found in household products. In 2010, Toxics Action Center wrote and released a report entitled “The Latest Science on Bisphenol A, Health and Exposure.” In 2011, Toxics Action Center produced

a second report finding widespread support among Maine’s business community for chemical safety reform, titled “Safe Chemicals, Better for Business.”<sup>3</sup>

### III. STATUTORY AND REGULATORY FRAMEWORK

In 2008, the Legislature adopted *An Act to Protect Children’s Health and the Environment from Toxic Chemicals in Toys and Children’s Products* (hereinafter referred to as the “Kid-Safe Products Act” or “Act”)<sup>4</sup> establishing state policy “to reduce exposure of children and other vulnerable populations to chemicals of high concern” and “confer[ring] upon the department the regulatory power to collect information on chemical use and prohibit the sale of children's products containing priority chemicals when safer alternatives are available.” 38 M.R.S.A. § 1692.

To accomplish its goals, the law provides for a multi-step process to regulate toxic chemicals, starting with designation of chemicals of concern. *Id.* § 1693. From that list, the law authorizes the Commissioner to designate up to 70 chemicals of high concern (“CHC”), *id.* § 1693-A, and, from among the CHC list, priority chemicals which are present in human bodily fluids, the home environment, or in consumer products used in the home. *Id.* § 1694. Next, the law authorizes the Department of Environmental Protection to require reporting of priority chemical use in children’s products, as well as submission of additional information needed about the likelihood the chemical will be released from various products, the extent to which exposure created by that use is likely to occur, the presence of the chemical in the environment or human body, and an assessment of the availability of safer alternatives. *Id.* § 1695. Finally, the law confers upon the Board of Environmental Protection the power to prohibit the sale of

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<sup>3</sup> Reports available at <http://www.toxicsaction.org/how-we-can-help/information>.

<sup>4</sup> P.L. 2007, ch. 643.

children's products containing greater than *de minimis* levels of priority chemicals when distribution of the product exposes children and other vulnerable groups to the priority chemical, and safer alternatives are available at a comparable cost. *Id.* §§ 1692, 1696.

This Petition is focused on the middle step in the process. It seeks to elevate four phthalates listed as chemicals of high concern to the status of priority chemicals in order to provide information that is not presently publicly available but which is necessary to allow Maine families to protect their children from unnecessary exposure to phthalates in consumer products and to begin collection of information that can lead to the identification and use of safer alternatives.

A. STATUTORY AND REGULATORY CRITERIA FOR DESIGNATION OF PRIORITY CHEMICALS.

A chemical of high concern may be designated as a priority chemical if the Commissioner finds, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention, that:

- A. The chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids;
- B. The chemical has been found through sampling and analysis to be present in household dust, indoor air or drinking water or elsewhere in the home environment; or
- D. The chemical is present in a consumer product used or present in the home.

38 M.R.S.A. §§ 1694(1)(A),(B) & (D). *See also* 06-096 C.M.R. ch. 880, § 4(B) (same).

Recognizing that all CHCs “are likely to meet the prerequisites for designation as priority chemicals,” 06-096 C.M.R. ch. 880, § 4(C), the Department has established by rule that the intent of prioritizing one CHC over another is:

- (1) To facilitate the gathering of information on the use of the chemical in children's products<sup>5</sup> and the extent to which children may be exposed to the chemical as a result of that usage;
- (2) To facilitate the gathering of information on the safety and availability of alternatives to use of the chemical in children's products; and/or
- (3) To facilitate the consideration of a ban on the sale of children's products to which the priority chemical has been intentionally added when safer alternatives are available.

06-096 C.M.R. ch. 880, § 4(A). Accordingly, when determining whether to designate a priority chemical, the department's rules direct the Commissioner to consider all available and relevant evidence related to the need for and appropriateness of such regulatory action including but not limited to,

- (1) The need for additional information on the use of the chemical in children's product;
- (2) The extent to which the chemical is used in children's products and the likelihood that children will be exposed to the chemical as a result of its presence in children's products;
- (3) The need for information on the availability and safety of alternatives to the chemical;
- (4) Whether regulatory action is necessary and appropriate in light of actions taken or underway with respect to the chemical in other states and jurisdictions; and
- (5) Whether the department and Maine CDC have adequate financial and human resources to accomplish the tasks associated with designation of the priority chemical.

*Id.*, ch. 880, § 4(C).

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<sup>5</sup> A children's product is defined in the *Kid-Safe Product Act* as "a consumer product intended for, made for or marketed for use by children under 12 years of age... and any consumer product containing a chemical of high concern that when used or disposed of will likely result in a child under 12 years of age or a fetus's being exposed to that chemical." 38 M.R.S.A. § 1691(7). Food and beverage packaging is exempt, "unless that product is intentionally marketed or intended for the use of children under 3 years of age." *Id.* § 1697(8).

B. DISCLOSURE OF INFORMATION ON PRIORITY CHEMICALS.

Once a priority chemical is designated, a manufacturer or distributor of a children's product for sale in the State that contains the chemical in an amount greater than a *de minimis* level<sup>6</sup> must provide written notice to the department within 180 days (or within 30 days of sale of a new children's product) identifying: the children's product, the number of units sold or distributed for sale in the State or nationally, the priority chemical or chemicals contained in the children's product, the amount of such chemicals in each unit of children's product and the intended purpose of the chemicals in the children's product. 38 M.R.S.A. § 1695(1); 06-096 C.M.R. ch. 880, § 5(A).

If requested by the Department, the notice from the manufacturer or distributor must also provide the following:

- A. Information on the likelihood that the chemical will be released from the children's product to the environment during the children's product's life cycle and the extent to which users of the children's product are likely to be exposed to the chemical;
- B. Information on the extent to which the chemical is present in the environment or human body; and
- C. An assessment of the availability, cost, feasibility and performance, including potential for harm to human health and the environment, of alternatives to the priority chemical and the reason the priority chemical is used in the manufacture of the children's product in lieu of identified alternatives. If an assessment acceptable to the department is not timely submitted, the department may assess a fee on the manufacturer or distributor to cover the costs to prepare an independent report on the availability of safer alternatives by a contractor of the department's choice.

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<sup>6</sup> *De minimis* levels are defined, in the case of intentionally-added chemicals, as the "practical quantification limit" or, in the case of a chemical that is a "contaminant" present in a children's product or product component, a concentration of 100 parts per million. 38 M.R.S.A. § 1691(8-B). An intentionally-added chemical is defined as "a chemical that was added during the manufacture of a product or product component to provide a specific characteristic, appearance or quality or to perform a specific function." 38 M.R.S.A. § 1691(9-A).

*Id.* § 1695(2); 06-096 C.M.R. ch. 880, § 5(B).

The Commissioner may waive all or part of the notification requirement for one or more specified uses of a priority chemical if the commissioner determines that substantially equivalent information is already publicly available, that the information is not needed, or that the specified use or uses are minor in volume. 38 M.R.S.A. § 1695(3); 06-096 C.M.R. ch. 880, § 5(C). The department may extend the deadline for submission of the information if it determines that more time is needed by the manufacturer or distributor to comply with the submission requirement or if the information is not needed at that time. *Id.*

The department may assess a fee payable by the manufacturer or distributor upon submission of the notification to cover the department's reasonable costs in managing the information collected. 38 M.R.S.A. § 1695(3); 06-096 C.M.R. ch. 881.

#### **IV. STRONG AND CREDIBLE SCIENTIFIC EVIDENCE DEMONSTRATES THAT PHTHALATES ARE CAUSING ACTUAL AND PRESENT HARM TO HUMAN HEALTH.**

Of the 46 chemicals remaining on Maine's list of CHCs, the scientific evidence is particularly strong with regard to the four phthalates proposed for regulation. For these chemicals, there is a strong and growing body of credible scientific evidence demonstrating that the chemicals are causing *actual and present harm* to the health and development of our most vulnerable populations at current levels of human exposure.

Three lines of evidence are generally used in the field of toxicology to confirm a causal link between exposure to a dangerous chemical and adverse health effects in humans. Unlike most other chemicals on the CHC list, for the four phthalates proposed for regulation in this Petition there is extensive and credible scientific evidence demonstrating, under all three lines, that the chemicals pose a serious and present threat to human health. As summarized below and



as documented in the attached *Review of the Science on Toxicity and Exposure*<sup>7</sup> by Dr. Deborah Rice, a toxicologist retired from Maine Centers for Disease Control and Prevention, there is broad scientific and regulatory consensus that (1) the four regulated phthalates are known to cause adverse health effects in carefully controlled animal studies, (2) that those same adverse effects are found in epidemiological studies of phthalate-exposed human populations, and (3) the biological mechanisms that plausibly explain how phthalates cause those adverse effects are well documented.

A. THE FOUR REGULATED PHTHALATES THREATEN THE HEALTH OF MAINE CHILDREN DURING THEIR MOST VULNERABLE STAGES OF DEVELOPMENT.

Phthalates are a class of chemicals that may have multiple adverse health effects on human health. The weight of credible scientific evidence is the strongest, with all three lines of evidence established, for three categories of adverse health effects associated with exposure to phthalates: reproductive harm (especially birth defects of male reproductive organs), harm to brain development (leading to learning and behavior problems), and sensitization of the immune system (leading to asthma and allergies).

It is well established in biology that phthalates are hormone-disrupting compounds: that is, they interfere with the expression of androgens, including the male sex hormone testosterone, by influencing gene expression of enzymes and proteins involved in testosterone production. This may result in decreased fertility in adult males, as well as profound effects on the development of reproductive organs during prenatal development. During fetal development in mammals, testosterone is essential for the development of male sex organs. Phthalate exposure during this period produces a constellation of effects in male offspring in animal models,

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<sup>7</sup> Deborah C. Rice, Ph.D., *Review of the Science on Toxicity and Exposure* (March, 2014), attached as Appendix B.

including abnormal penile development, abnormalities of the sperm-producing structures, hypospadias (urethral opening on the underside of the penis instead of the tip), decreased anogenital distance (a marker of feminization), and cryptorchidism (undescended testes).<sup>8</sup>

Similar effects have been observed in human studies associated with prenatal exposure to specific phthalates. Shorter anogenital distance is associated with poor semen quality in young men (Mendiola et al., 2011),<sup>9</sup> as well as an increased risk for prostate cancer (Castaño-Vinyals et al., 2012). Cryptorchidism is associated with an increased risk of testicular cancer. Effects on sexual development in both boys and girls are associated with phthalate exposure during childhood. Reproductive effects such as decreased gestational age and increased pregnancy loss have also been observed in human studies.

A critical issue is the potential for phthalate exposure to affect intellectual performance and other aspects of behavior. Prenatal phthalate exposure in humans is associated with poorer psychomotor development during infancy, poorer cognitive performance during childhood, and poorer social behavior. Not surprisingly, prenatal phthalate exposure is associated with less masculine play behavior in boys. Childhood phthalate exposure is associated with decreased IQ and vocabulary scores, and increased adverse scores for measures of attention, impulsivity, and ADHD behaviors. Animal studies also document adverse behavioral effects following developmental phthalate exposure, and well as changes in brain neurochemistry. Possible mechanisms include suppression of maternal thyroid hormone during pregnancy; interference with calcium signaling (important for communication between nerve cells); interference with receptors on cells that are involved in multiple processes during embryonic development; and

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<sup>8</sup> *Id.*

<sup>9</sup> All research studies cited in this Petition are provided to the Department and Maine Center for Disease Control and Prevention in an electronic format on compact disc, attached hereto as Appendix F.

interference with normal lipid metabolism, which is crucial for brain development (Miodovnik et al., 2014).

Phthalates also adversely affect immune function. They produce specific pro-inflammatory effects in intact animals and *in vitro* (tissue culture or cell) systems. Phthalate exposure is associated with an increase in asthma, wheezing, and eczema in children, and an increase in inflammatory response in both children and adults.

B. DESPITE A GROWING INTERNATIONAL REGULATORY CONSENSUS TO ACT, CRITICAL INFORMATION IS STILL LACKING ABOUT WHICH PRODUCTS RESULT IN EXPOSURE TO THE REGULATED PHTHALATES.

The scientific consensus about the threat to human health is leading to a growing consensus for action among regulators. As shown in the policy and regulatory chart in Section VII(D) below, the European Chemicals Agency will completely phase out the use of three of the four regulated phthalates as substances of very high concern by February 2015, unless pending requests for certain exemptions are granted.<sup>10</sup> (*See* Ex. E-1.) The U.S. Congress, in the wake of widespread toy recalls from China, passed the Consumer Product Safety Improvement Act of 2008, which banned these same three phthalates in toys and child care products. 122 STAT. 3016 (*codified at* 15 U.S.C. § 2051, *et seq.*) (*see also* Ex. E-2.) The U.S. EPA has prioritized the same three phthalates (among others) for risk assessment and possible *future* regulation under Toxic Substances Control Act of 1976. (*See* Ex. E-3).

Similarly, in California, three of the regulated phthalates were listed under Proposition 65 (1986) as known to cause cancer and/or developmental toxicity, triggering generic warnings of exposure for products sold in California (Ex. E-4), and all four regulated phthalates are now

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<sup>10</sup> The three phthalates that will be banned in Europe as of February 2015 are DEHP, DBP, and BBP.

listed as “Candidate Chemicals” for possible future action to require evaluation of safer alternatives in priority products under the state’s new Safer Consumer Products Regulation. (Ex. E-5.) In Washington State, all four regulated phthalates have been named as Chemicals of High Concern for Children. This requires manufacturers to report chemical use in products intentionally marketed to children, but not in other consumer products. (Ex. E-6.)

Despite the growing international consensus that these four phthalates are a regulatory priority, major gaps in existing laws and regulations leave Maine children unprotected. Congressional action to ban phthalates from toys and child care products leaves untouched the more significant sources of daily household exposure to these chemicals from other common products. While the EPA and at least two other states have prioritized and red-flagged the four phthalates, none have the legal tools to further regulate these chemicals in a timely and effective manner.

Meanwhile, the European phase-out of use of three of the regulated phthalates – while demonstrating the magnitude of the threat – also poses a serious contradiction for Maine. Within one year, products containing those phthalates can no longer be sold in Europe but will still be sold in the U.S. and Maine. Maine consumers and retailers will be unable to identify which products contain phthalates and which are phthalate-free. Worse, without the ability to identify and avoid products containing banned phthalates, Maine and other U.S. states may become a target market for manufacturers looking to dump older and cheaper products.

Indeed, currently no consumer has access to information on phthalates in specific products needed to protect themselves or their families. No retailer has it either. Nor does the Department have the information that would be necessary to decide if additional actions should be proposed – such as the need to require alternatives assessments or whether the presence of

safer alternatives warrant a future sales prohibition. Only with knowledge of which products contain the regulated phthalates, and to what extent, can any kind of informed decision be made.

This is precisely the information the Maine Kid-Safe Products Act is designed to generate. It is information currently unavailable to Maine, the EPA or other states. Adoption of the proposed rule would thus add real value, and at minimal cost to industry,<sup>11</sup> to the national discussion on phthalates and, as proposed in this Petition, do so at little to no cost to the state government.

## **V. THE PROPOSED RULE**

The proposed Chapter 888 rule (see Appendix A), would designate the four regulated phthalates – di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), and diethyl phthalate (DEP) – as priority chemicals.

Once designated, manufacturers and distributors of specified product categories that contain an “intentionally added” regulated phthalate must disclose information on the use of the chemical in consumer products sold in Maine. (Phthalates present only as “contaminants” are *excluded* from this rule, thus simplifying the reporting and reducing compliance costs for business and state government). Covered product categories include apparel and footwear, arts and crafts products, building products, cosmetic and personal care products, home maintenance products, household and commercial cleaning products, household furniture and furnishings, and personal accessories.

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<sup>11</sup> The costs to product manufacturers would be for a one-time submission of data they routinely collect and can readily access from their supply chain in the course of normal business, together with the initial compliance fee.

Manufacturers must report on the amount and function of the regulated phthalate in each product sold, and provide any assessment that has already been performed by the manufacturer of the availability, cost, feasibility and/or performance, including potential for harm to human health and the environment, of alternatives to regulated phthalates and the reason regulated phthalates are used in the manufacture of the children's product in lieu of identified alternatives.

The proposed deadlines for reporting are staggered by size of manufacturer based on the manufacturer's annual sales: 12 months for the largest manufacturers, 18 months for large manufacturers, and 24 months for medium manufacturers. For small manufacturers, the deadline would be set by the Department, based on review of materials previously submitted for medium manufacturers.

For the purpose of this rule, the size of a manufacturer is defined as:

- (1) "Largest manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Maine, of more than one billion dollars, based on the manufacturer's most recent tax year filing;
- (2) "Larger manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Maine, of more than two hundred fifty million but less than or equal to one billion dollars, based on the manufacturer's most recent tax year filing;
- (3) "Medium size manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Maine, of more than one hundred million but less than or equal to two hundred fifty million dollars, based on the manufacturer's most recent tax year filing; and
- (4) "Small manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Maine, of less than or equal to one hundred million dollars, based on the manufacturer's most recent tax year filing.

The reporting requirements are waived for any children's product that contains intentionally added regulated phthalates that is subject to reporting to the state of Washington under Chapter 173-334 WAC if the manufacturer has provided substantially equivalent information to the information required by this rule to the state of Washington and if that

information is publically available from the state of Washington's searchable online database. A manufacturer may petition the Commissioner for an individual waiver based on a demonstration that substantially equivalent information as that required by this rule is already publicly available.

Finally, a one-time reporting fee will assessed in accordance with Department rule, 06-096 CMR ch. 881(3).

## **VI. THE REGULATED PHTHALATES MEET EACH OF THE THREE STATUTORY CRITERIA FOR DESIGNATION AS PRIORITY CHEMICALS.**

The prerequisite for designation of a priority chemical is a showing that the chemical is either present in: (1) human fluid or tissue, (2) the home environment, *or* (3) consumer products. 38 M.R.S.A. §§ 1694(A),(B) & (D); 06-096 C.M.R. ch. 880, § 4(B).<sup>12</sup> For the four phthalates at issue in this Petition, in making the CHC designation the Department has already conclusively determined that each chemical is present in both human fluids and indoor air or dust. *See* Maine Department of Environmental Protection, *Deriving Chemicals of High Concern Process Documentation, Appendix III, Chemical Specific Inclusion Criteria* at pp. 5-9, 18 (July 1, 2012) (hereinafter as "*CHC Basis Statement*").

Accordingly, there can be no dispute that the §§ 1694(A) & (B) exposure criteria are met. Nonetheless, it is informative to review the evidence of exposure to the four phthalates, which is mounting in both strength and breadth. Additionally, the available data show that the regulated phthalates are also present in consumer products used or present in the home, thus also meeting the third criterion. 38 M.R.S.A. § 1694(D).

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<sup>12</sup> The criteria are similar to the designation of a CHC. *Cf.* 06-096 C.M.R. ch. 880, § 3 (CHC) with *id.*, § 4(B)(2) (priority chemicals).

A. THE FOUR REGULATED PHTHALATES ARE PRESENT IN HUMAN BODILY FLUIDS.

The Department has already found that each of the four regulated phthalates is present in human bodily fluids. *CHC Basis Statement* at 5-9, 18. Thus, criterion § 1694(A) is met. Since then, however, the evidence of human exposure to the regulated phthalates has grown. As documented by Dr. Deborah C. Rice in the attached support statement, each of the four phthalates proposed for regulation have been found in humans during the conduct of multiple epidemiological studies of the general population in the United States, Europe and Asia.<sup>13</sup> Specifically, Dr. Rice lists more than 50 separate studies with credible scientific evidence that documents the presence of metabolites of the four CHC phthalates in breast milk, fetuses, blood and urine.<sup>14</sup> Among those is a 2014 study by Petitioner Alliance for a Clean and Healthy Maine entitled *Hormones Disrupted: Toxic Phthalates in Maine People*, which found each of the four regulated phthalates in urine samples taken from all 25 of the 25 adult Maine residents tested.

The U.S. Centers for Disease Control and Prevention (CDC) has determined urinary concentrations of the four regulated phthalates based on the most recent data available, from 2009-2010. (CDC, 2013). CDC's surveys found that each of the four phthalates proposed for regulation by the Petition was present in virtually all individuals tested. According to the analysis, higher levels of phthalates are present in females compared to males, and in children compared to adolescents and adults. This pattern was also observed in a study representative of the Canadian population, which found this pattern for each of the five commonly detected phthalates (Saravanabhaven et al., 2013). These findings suggest that fetuses and children are

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<sup>13</sup> Dr. Deborah C. Rice, *Support for the Designation of Certain Phthalates as Priority Chemicals*, April 2014, attached as Appendix C.

<sup>14</sup> Each of the 54 studies reviewed by Dr. Rice is provided in electronic format in Appendix F.



more susceptible to the threat of adverse health effects from phthalates due to higher exposure levels as well as the greater vulnerability of developing organ systems.

B. THE FOUR REGULATED PHTHALATES ARE PRESENT IN HOUSEHOLD DUST AND INDOOR AIR.

The Department has already found that each of the four regulated phthalates is present in the home environment. *CHC Basis Statement* at 5-9, 18. Thus, criterion § 1694(B) is also met. Since then, the evidence has grown. As documented by Dr. Deborah C. Rice in the attached support statement, phthalates are not chemically bound in products and therefore migrate into the surrounding environment. Phthalates have been routinely found in house dust and indoor air in multiple studies. This provides compelling credible scientific evidence that these chemicals are migrating out of products and into the home environment.

Dr. Rice has provided more than a dozen separate studies documenting that the four phthalates in this Petition have been identified in house dust. In those studies that also measured other contaminants in addition to phthalates, the regulated phthalates were often found at higher concentrations than other chemicals. In general, DEHP was detected at higher levels than the other CHC phthalates. Levels of DEHP, DEP, DBP, and BBP are 5 to 10 times higher in dust in the U.S. compared to China. (*See Appendix C*).

Phthalates are semi-volatile chemicals, and so can sublime (move from the solid to the gas phase) from products directly or from house dust in to the air. Dr. Rice also documents half a dozen studies that have detected DEHP, DBP, BBP, and DEP in indoor air.

C. THE FOUR REGULATED PHTHALATES ARE PRESENT IN CONSUMER PRODUCTS.

A wide variety of consumer and health databases and reports by authoritative government agencies, as well as independent testing, have conclusively demonstrated that the four regulated

phthalates are contained in consumer products used or present in the home. § 1694(D). This evidence is provided in Appendix D, and includes the following:

- **U.S. EPA’s Chemical Data Reporting** system, which provides direct evidence from phthalates manufacturers that the downstream use of the chemicals includes consumer products;
- **Household Products Database**, managed by the Department of Health and Human Services in collaboration with the National Institutes of Health, National Library of Medicine Specialized Information Services, which lists the following uses:
  - DEP in arts and crafts supplies, auto products, home decorating supplies, and personal care products;
  - BBP in arts and crafts supplies, auto products, home maintenance products, home decorating products, and yard and landscaping products;
  - DBP in auto products, home maintenance products, home decorating products, and personal care products; and
  - DEHP in home maintenance products;
- **Danish Environmental Protection Agency**, which conducted 125 product testing surveys of toxic chemicals in consumer products showing DBP, BBP, DEHP, and DEP in building products; home furniture and decorations; clothing; and beauty, personal care, and cleaning products; (These surveys were used by the Department to establish Maine’s list of Chemicals of High Concern).<sup>15</sup>
- **European Chemicals Agency, “Annex XV Restriction Report: Proposal for a Restriction,”** which documents widespread use of DBP, BBP, and DEHP in consumer products sold in Europe;
- **Washington Department of Ecology, Children’s Safe Products Act Database**, which includes reports from product manufacturers to the state of Washington documenting the use of DBP, BBP, and DEHP in products intended for or marketed to children, including footwear, clothing accessories, jewelry, arts and crafts supplies, baby supplies, clothing, bedding, and toys; and the use of DEP in children’s products, including footwear, cosmetics and fragrances, toys and games, baby feeding and hygiene products, clothing, bedding, and artists’ supplies;

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<sup>15</sup> See Maine Department of Environmental Protection, June 29, 2012. <http://www.maine.gov/dep/safechem/highconcern/documents/Appendix%20V%20Maine%20DEP%20CHC%20Process%20Document.pdf>

- **Washington State Department of Ecology product reporting compliance testing**, which revealed phthalates in various children's products and children's and consumer packaging, including bath toys and cosmetics, footwear, and fragrances, and high levels of phthalates (especially DEHP) in plastic packaging use to market and sell children's products; and
- Independent testing, including:
  - **HealthyStuff.Org** product testing has found the four phthalates in tablecloths, furniture, vinyl flooring, shower curtains, wallpaper, garden hoses, inflatable swimming pools, plastic clothing such as raincoats, children's toys, automobile upholstery and tops. HealthyStuff.org testing has shown DEP in carpets, paints, and personal care products such as soap, shampoo, hair spray, nail polish, deodorants, and fragrances;
  - **2011 Tests by Women's Voices for the Earth** which detected DBP, BBP, DEP, and DEHP in cleaning products such as air sanitizers and multi-surface cleaning sprays produced by companies that claimed to have removed this class of chemicals from their products;
  - **Clean Water Fund and the Healthy Legacy Coalition** found DBP, BBP, DEP and DEHP in house dust of several homes in Minnesota; and
  - **2012 Tests by Greenpeace** showed very high concentrations of phthalates including DEHP and BBP in clothing that bore a plastisol print of an image, logo, or text. Some products tested contained phthalates at levels of up to 37.6% by weight.

Despite this widespread credible scientific evidence, none of these information sources provide the information that would be obtained by this proposed rule. Each of these data sources has limitations, as explained in the attached support document. (*See Appendix D*). Only by adoption of the proposed rule will the Maine Department of Environmental Protection and the interested public learn which specific products sold in Maine contain the regulated phthalates.

The above peer-reviewed and independent studies, individually and in aggregate, provide overwhelming credible scientific evidence that the four regulated phthalates have been found in human bodily fluid, the household environment, and consumer products used or present in the home. Accordingly, the Department should find that, just as it did in 2010, the prerequisites for

designation are met. Indeed, the Department should further find that the evidence relevant to the above factors is increasing in strength and breadth.

**VII. THE FOUR PHTHALATES ARE AMONG THE TOP CANDIDATES FOR PRIORITIZATION BECAUSE OF THE SEVERITY OF THE KNOWN HAZARDS TO HUMAN HEALTH AND HIGH LEVELS OF EXPOSURE.**

Of all the chemicals remaining on Maine’s CHC list, Petitioners contend that the four phthalates are among the top candidates for prioritization because of the severity of the known hazards to human health, particularly during fetal and developmental stages, and the widespread exposure to children and pregnant women in the home, school and work environments. As explained below, the timing of this Petition has become critical. Aside from limited information collected in Europe and Washington state, very little is known about which specific products contain the four regulated phthalates. Thus, to quote the Department’s fact sheet for the other three recently named priority chemicals, “due to its uniqueness, the information the Department would collect through this rule will serve to inform future policy in a manner otherwise unattainable through any other source.” Maine Department of Env’tl Prot., *Rule Chapter 884 Designation of Cadmium as a Priority Chemical and Regulation of Cadmium in Children’s Products Supplemental Basis Statement Response to Comments*, at 2 (May 2014).

In addition, as discussed below, the four proposed phthalates rank highly when compared against each of the Department’s Rule 880(4)(C) criteria regarding the need for and appropriateness of regulatory action by the State.

- A. RULE 880(4)(C)(1): REPORTING ON REGULATED PHTHALATES IN CHILDREN’S PRODUCTS IS NEEDED TO ALLOW CONSUMERS AND RETAILERS TO IDENTIFY AND AVOID PRODUCTS THAT INCREASE THE THREAT OF ADVERSE HEALTH EFFECTS.

Aside from reporting to the State of Washington of products that are intentionally marketed to young children (which are exempted from the proposed rule here) and random

sampling of small numbers of products by public health organizations and interest groups, no information is available on which products sold in Maine contain the regulated phthalates. As a result, consumers are without the ability to reduce their families' exposure to phthalates. Likewise, Maine retailers are without the information needed to offer cleaner and safer alternatives. This problem is acutely demonstrated by the 2014 study *Hormones Disrupted: Toxic Phthalates in Maine People*. Of the 25 Mainers who volunteered to be tested for phthalates in a recent biomonitoring snapshot, all 25 had phthalates in their bodies. None could identify their possible sources of exposure; nor did they know how to reliably reduce their risk of further exposure.<sup>16</sup>

This information gap will soon become more pronounced because the European Chemicals Agency has proposed to ban three of the four regulated phthalates effective February 2015. Yet, these chemicals will still be legally used in similar products sold in Maine and the United States. The information required by the proposed rule is needed to enable consumers and businesses to make voluntary decisions to seek alternatives or avoid use of products containing chemicals that have been banned in Europe. Likewise, the information is needed so that consumers can distinguish between phthalate-free products sold in Europe and phthalate-contaminated versions of the same product sold in Maine.

Information on phthalate use is also needed in order to determine future priorities for action under the Kids Safe Products Act, such as requiring product manufacturers to evaluate the availability of safer alternatives or prohibiting the sale of specific products containing regulated phthalates because safer alternatives are available and affordable. Specifically, information on

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<sup>16</sup> Alliance for a Clean and Healthy Maine (March 2014), at page 13, attached in Appendix F.

current uses of the four regulated phthalates in consumer products is necessary to determine, for example:

- Which products are the greatest sources of exposure to phthalates?
- For which categories of products would it be most useful to assess the availability of safer and affordable alternatives?
- Which products with phthalates could be prohibited for sale in Maine, based on availability and affordability of safe alternatives?

Finally, due to increasing scientific and regulatory consensus on the hazards, safer alternatives to phthalates are now becoming more widely available, but the lack of public reporting on phthalate uses in products (and lack of labeling of products to indicate they contain phthalates) makes it difficult if not impossible for consumers and businesses to discern between products with phthalates versus products already using phthalate-free alternatives.

For example, a few years ago virtually any PVC plastic product (sometimes labeled with the number 3 inside a triangle) likely contained phthalates, since 90% of phthalates are used as plasticizers to soften PVC plastic and make it more flexible. Today, phthalate-free plasticizers are increasingly being used in PVC plastic, and PVC cannot always be easily distinguished from other phthalate-free alternatives such as polypropylene plastic. Consumers will benefit from information that discerns between soft plastics with or without phthalates.

As another example, personal care product manufacturers may likely be pushed to develop safer alternatives to phthalates as an ingredient in synthetic fragrances. Currently, the listing of “fragrance” on the ingredients label is a rough indicator of phthalates in a product. Having information that will discern between fragrance-added products with and without phthalates will be helpful for consumers and retailers.

- B. RULE 880(4)(C)(2): PHTHALATES ARE SO WIDELY USED IN CHILDREN’S PRODUCTS THAT VIRTUALLY ALL MAINE CHILDREN ARE AND WILL CONTINUE TO BE EXPOSED.

As discussed above, the available product databases, reporting in Washington State, and limited independent testing available to date have demonstrated widespread use of phthalates in children’s and consumer products<sup>17</sup> covered under the proposed rule. So also, the epidemiological, household dust, and indoor studies have demonstrated almost universal exposure to children (and adults). Combined, these factors demonstrate that the four regulated phthalates are so widely used in children’s products that virtually all Maine children are and will continue to be exposed. Indeed, in the recent snapshot of phthalate exposure in 25 Maine people, all 25 participants tested were found to have phthalates in their urine, consistent with national CDC data showing that phthalate exposure is ubiquitous.

- C. RULE 880(4)(C)(3): THE DEPARTMENT MUST COLLECT EXISTING INFORMATION ON THE AVAILABILITY AND SAFETY OF ALTERNATIVES TO DETERMINE WHETHER FULL SCALE ALTERNATIVES ASSESSMENTS ARE NECESSARY.

The proposed rule seeks reporting of existing alternatives assessments, but does not require manufacturers to conduct new assessments. This is a key step in a measured approach to toxics regulation. For example, information gathering on BPA use in toys, childcare articles, and baby food informed the next step, in which the Department required alternatives assessments and then subsequently phased-out BPA use in baby food and infant formula containers. The

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<sup>17</sup> See 06-096 C.M.R. ch. 880, § 1(G) & (J). The definition of “children’s product” in Maine is more expansive than under the Washington State Act and includes not just products “intended for, made for or marketed for use by children under 12 years of age” as in Washington, but also “any consumer product containing a chemical of high concern that when used or disposed of will likely result in a child under 12 years of age or a fetus being exposed to that chemical.” 06-096 C.M.R. ch. 880, § 1(G). Consumer products include any item sold for residential or commercial use, including component parts and packaging, that is sold for indoor use in a residence, child care facility or school, or outdoor use if a child under 12 years of age may have direct contact with the item.

Department should follow the same approach here, starting by collection of *existing* information on use and available alternatives and using that information to determine whether additional information submission, such as alternatives assessments, is necessary.

D. RULE 880(4)(C)(4): REGULATORY ACTION IS NECESSARY AND APPROPRIATE IN LIGHT OF ACTIONS TAKEN OR UNDERWAY WITH RESPECT TO THE CHEMICAL IN OTHER STATES AND JURISDICTIONS.

As shown in the table below, many authoritative government agencies have prioritized the regulated phthalates, including the European Chemicals Agency, United States Congress, United States Environmental Protection Agency, and the States of California, Washington and Maine (among others). Yet, none of these jurisdictions have taken regulatory actions that would adequately inform the government or citizens of Maine as to which consumer products contain these phthalates, nor timely lead to significant reductions in the exposure of Maine residents to phthalates.

So far, no regulatory body has obtained information on these four phthalates for an adequately comprehensive range of product categories; the one existing regulation in Washington state confine product categories included to only those products intended for children, which is a small subset of all product sources of phthalates exposure. The Kid-Safe Products Act provides an opportunity for the state of Maine to complement existing regulations on phthalates in other states because the law defines “children’s products” under Maine law to include consumer products not intended for children that are nevertheless used frequently around children in the home, schools, and childcare facilities; as well as consumer products that would expose pregnant women to phthalates and therefore risk fetal harm.



As shown below, the four regulated phthalates have been prioritized by several authoritative government agencies. (An “X” indicates which phthalates are subject to the specified authority).

Gov’t	Policy, and Effect on Products Sold in Maine	BBP	DBP	DEHP	DEP
EU	Complete phase-out in Europe effective Feb. 2015 unless specific uses are authorized to continue (under REACH, the 2007 EU chemical policy). Has <i>no</i> effect on products sold in U.S.	X	X	X	
US	Banned in toys and childcare articles, but <i>not</i> in other consumer products (by the Consumer Product Safety Improvement Act of 2008).	X	X	X	
US	Prioritized in a 2012 EPA Action Plan for risk assessment and possible <i>future</i> regulation under Toxic Substances Control Act of 1976.	X	X	X	
CA	Listed under Proposition 65 (1986) as known to cause cancer (C) or developmental toxicity (D), triggering generic warnings of exposure in CA, but does <i>not</i> identify the chemicals in a product.	X (D)	X (D)	X (C, D)	
CA	Listed as Candidate Chemicals for possible <i>future</i> action to require evaluation of safer alternatives in Priority Products under Safer Consumer Products Regulation. [* indicates also on top “Initial” list].	X *	X *	X *	X
WA	Named as Chemicals of High Concern for Children. Manufacturers required to report chemical use in products intentionally marketed to children, but <i>not</i> in other consumer products.	X	X	X	X
ME	Listed as Chemicals of High Concern. Rule would designate as Priority Chemicals and require reporting of use in consumer products subject to Kid-Safe Products Act of 2008.	X	X	X	X

Legislative proposals to overhaul the outdated U.S. law on toxics, the Toxic Substances Control Act, appear unlikely to move forward in the near future and even if passed will take several more years to implement. In the event of a stronger federal law that authorizes the U.S. EPA to more rigorously evaluate and assess chemicals for safety, the U.S. EPA will be years behind in its efforts to gather information on the 80,000 chemicals now in commerce plus a

slough of new chemicals entering the market. Therefore, individual states will still play a key role in providing information to the federal government on priority chemicals of high concern, which will enable swifter federal action.

Accordingly, this proposed action by Maine rule is appropriate now because of the lack of regulation in other jurisdictions regarding use of these four phthalates in consumer products to which children and fetuses are exposed. In the event that another state or the U.S. government passes restrictions on phthalates in consumer products, the information gathered by the proposed Chapter 888 rule in Maine would advance, and not duplicate, these future policies.

- E. RULE 880(4)(C)(5): THE PROPOSED RULE IS SELF-FUNDING SO THAT THE DEPARTMENT WILL HAVE ADEQUATE FINANCIAL AND HUMAN RESOURCES TO PROCESS INFORMATION REPORTING REQUIRED BY THE RULE.

The proposed rule should impose minimal, if any costs on the Department and the Maine CDC for the following reasons. First, as the Department has previously found with the designation of cadmium, mercury, and arsenic,<sup>18</sup> because the proposed rule applies to manufacturers or distributors of certain children's products, the fiscal impacts will fall mainly on manufacturers of certain children's products which contain intentionally added amounts of the four regulated phthalates. Filing the required report information with the Department is expected to cost a complying entity nominal time and effort.

Second, also as with the recently adopted priority chemical designation for cadmium, mercury, and arsenic, regulated entities will pay a one-time reporting fee to the Department to cover the costs associated with information management in accordance with Department rule,

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<sup>18</sup> See *Rule Making Fact Sheet and Adoption Package* for cadmium, 06-096 C.M.R. ch. 884, mercury, 06-096 C.M.R. ch. 886, and arsenic, 06-096 C.M.R. ch. 887.

06-096 CMR 881(3). The reporting fee should be sufficient to pay the reasonable costs of administering this rule.

Third, the Department recently deferred action on the proposed designation of formaldehyde as a priority chemical. This delay will make available additional time and money from the Department's budget. Additionally, Petitioners note that the regulatory tasks involved with oversight of the four regulated phthalates are effectively identical to the work required for the three other recently designated priority chemicals. Because the Department already has the necessary administrative mechanisms set up, there will be few, if any, additional costs in adding additional chemicals – and these costs will be covered by the reporting fee.

Fourth and finally, Petitioners have provided extensive documentation of the available evidence for every element required to approve the proposed rule. Thus, neither the Department nor Maine CDC need expend significant resources to process this designation. Rather, Petitioners have provided a complete review of the current state of the credible scientific evidence with regard to adverse health hazards and exposures to phthalates. (*See* Appendices B, C and F.) Likewise, Petitioners have researched and documented all available known product databases that track use of the regulated phthalates in products, and have provided copies of all current regulatory practices in other jurisdictions. (*See* Appendices D and E). While the Department and Maine CDC must certainly perform the necessary due diligence, Petitioners have conscientiously sought to reduce the effort needed by providing all needed materials in advance.

Also, the Department now has resources freed up in the next year that would have supported the reporting of the widely used chemical of high concern known as formaldehyde. On April 29, 2014, the Department announced that it was dropping its proposed rule to

designated formaldehyde as a priority chemical. The Department should reallocate its existing resources it committed to support the formaldehyde rule to now instead support the proposed phthalates rule. Given the prolonged and staggered reporting deadlines for phthalates, which would stretch from late 2015 to 2017 and beyond, compared to the once-proposed reporting deadline for formaldehyde (late 2014), the Department can easily conserve its freed up resources to manage the light duty of preparing for and receiving the later-submitted chemical use reports for phthalates.

### VIII. CONCLUSION

For the reasons herein contained, the petitioners request that the Department adopt the proposed rule to designate phthalates as priority chemicals and require chemical use reporting.

Respectfully Submitted,

May 14, 2014

Alliance for a Clean and Healthy Maine,  
on behalf of all Petitioners.

By: \_\_\_\_\_

Emma Halas-O'Connor  
Coalition and Advocacy Coordinator  
Alliance for a Clean and Healthy Maine  
565 Congress Street, Suite 204  
Portland, ME 04101  
(207) 272-9581 (cell)  
(207) 699-5799 (direct)  
ehalasoc@preventharm.org

## APPENDICES

**Appendix A:** Citizen Petition to Initiate Rulemaking to Designate Four Members Of The Chemical Class Phthalates As Priority Chemicals.

- Ex. A-1. Summary of Petitioners
- Ex. A-2. State of Maine Petition to Require Agency Rulemaking (Petition Cover Page)
- Ex. A-3. Proposed New Rule
- Ex. A-4. Verified Signature Pages

**Appendix B:** Deborah C. Rice, Ph.D. (March 2014). Phthalates: Maine Chemicals of High Concern: A Review of the Science on Toxicity and Exposure.

Note: Each of the studies cited in Appendix B are included in Appendix F.

**Appendix C:** Deborah C. Rice, Ph.D. (April 2014). Support for the Designation of Certain Phthalates as Priority Chemicals.

Note: Each of the studies cited in Appendix C are included in Appendix F.

**Appendix D:** Environmental Health Strategy Center (May 2014). Phthalates in Consumer Products Used or Present in the Home.

- Ex. D-1. United States Environmental Protection Agency. Chemical Data Reporting on DBP, BBP, DEHP, and DEP. (<http://epa.gov/cdr/>)
- Ex. D-2. United States Department of Health & Human Services. Household Products Database: Health & Safety Information on Household Products. Data on DBP, BBP, DEHP, and DEP. (<http://householdproducts.nlm.nih.gov/cgi-bin/household/list?tbl=TblChemicals&alpha=A>)
- Ex. D-3. Danish Environmental Protection Agency (2001-2013). Data on DBP, BBP, DEHP, and DEP from the Danish Surveys on Chemicals in Consumer Products. (<http://eng.mst.dk/topics/chemicals/consumers-consumer-products/danish-surveys-on-consumer-products/>)
- Ex. D-4. European Chemicals Agency (ECHA). Authorisation List of Substances of Very High Concern. (<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>)

- Ex. D-5. European Chemicals Agency (August 2012). Annex XV Restriction Report: Proposal for a Restriction. Section B2: Manufacture & Uses (pp. 33-57). ([http://echa.europa.eu/documents/10162/13641/restriction\\_report\\_phthalates\\_en.pdf](http://echa.europa.eu/documents/10162/13641/restriction_report_phthalates_en.pdf))
- Ex. D-6. State of Washington, Department of Ecology. Children's Safe Products Act: Search Data on DBP, BBP, DEHP, and DEP. (<http://www.ecy.wa.gov/programs/swfa/cspa/search.html>)
- Ex. D-7. Stone, Alex, Sc.D., Senior Chemist, WA State Department of Ecology, Hazardous Waste & Toxics Reduction Program (March 2014). Phthalates in Children's Products and Consumer and Children's Packaging. Washington State Department of Ecology. (<https://fortress.wa.gov/ecy/publications/publications/1404017.pdf>)
- Ex. D-8. HealthyStuff.org (2014). Walgreens, will you Mind the Store? (<http://www.healthystuff.org/findings.04162014.walgreensMTS.php>)
- Ex. D-9. HealthyStuff.org (2014). March Badness: Toxic University Stuff. (<http://www.healthystuff.org/findings.03192014.marchbadness.php>)
- Ex. D-10. Scranton, Alexandra (November 2011). Dirty Secrets: What's Hiding in your Cleaning Products? Women's Voices for the Earth. (<http://www.womensvoices.org/issues/reports/dirty-secrets/>)
- Ex. D-11. LaBo, Kim, Ande Saunders, and Kathleen Schuler (2014). Hidden Harm: Household Dust's Dirty Secret. Clean Water Fund and Healthy Legacy. (<http://www.cleanwateraction.org/files/publications/Hidden Harm - Household Dusts Dirty Secret.pdf>)
- Ex. D-12. Greenpeace (2012). Toxic Threads: The Big Fashion Stitch-Up. (<http://www.greenpeace.org/international/en/publications/Campaign-reports/Toxics-reports/Big-Fashion-Stitch-Up/>)

#### **Appendix E: Regulatory Status of Phthalates**

- Ex. E-1. European Chemicals Agency (ECHA). Authorisation List of Substances of Very High Concern. (<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>)
- Ex. E-2. United States Consumer Product Safety Commission: Phthalates. (<https://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information/>).

- Ex. E-3. United States Environmental Protection Agency (EPA). Phthalates Action Plan. Revised March 14, 2012. (<http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/phthalates.html>)
- Ex. E-4. State of California Environmental Protection Agency, Office of Environmental Health Hazard Assessment. Safe Drinking Water and Toxic Enforcement Act of 1986.. Chemicals Known to the State to Cause Cancer or Reproductive Toxicity. May 2, 2014. ([http://oehha.ca.gov/prop65/prop65\\_list/newlist.html](http://oehha.ca.gov/prop65/prop65_list/newlist.html))
- Ex. E-5. State of California Environmental Protection Agency. Safer Consumer Products Regulations-Informational List of Candidate Chemicals and Chemical Groups. October 18, 2013. (<https://dtsc.ca.gov/scp/index.cfm>)
- Ex. E-6. Washington State Department of Ecology. The Reporting List of Chemicals of High Concern to Children (CHCC List). (<http://www.ecy.wa.gov/programs/swfa/cspa/chcc.html>)
- Ex. E-7. Maine Department of Environmental Protection. List of Chemicals of High Concern. (<http://www.maine.gov/dep/safechem/highconcern/>)

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\*These studies will be submitted under a separate cover.