Citizen Petition to Initiate Rulemaking
To Require Safer Alternatives to Bisphenol A (BPA) in
Food and Beverage Packaging for Young Children

Exhibit 6: L.D. 1129 – Committee Amendment (approved as PL 2011, Ch 319)

L.D. 1129

Date: (Filing No. H-)

ENVIRONMENT AND NATURAL RESOURCES

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STATE OF MAINE
HOUSE OF REPRESENTATIVES
125TH LEGISLATURE
FIRST REGULAR SESSION

COMMITTEE AMENDMENT " " to H.P. 841, L.D. 1129, Bill, "An Act To Provide the Department of Environmental Protection with Regulatory Flexibility Regarding the Listing of Priority Chemicals"

Amend the bill by striking out everything after the enacting clause and before the summary and inserting the following:

'**Sec. 1. 5 MRSA §8060, sub-§7** is enacted to read:

7. **Agenda listing required.** Notwithstanding any provision of law to the contrary, a rule may not be proposed pursuant to Title 38, chapter 16-D unless the chemicals affected by that proposed rule were specifically disclosed to the Legislature prior to the initiation of the rule-making process as part of a regulatory agenda, except that this subsection may not be construed to prohibit an agency from initiating appropriate rule-making proceedings in response to any person who petitions for adoption or modification of rules pursuant to section 8055.

Sec. 2. 38 MRSA §1691, as enacted by PL 2007, c. 643, §2, is amended to read:

§1691. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Alternative. "Alternative" means a substitute process, product, material, chemical, strategy or combination of these that serves a functionally equivalent purpose to a chemical in a children's product.

2. Chemical. "Chemical" means a substance with a distinct molecular composition or a group of structurally related substances and includes the breakdown products of the substance or substances that form through decomposition, degradation or metabolism.

2-A. Chemical of concern. "Chemical of concern" means a chemical identified by the department pursuant to section 1693.

3. Chemical of high concern. "Chemical of high concern" means a chemical identified by the department pursuant to section ~~1693~~ 1693-A.

4. Chemical of low concern. "Chemical of low concern" means a chemical for which adequate toxicity and environmental data are available to determine that it is not a chemical of high concern, a chemical of concern, a chemical of ~~moderate~~ potential concern or a chemical of unknown concern.

5. Chemical of potential concern. "Chemical of ~~moderate~~ potential concern" means a chemical identified by an authoritative governmental entity on the basis of credible scientific evidence as being suspected of causing an adverse health or environmental effect listed in section 1693, subsection 1.

6. Chemical of unknown concern. "Chemical of unknown concern" means a chemical for which insufficient data are available to classify it as a chemical of high concern, a chemical of concern, a chemical of ~~moderate~~ potential concern or a chemical of low concern.

7. Children's product. "Children's product" means a consumer product intended for, made for or marketed for use by children under 12 years of age, such as baby products, toys, car seats, personal care products and clothing, and any consumer product containing a chemical of high concern that when used or disposed of will likely result in a ~~child's~~ child under 12 years of age or a fetus's being exposed to that chemical.

8. Consumer product. "Consumer product" means any item sold for residential or commercial use, including any component parts and packaging~~. "Consumer product" does not include a food or beverage or an additive to a food or beverage, a tobacco product or paper or forest products or a pesticide regulated by the federal Environmental Protection Agency. "Consumer product" also does not include a drug or biologic regulated by the federal Food and Drug Administration or the packaging of a drug or biologic regulated by the federal Food and Drug Administration if the packaging is regulated by the federal Food and Drug Administration.~~, that is sold for:

A. An indoor use in a residence, child care facility or school; or

B. An outdoor residential use if a child under 12 years of age may have direct contact with the item.

"Consumer product" does not include a food or beverage or an additive to a food or beverage, a tobacco product or paper or forest products or a pesticide regulated by the United States Environmental Protection Agency. "Consumer product" also does not include a drug or biologic regulated by the United States Department of Health and Human Services, Food and Drug Administration or the packaging of a drug or biologic regulated by the Food and Drug Administration if the packaging is regulated by the Food and Drug Administration. "Consumer product" also does not include an item sold for outdoor residential use that consists of a composite material made from polyester resins.

8-A. Credible scientific evidence. "Credible scientific evidence" means the results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal or publication of an authoritative federal or international governmental agency, including but not limited to the United States Department of Health and Human Services, National Toxicology

Program, Food and Drug Administration and Centers for Disease Control and Prevention; the United States Environmental Protection Agency; the World Health Organization; and the European Union, European Chemicals Agency.

8-B. De minimis level. "De minimis level" means:

A. For a chemical of high concern or priority chemical that is an intentionally added chemical in a component of a children's product, the practical quantification limit; or

B. For a chemical of high concern or priority chemical that is a contaminant present in a component of a children's product, a concentration of 100 parts per million.

9. Distributor. "Distributor" means a person who sells consumer products to retail establishments on a wholesale basis.

9-A. Intentionally added chemical. "Intentionally added chemical" means 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.

10. Manufacturer. "Manufacturer" means any person who manufactured a final consumer product or whose brand name is affixed to the consumer product. In the case of a consumer product that was imported into the United States, "manufacturer" includes the importer or first domestic distributor of the consumer product if the person who manufactured or assembled the consumer product or whose brand name is affixed to the consumer product does not have a presence in the United States.

10-A. Practical quantification limit. "Practical quantification limit" means the lowest concentration of a chemical that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness and comparability during routine laboratory operating conditions. The practical quantification limit is based on scientifically defensible, standard analytical methods. The practical quantification limit for a given chemical may be different depending on the matrix and the analytical method used.

11. Priority chemical. "Priority chemical" means a chemical identified as such by the commissioner pursuant to section 1694, subsection 1.

12. Safer alternative. "Safer alternative" means an alternative that, when compared to a priority chemical that it could replace, would reduce the potential for harm to human health or the environment or that has not been shown to pose the same or greater potential for harm to human health or the environment as that priority chemical.

Sec. 3. 38 MRSA §1693, as enacted by PL 2007, c. 643, §2, is repealed and the following enacted in its place:

§1693. Identification of chemicals of concern

1. Criteria. By January 1, 2010, the department, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention, shall publish a list of chemicals of high concern, referred to after September 1, 2011 as "the list of chemicals of concern." A chemical may be included on the list only if it has been identified by an authoritative governmental entity on the basis of credible scientific evidence as being:

A. A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor;

B. Persistent, bioaccumulative and toxic; or

C. Very persistent and very bioaccumulative.

2. Revisions. By January 1, 2012, the department, with input from interested persons and with the concurrence of the Department of Health and Human Services, Maine Center for Disease Control and Prevention, shall remove any chemical from the list published pursuant to subsection 1 that it finds is:

A. Used solely in an item that is not a consumer product, including, but not limited to, a food or beverage, drug or biologic, paper or forest product or pesticide; or

B. Used solely in a consumer product that is exempt from the requirements of this chapter pursuant to section 1697.

The department may periodically review and revise the list published pursuant to subsection 1. The department may add chemicals to the list if, in the judgment of the Department of Health and Human Services, Maine Center for Disease Control and Prevention, the chemical meets one or more of the criteria in subsection 1.

3. Removal by petition. A person may petition the department to remove a chemical from the list published pursuant to subsection 1. The department, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention, may grant a petition if the person demonstrates to the satisfaction of the department that the chemical:

A. Does not meet the criteria for listing pursuant to subsection 1; or

B. Meets the criteria for removal from the list pursuant to subsection 2.

Upon receipt of a petition under this subsection, the department shall notify interested persons and provide an opportunity for review and comment on the evidence submitted by the petitioner. The department shall make a determination within 180 days of receipt of the petition and notify interested persons of the basis for its decision. If the petition is granted, the department shall immediately remove the chemical from the list published pursuant to subsection 1.

Sec. 4. 38 MRSA §1693-A is enacted to read:

§1693-A. Identification of chemicals of high concern

1. List. By July 1, 2012, the department shall publish a list of no more than 70 chemicals of high concern. The Department of Health and Human Services, Maine Center for Disease Control and Prevention, in consultation with the department, shall develop the list. To be listed as a chemical of high concern, a chemical must be on the list of chemicals of concern pursuant to section 1693 and meet the eligibility criteria of subsection 2.

2. Criteria. A chemical of concern on the list of chemicals of concern pursuant to section 1693 may be included in the list published pursuant to subsection 1 if the department, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention, determines that there is strong credible scientific evidence that the chemical is a reproductive or developmental toxicant,

endocrine disruptor or human carcinogen, and there is strong credible scientific evidence that the chemical meets one or more of the following criteria:

A. The chemical has been found through biomonitoring studies to be present in human blood, human breast milk, human 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

C. The chemical has been added to or is present in a consumer product used or present in the home.

3. Updates. The commissioner shall review the list published pursuant to subsection 1 at least every 3 years. The commissioner shall remove any chemical from the list of chemicals of high concern that has been designated as a priority chemical pursuant to section 1694 or that no longer meets any of the criteria of subsection 2. The commissioner may identify additional chemicals of high concern according to the criteria and requirements of this section. The list of chemicals of high concern may not consist of more than 70 or fewer than 10 chemicals of high concern, unless fewer than 10 chemicals of high concern meet any of the criteria under subsection 2.

4. Rules. The department shall adopt rules to implement the provisions of this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 5. 38 MRSA §1694, as enacted by PL 2007, c. 643, §2, is amended to read:

§1694. Identification of priority chemicals

Effective July 1, 2012, a chemical is eligible for designation as a priority chemical only if that chemical has been identified and listed as a chemical of high concern pursuant to section 1693-A.

1. Criteria. The commissioner may designate a chemical of high concern 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:

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

~~C. The chemical has been found through monitoring to be present in fish, wildlife or the natural environment;~~

D. The chemical is present in a consumer product used or present in the home~~;~~.

~~E. The chemical has been identified as a high production volume chemical by the federal Environmental Protection Agency; or~~

~~F. The sale or use of the chemical or a product containing the chemical has been banned in another state within the United States.~~

~~The commissioner shall designate at least 2 priority chemicals by January 1, 2011.~~

2. Designation. The commissioner shall designate at least 2 priority chemicals by January 1, 2011. The commissioner ~~shall review the list of chemicals of high concern at least every 3 years and~~ may designate additional priority chemicals if the commissioner finds that the chemicals meet one of the criteria listed in subsection 1.

The commissioner shall adopt rules to implement the provisions of this section. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 6. 38 MRSA §1695, sub-§1, as enacted by PL 2007, c. 643, §2, is amended to read:

1. Reporting of chemical use. Not later than 180 days after a priority chemical is identified pursuant to section 1694, a person who is a manufacturer or distributor of a children's product for sale in the State that contains a priority chemical in an amount greater than a de minimis level shall notify the department in writing unless waived by the commissioner pursuant to this section or exempt from this chapter pursuant to section 1697. This written notice must identify 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.

Sec. 7. 38 MRSA §1696, sub-§1, as enacted by PL 2007, c. 643, §2, is amended to read:

1. Authority. The board may adopt rules prohibiting the manufacture, sale or distribution in the State of a children's product containing a priority chemical in an amount greater than a de minimis level if the board finds, after consideration of information filed under section 1695 and other relevant information submitted to or obtained by the board, that:

A. Distribution of the children's product directly or indirectly exposes children and vulnerable populations to the priority chemical; and

B. One or more safer alternatives to the priority chemical are available at a comparable cost.

If there are several available safer alternatives to a priority chemical, the board may prohibit the sale of children's products that do not contain the safer alternative that is least toxic to human health or least harmful to the environment.

A rule established pursuant to this subsection must specify the effective date of the prohibition, which may not be sooner than 12 months after notice of the proposed rule is published as required under Title 5, section 8053, subsection 5. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 8. 38 MRSA §1696, sub-§2, ¶¶A and B, as enacted by PL 2007, c. 643, §2, are amended to read:

A. Presume that an alternative is a safer alternative if the alternative is not a chemical of ~~high~~ concern;

B. Presume that a safer alternative is available if the sale of the children's product containing the priority chemical has been banned by another state within the United States based on the availability of a safer alternative;

Sec. 9. 38 MRSA §1697, sub-§§9 to 11 are enacted to read:

9. Regulatory efficiency. The department may, in exercising its discretionary authority under this chapter, consider the extent to which a chemical of high concern in a children's product is adequately regulated by the Federal Government or an agency of this State to reduce or prevent the same public health threats that would be the basis for addressing the chemical under this chapter.

10. Inaccessible components. The requirements of sections 1695 and 1696 do not apply to a priority chemical contained in a component of a children's product that during reasonably foreseeable use and abuse would not come into direct contact with a child's skin or mouth, such as inaccessible components of children's products. The department may adopt a rule, based on a case-by-case evaluation, to subject such components to the requirements of sections 1695 and 1696. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

11. Contaminants. The requirements of sections 1695 and 1696 do not apply to a priority chemical that occurs in a product component only as a contaminant if the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component.

Sec. 10. 38 MRSA §1698, first ¶, as enacted by PL 2007, c. 643, §2, is amended to read:

The department is authorized to participate in an interstate clearinghouse to promote safer chemicals in consumer products in cooperation with other states and governmental entities. The department may cooperate with the interstate clearinghouse to classify existing chemicals in commerce into one of ~~4~~ 5 categories: chemicals of high concern, chemicals of ~~moderate~~ concern, chemicals of potential concern, chemicals of unknown concern and chemicals of low concern.

Sec. 11. 38 MRSA §1699-A, sub-§2, as enacted by PL 2007, c. 643, §2, is amended to read:

2. Certificate of compliance. If there are grounds to suspect that a children's product is being offered for sale in violation of this chapter, the department may request the manufacturer or distributor of the product to provide a certificate of compliance with the provisions of this chapter. Within ~~10~~ 30 days of receipt of a request under this subsection, the manufacturer or distributor shall:

A. Provide the department with the certificate attesting that the children's product does not contain the priority chemical; or

B. Notify persons who sell the product in this State that the sale of the children's product is prohibited and provide the department with a list of the names and addresses of those notified.

Sec. 12. 38 MRSA §2322, sub-§8, as enacted by PL 2009, c. 579, Pt. A, §3, is amended to read:

8. Toxic chemical. "Toxic chemical" means a chemical that has been identified as a chemical of ~~high~~ concern pursuant to section 1693 or a chemical the use or release of which is subject to reporting under the SARA, Title III, Section 312 or 313.

Sec. 13. Delayed priority chemical reporting; retroactivity. Notwithstanding the Maine Revised Statutes, Title 38, section 1695, subsection 1, a manufacturer or distributor of a children's product containing a priority chemical identified pursuant to Title 38, section 1694 is not required to comply with the reporting requirements of Title 38, section 1695, subsection 1 until the effective date of this section. This section applies retroactively to July 8, 2011.'

SUMMARY

This amendment replaces the bill. The amendment makes a number of changes to the priority chemical program.

1. It prohibits the Department of Environmental Protection from initiating rulemaking under the Maine Revised Statutes, Title 38, chapter 16-D unless the chemical at issue has been included in a regulatory agenda disclosed to the Legislature pursuant to the Maine Administrative Procedure Act or the rulemaking is in response to a petition by a person to adopt or modify a rule pursuant to the Maine Administrative Procedure Act.

2. It changes the name of the list of "chemicals of high concern" to "chemicals of concern." Conforming name changes are made throughout the amendment. By January 1, 2012, the department is required to remove chemicals from the original list that are exempt from regulation. A person may petition for removal of chemicals that don't meet the listing criteria.

3. By July 1, 2012, a new list of up to 70 "chemicals of high concern" must be developed by the Department of Health and Human Services, Maine Center for Disease Control and Prevention and published by the Department of Environmental Protection based on a finding of strong credible evidence of toxicity and one or more indicators of likely exposure.

4. The Department of Environmental Protection, in rule, is required to specify appropriate de minimis levels for each chemical of high concern. "De minimis level" is defined. For a chemical present in a product as a contaminant, the de minimis level is 100 parts per million. For a chemical that's intentionally added to a product by a manufacturer, the de minimis level is the practical quantification limit, which is the lowest concentration of the chemical that can be reliably and accurately measured.

5. The Commissioner of Environmental Protection is required to review the published list of chemicals of high concern at least every 3 years and may, with the concurrence of the Department of Health and Human Services, Maine Center for Disease Control and Prevention, remove chemicals that no longer meet the listing criteria and may add chemicals that meet the criteria. The list of chemicals of high concern may not consist of more than 70 or fewer than 10 chemicals, unless fewer than 10 meet the listing criteria.

6. Effective July 1, 2012, a "priority chemical" may be designated only if the chemical has been listed on the list of chemicals of high concern.

7. The definition of "children's product" is amended by limiting it to those products intended, made and marketed for use by children under 12 years of age and other consumer products through which a child under 12 years of age or a fetus is likely to be exposed to a chemical of concern.

8. The definition of "consumer product" is narrowed to mean items sold for indoor use in a residence, child care facility or school, or for outdoor residential use if children may have direct contact with the items.

9. Definitions of "credible scientific evidence" and "practical quantification limit" have been added.

10. The criteria to be considered for designating a priority chemical are reduced from 6 to 3.

11. In determining whether a safer alternative is available, the Department of Environmental Protection may presume that a safer alternative is available if another state bans that chemical only if that state based its action on the availability of safer alternatives.

12. It provides that the Department of Environmental Protection may consider the extent to which a chemical is adequately regulated by the Federal Government or another state agency in Maine in exercising its discretionary authority under the law.

13. It provides that the following are exempt from the requirements for disclosing information for priority chemicals and from any sales prohibition:

A. Inaccessible components, except that the Department of Environmental Protection may adopt a rule based on a case-by-case evaluation to subject inaccessible components to those requirements; and

B. A priority chemical that occurs in a product component only as a contaminant, if the manufacturer had a manufacturing control plan and exercised due diligence.

14. It allows a manufacturer 30 days instead of 10 days to respond to the Department of Environmental Protection's request for a certificate of compliance.

15. It provides that any reporting requirements for products containing existing priority chemicals that have been adopted by rule by the Department of Environmental Protection are extended to the effective date of this legislation. It makes this provision retroactive to the date the reports are currently required, July 8, 2011.

FISCAL NOTE REQUIRED

(See attached)