

MAINE STATE LEGISLATURE

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SMG
ROR

Date: 5/31/11

(Filing No. H- 421)

ENVIRONMENT AND NATURAL RESOURCES

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

COMMITTEE AMENDMENT "A" 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.

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

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

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

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

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

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

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

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

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

39 **8-A. Credible scientific evidence.** "Credible scientific evidence" means the results
40 of a study, the experimental design and conduct of which have undergone independent
41 scientific peer review, that are published in a peer-reviewed journal or publication of an
42 authoritative federal or international governmental agency, including but not limited to
43 the United States Department of Health and Human Services, National Toxicology

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

4 **8-B. De minimis level.** "De minimis level" means:

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

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

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

11 **9-A. Intentionally added chemical.** "Intentionally added chemical" means a
12 chemical that was added during the manufacture of a product or product component to
13 provide a specific characteristic, appearance or quality or to perform a specific function.

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

20 **10-A. Practical quantification limit.** "Practical quantification limit" means the
21 lowest concentration of a chemical that can be reliably measured within specified limits
22 of precision, accuracy, representativeness, completeness and comparability during routine
23 laboratory operating conditions. The practical quantification limit is based on
24 scientifically defensible, standard analytical methods. The practical quantification limit
25 for a given chemical may be different depending on the matrix and the analytical method
26 used.

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

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

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

35 **§1693. Identification of chemicals of concern**

36 **1. Criteria.** By January 1, 2010, the department, in concurrence with the
37 Department of Health and Human Services, Maine Center for Disease Control and
38 Prevention, shall publish a list of chemicals of high concern, referred to after September
39 1, 2011 as "the list of chemicals of concern." A chemical may be included on the list
40 only if it has been identified by an authoritative governmental entity on the basis of
41 credible scientific evidence as being:

- 1 A. A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor;
- 2 B. Persistent, bioaccumulative and toxic; or
- 3 C. Very persistent and very bioaccumulative.

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

- 8 A. Used solely in an item that is not a consumer product, including, but not limited
9 to, a food or beverage, drug or biologic, paper or forest product or pesticide; or
- 10 B. Used solely in a consumer product that is exempt from the requirements of this
11 chapter pursuant to section 1697.

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

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

- 21 A. Does not meet the criteria for listing pursuant to subsection 1; or
- 22 B. Meets the criteria for removal from the list pursuant to subsection 2.

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

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

30 **§1693-A. Identification of chemicals of high concern**

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

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

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

3 A. The chemical has been found through biomonitoring studies to be present in
4 human blood, human breast milk, human urine or other bodily tissues or fluids;

5 B. The chemical has been found through sampling and analysis to be present in
6 household dust, indoor air or drinking water or elsewhere in the home environment;
7 or

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

10 3. Updates. The commissioner shall review the list published pursuant to subsection
11 1 at least every 3 years. The commissioner shall remove any chemical from the list of
12 chemicals of high concern that has been designated as a priority chemical pursuant to
13 section 1694 or that no longer meets any of the criteria of subsection 2. The
14 commissioner may identify additional chemicals of high concern according to the criteria
15 and requirements of this section. The list of chemicals of high concern may not consist of
16 more than 70 or fewer than 10 chemicals of high concern, unless fewer than 10 chemicals
17 of high concern meet any of the criteria under subsection 2.

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

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

22 **§1694. Identification of priority chemicals**

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

26 **1. Criteria.** The commissioner may designate a chemical of high concern as a
27 priority chemical if the commissioner finds, in concurrence with the Department of
28 Health and Human Services, Maine Center for Disease Control and Prevention:

29 A. The chemical has been found through biomonitoring to be present in human
30 blood, including umbilical cord blood, breast milk, urine or other bodily tissues or
31 fluids;

32 B. The chemical has been found through sampling and analysis to be present in
33 household dust, indoor air; or drinking water or elsewhere in the home environment;
34 or

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

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

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

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

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

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

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

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

13 **1. Reporting of chemical use.** Not later than 180 days after a priority chemical is
14 identified pursuant to section 1694, a person who is a manufacturer or distributor of a
15 children's product for sale in the State that contains a priority chemical in an amount
16 greater than a de minimis level shall notify the department in writing unless waived by
17 the commissioner pursuant to this section or exempt from this chapter pursuant to section
18 1697. This written notice must identify the children's product, the number of units sold or
19 distributed for sale in the State or nationally, the priority chemical or chemicals contained
20 in the children's product, the amount of such chemicals in each unit of children's product
21 and the intended purpose of the chemicals in the children's product.

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

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

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

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

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

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

41 **Sec. 8. 38 MRSA §1696, sub-§2, ¶¶A and B,** as enacted by PL 2007, c. 643,
42 §2, are amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

132/1/12

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

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

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

12 SUMMARY

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

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

20 2. It changes the name of the list of "chemicals of high concern" to "chemicals of
21 concern." Conforming name changes are made throughout the amendment. By January
22 1, 2012, the department is required to remove chemicals from the original list that are
23 exempt from regulation. A person may petition for removal of chemicals that don't meet
24 the listing criteria.

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

30 4. The Department of Environmental Protection, in rule, is required to specify
31 appropriate de minimis levels for each chemical of high concern. "De minimis level" is
32 defined. For a chemical present in a product as a contaminant, the de minimis level is
33 100 parts per million. For a chemical that's intentionally added to a product by a
34 manufacturer, the de minimis level is the practical quantification limit, which is the
35 lowest concentration of the chemical that can be reliably and accurately measured.

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

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

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

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

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

12 10. The criteria to be considered for designating a priority chemical are reduced from
13 6 to 3.

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

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

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

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

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

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

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

34 **FISCAL NOTE REQUIRED**

35 **(See attached)**

COMMITTEE AMENDMENT



125th MAINE LEGISLATURE

LD 1129

LR 1541(02)

An Act To Provide the Department of Environmental Protection with Regulatory Flexibility Regarding the Listing of Priority Chemicals

Fiscal Note for Bill as Amended by Committee Amendment "A"

Committee: Environment and Natural Resources

Fiscal Note Required: Yes

Fiscal Note

Minor cost increase - Other Special Revenue Funds

Fiscal Detail and Notes

Requiring the Department of Environmental Protection (DEP) to decide petitions for de-listing of chemicals as chemicals of high concern, to notify interested persons and to provide opportunities for review and comment within 180 days of submission, to engage in rulemaking to specify appropriate de minimis levels for each chemical of high concern and to submit an agency regulatory agenda to the appropriate joint standing committee and to the Secretary of State will result in minor administrative costs that the DEP can absorb within existing budgeted resources. Additional costs to the Maine Center for Disease Control and Prevention in the Department of Health and Human Services can be absorbed within existing budgeted resources.