SUPPLEMENTAL BASIS STATEMENT

CHAPTER 882
DESIGNATION OF BISPHENOL A AS A PRIORITY CHEMICAL AND REGULATION OF BISPHENOL A IN CHILDREN'S PRODUCTS

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COMMENTS

Section 1. Applicability

1(A)

1. Comment: The commenter suggests that bisphenol A is present in polycarbonate plastics and epoxy resins only as a trace level of impurity, typically in the low parts per million range. The commenter contends that it is not intentionally added to children's products and would serve no functional purpose in these products. The commenter contends that because bisphenol A is a chemical that is used in the manufacturing processes to make materials such as polycarbonate plastic and epoxy resins and undergoes a chemical reaction with one or more other chemicals in the manufacturing process to produce the plastic or resin, then bisphenol A falls under the exemption in 38 MRSA § 1697 (2), which states, "The requirements of this chapter do not apply to priority chemicals used in or for industry or manufacturing, including chemicals processed or otherwise used in or for industrial or manufacturing purposes." The commenter asserts that the department does not have the authority to apply the law to products that contain impurities that are not intentionally-added. The commenter points to examples that reported trace levels of bisphenol A in plastic baby bottles and liners that are not made from polycarbonate plastic, as well as in food containers that were not expected to contain BPA. The commenter asserts that, based on this premise, the necessary prerequisite for a ban under *Chapter 880: Regulation of Chemical Use in Children's Products* has not been met and the board does not have the authority to ban the children's products identified in the proposed rule. (8)

   Response: The industry exemption applies to chemicals used in industrial processes, such as solvents or wetting agents, that do not and are not intended to become incorporated into the final product either through an additive or reactive process. Bisphenol A is the building block of the polycarbonate plastic from which the reusable food and beverage containers, toys and childcare articles and tableware addressed in this rule are made and the epoxy resins that line the infant formula and baby food packaging to which this rule applies. As such, it contributes to the attributes of these materials (e.g., clarity and shatter resistance, or adhesion and flexibility, respectively) and is therefore appropriately considered to have been "intentionally added" to impart these desired characteristics in the final product. Additionally, free, unreacted bisphenol A remains present in these materials and continues to leach out of them through hydrolysis and other processes over the life of the product. No change to the rule.

1(B) Exemptions

2. Comment: The commenter recommends that the department include all of the statutory exemptions in the rule to clarify that all apply to bisphenol A. (8)

   Response: The department opted to include only those statutory exemptions that apply directly to the chemical addressed in this rule and exclude those that have no relevance. For example, industry has pointed out that parts of vehicles, such as headlight lenses, contain BPA, therefore the transportation exemption was included, but the mercury-added products exemption was not because the proposed rule does not address mercury. To include these irrelevant categories would serve no useful purpose in the rule. No change to the rule.

3. Comment: The commenter suggests that the language in section 1(B)(1) of the rule limits the scope of the used product exemption. (8)

   Response: The alteration in language between 38 MRSA §1697 (1) and section 1(B)(1) was inadvertent and, while the department does not consider the language to substantively alter the meaning or applicability of the law or rule, this section has been amended as follows to be identical to the language in the statute:

Used products. This chapter does not apply to chemicals in ~~the re-sale of products that have been previously~~ used products ~~by consumers~~.

Section 2. Definitions

2(C) Child Care Article

4. Comment: The commenter suggests that the department amend the proposed definition of "childcare article" to be consistent with federal law by designating applicability to products intended for children ages three years or younger. To that end, the commenter proposes that the department replace the proposed definition for "child care article" with the following language from Section 108(e) of the Consumer Product Safety Improvement Act of 2008: "Child care article means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething." (39)

   Response: The department concurs that the suggested change does not alter the rule's intended purpose, and will help make it consistent with other similar rules in the US, making compliance easier for the regulated community. The department has made the suggested change to the proposed rule.

2(G) Reusable Food and Beverage Container

5. Comment: The commenter raises the following objections to the definition of "reusable food container":
   - The definition is circular because the term "receptacle" is the same or more broad than "container;"
   - It is overly broad because the commenter interprets it as covering any container or receptacle that might be used by a food manufacturer, processor or end user and that most kitchen containers would store food and beverages from time to time;
   - The listed examples do not limit the definition's scope and are not illustrative of the scope since the examples are for beverages, not food and that the definition could be interpreted to encompass all cups, glasses, pitchers and large beverage containers, food storage and serving containers, microwave cookware, kitchen appliance bowls, many kitchen items (including measuring spoons), and cooking items such as pots, pans and baking dishes.;
   - The usual or intended purpose of the receptacle is irrelevant, only actual use;
   - The Basis Statement does not provide further examples for context or additional meaning of the term;
   - The definition seems to overlap with the definitions for "tableware" and "childcare articles," while the substantive requirements of the regulation are different for these different categories of products.
   - "Reusable" is not defined (are containers that are reused only once, or emptied within seconds of being filled covered by the ban?);
   - It violates the Due Process Clause because it "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits." The commenter implies that the proposed definition does not "enable those to whom the law is to be applied to reasonably determine their rights" and that it has not been written in "language that the common world will understand, of what the law intends to do if a certain line is passed."
   - That the lack of a meaningful definition of the products at issue directly threatens effective regulatory decision making, including the exposures that may or may not be of concern and which are intended to be one of the lynchpins of the regulatory scheme. (8)

Response: The department adopted this language, the first sentence of which is identical to Connecticut's definition to maintain consistency with other states in the region who have adopted similar legislation and to reduce the burden of compliance for the regulated community. The illustrated examples are not intended to limit the scope of the definition, merely to serve as examples. Intended use is relevant; the department cannot regulate how a consumer will use a product or what products a consumer may use for food storage. The department recognizes that there is potential for overlap between the definitions of "reusable food and beverage container" and "tableware" such as in the case of a container that is sold, intended or labeled for "store and serve" functions. In the case of overlap, the more stringent requirements apply. The term "reusable" is a common term—meaning "able to be used again"—that does not require further clarification. The department presumes that manufacturers will know whether the products they produce are intended for reuse or not, that people of ordinary intelligence comprehend the meaning of "container" and "storage" and that those to whom the rule applies—manufacturers of reusable food and beverage containers—can be reasonably expected to know what products they manufacture and for what purpose those products are intended. The broad reach of the definition is intentional; foods or beverages that are stored in a container can be anticipated to be in prolonged contact with the material of which that container is made, increasing the likelihood of migration of the priority chemical into those foods or beverages, thus increasing likelihood of exposure. However, to provide greater specificity to the definition, the department has added the following language to section 2(G):

> ***G. Reusable food or beverage container.*** *"Reusable food or beverage container" means a ~~receptacle~~ container with a lid, cover, cap or nipple that is manufactured or intended for storing, carrying or transporting food or beverages, including, but not limited to, baby bottles, spill-proof cups, sports bottles and thermoses. "Reusable food or beverage container" does not include a receptacle that contains food or beverage when sold or purchased.*

2(H) Tableware

6. Comment: The commenter recommends that the department amend the proposed definition of tableware to specify those products intended for children ages three years or younger. (39)

Response: While the department appreciates the commenter's desire to narrow the scope of information request to those products intended only for young children, 06-096 Chapter 880, Regulation of Chemical Use in Children's products, section 1(F) defines a child as 18 years or younger for purposes of the Safer Chemical Program. Children's bodies continue to develop and be influenced by hormones well beyond the commenter's proposed three year age. Furthermore, the department considers it reasonable to assume that young children are likely to use and come into contact with tableware that is not specifically manufactured or intended for that age range. No change to the rule.

2(I) Toy

7. Comment: The commenter suggests that the definition of "toy" could be interpreted to include sporting protective gear, such as a hockey mask. (9)

Response: It is not the intent of the department to include sports equipment in the scope of the information request in section 4(B) of the proposed rule. To clarify that intent, the department has revised the definition of toy to include the following additional language:

> *"Toy" does not include helmets, masks, goggles or other personal protective equipment designed to protect the wearer's body from injury during sports and recreation activities.*

8. Comment: The commenter proposes that the department replace the proposed definition of "toy" with the following language to be consistent with federal law: "'Children's toy' means a consumer product

designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays." (39)

Response: The department concurs that consistency with federal definitions could ease compliance burdens for manufacturers and the suggestion does not substantially alter the definition's intended purpose. The department has made the proposed change.

Section 3. Designation of bisphenol A as a priority chemical.

Support for designation

9. Comment: The commenters express support for the proposed designation of BPA as a priority chemical. (1-6, 13-16, 19, 20-37, 40-62. In addition to the individually-listed commenters, the department received 305 emails, 40 faxes, 59 letters and a petition with 852 signatures supporting the proposal).

10. Comment: The commenter contends that the proposed rule is a reasonable proposal backed by significant science, process, the actions of several other states, many countries around the world, and some forward-thinking manufacturers who agree that BPA is not appropriate for use in many consumer products, especially those used to carry and transport food, especially for children. (28)

11. Comment: The commenter contends that bisphenol A should be designated and restricted as a priority chemical because: it is a known endocrine disruptor; it is one of the top five priority chemicals for US EPA regulatory scrutiny; Canada has announced that bisphenol A will be designated as one of 91 chemicals under their List of Toxic Substances; the National Institute for Health is spending more than 30 million dollars to research bisphenol A; the United Nations is convening an international BPA summit this fall to deal with the issue worldwide; and eight states comprising more than 15% of the nation's population have already taken action. (35)

Response to comments 9-11: The department acknowledges the commenters' support. No change to the rule.

Opposition to Designation

12. Comment: The commenters are opposed to designation of bisphenol A as a Priority Chemical. (8-12, 16, 17, 38, 39, 63, 64)

Response: The department acknowledges the commenters' opposition. No change to the rule.

13. Comment: The commenter suggests that it is a waste of money to address BPA on a state level and that instead the department's resources would be better spent promoting federal legislation that would remove dangerous products like BPA nationwide. (38)

Response: The department agrees that a comprehensive chemicals policy at the federal level would be the best way to reduce children's exposures to hazardous chemicals. However, in the absence of a functional federal system to address chemical hazards, the states have an obligation and opportunity to take regulatory action to protect its citizens. Concurrently, the department is actively promoting federal systems that require chemical and product manufacturers to develop and provide chemical health and safety information, as well as exposure and use data to regulators, businesses, and the public; demonstrate that chemicals and products are safe and do not endanger the public or the environment; identify and prioritize chemicals of concern and regulate the most problematic chemicals in commerce, protect the most vulnerable, including pregnant women and children; require manufacturers to assess and identify safer alternatives to chemicals of concern; assess emerging chemicals of concern for public and environmental safety before they go into widespread

commerce and use; strengthen the federal chemical regulation system, while expressly preserving the authority of state and localities to implement measures to manage chemicals of concern; and enhance the role of states in TSCA implementation, promote data and information sharing, and provide sustained funding for state programs. No change to the rule.

14. Comment: The commenter asserts that if the Board were to identify BPA as a chemical of concern or as a chemical that is unsafe it therefore identifies any product that has BPA in it as being unsafe unless there is some sort of clear designation from the Board that it is safe in other respects. (16)

    Response: 38 MRSA §16-D conferred on 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. The Legislature directed the department to publish a list of Chemicals of High Concern and, from that list, designate a minimum of two Priority Chemicals before January 1, 2011. Bisphenol A is on the Chemicals of High Concern list, developed in consultation with the Maine Department of Health and Human Services, Center for Disease Control and Prevention (CDC because it has been identified by other authoritative sources as an endocrine disruptor or a reproductive toxicant. Nothing in the law provides the department with the authority to designate a chemical that appears on the Chemicals of High Concern list as "safe." No change to the rule.

15. Comment: The commenter points out that there are food processors, manufacturers and retailers in Maine that could potentially be impacted by this listing and future listings culled from the department's list of 1,750 chemicals of high concern. (17)

    Response: The department is aware that the designation of priority chemicals could have an impact on manufacturers and retailers in Maine. This impact could be negative, in the case of retailers and manufacturers of the priority chemical, and the impact could be positive in the case of those who manufacture and sell products that employ safer alternatives to priority chemicals. However, as stated in 38 MRSA §1692, "It is the policy of the State, consistent with its duty to protect the health, safety and welfare of its citizens, to reduce exposure of children and other vulnerable populations to chemicals of high concern by substituting safer alternatives when feasible." No change to the rule.

3(A) Presence on chemicals of high concern list

16. Comment: The commenter points out that the correct name for the parent list is "The OSPAR List of Substances of Possible Concern." (8)

    Response: The department's omission of the term "possible" was inadvertent and has been corrected in the basis statement.

17. Comment: The commenter contends that whether BPA should be considered a Chemical of High Concern by the State of Maine or whether BPA is harmful to children are questions NOT at issue in the consideration of proposed Chapter 882; those questions have already been resolved. The commenter states that bisphenol A has already been designated as a Chemical of High Concern (CHC) by the Maine Department of Environmental Protection and that CHCs have, by definition of the statute, already been determined to be harmful by an authoritative government entity on the basis of credible scientific evidence. The commenter asserts that bisphenol A has already been named as a Chemical of High Concern and is therefore already proven harmful to children on the basis of credible scientific evidence. The commenter contends that comments about or opposition to the proposed Chapter 882 based on attempts to reject or reconsider these prior actions are not relevant to Chapter 882 or to the Board's deliberation and decision about the proposed rule. (5)

18. Comment: The commenter opposes the presence of bisphenol A on the Chemicals of High Concern list on the basis of the source lists from which the department derived BPA. The commenter asserts that the OSPAR list is not credible, the European Union endocrine disruptor list is not a list and the

National Toxicology Program monograph on BPA was inconclusive and that not one of the three entities has identified bisphenol A "as being known as" a developmental toxicant or an endocrine disruptor, which is required by Section 1693 of the statute. The commenter suggests that while governments support and participate in the OSPAR Commission, the Commission itself is not a governmental entity with the authority to act like or advise a government. Additionally, the commenter indicates that the OSPAR Commission is focused on the protection of the marine environment and does not undertake work in areas that are relevant to human health, in particular related to children's health, toys or children's products. The commenter asserts that OSPAR selected bisphenol A for their list of substances of possible concern on the basis that bisphenol A is a "potential endocrine disruptor." However, the commenter indicates, OSPAR has also made it clear that bisphenol A is a potential endocrine disruptor since no criteria for identifying endocrine disruptors have been established. Therefore, the commenter asserts, it is not possible for OSPAR to identify bisphenol A "as being known as" an endocrine disruptor. The commenter contends that the European Commission's Community Strategy for Endocrine Disruptors does not mention bisphenol A; refers to substances suspected of being endocrine disruptors and consists of numerous recommendations and actions for further research and evaluation. The commenter points out that the categorization of bisphenol A as a Category 1 endocrine disruptor is not a conclusion that bisphenol A is an endocrine disruptor but only indicates priority for further evaluation. The commenter suggests that the comprehensive risk assessment of bisphenol A published in 2003 and updated in 2008 confirms that bisphenol A does not pose a risk to the general public, including infants and children, from all current sources of exposure including use of polycarbonate plastic and epoxy resins in consumer products. The commenter asserts that the NTP-CERHR evaluation of bisphenol A as "some concern" indicates that more research is needed in certain areas to better understand whether bisphenol A is a human health concern, rather than "being known as a" developmental toxicant. The commenter suggests that because the OSPAR list and European Commission list were not listed in the legislation as governmental entities that the department and CDC may cite when developing the CHC list, they are not suitable for consideration in the designation of chemicals of high concern. The commenter contends that bisphenol A cannot be legitimately designated as a priority chemical, and the proposed designation of bisphenol A as a priority chemical is fundamentally flawed and should be rescinded. (8)

19. Comment: The commenter contends that the prerequisites for designation of BPA as a priority chemical have not been met and do not adhere to the mandates of the statute. The commenter asserts that the Chemicals of High Concern list was published in error. The commenter claims that BPA has not been identified as a "known" reproductive or developmental toxicant or endocrine disruptor by any authoritative governmental entity. The commenter contends that OSPAR is not an authoritative governmental expert or regulatory entity and its previous work on designating hazardous substances has been replaced by REACH; that the EC endocrine disruptor list cited by DEP is intended only to prioritize substances for further research and evaluation as to their potential to cause health effects; and that BPA was not designated as a reproductive or developmental toxicant or endocrine disruptor by the National Toxicology Program. (10)

20. Comment: The commenter asserts that the CHC list is intended to be dynamic subject to update/change and, regardless of the adequacy of data or scrutiny by other regulatory agencies during compilation of the initial list, the criteria are clearly met at this point from US EPA sources alone. (58)

Response to comments 17-20: The department developed this list in consultation with a toxicologist from the Maine CDC and published it, as well as a background document that describes the sources for the chemicals listed, on the department's website at http://www.maine.gov/dep/oc/safechem/highconcern/.

Applying the commenters' standard of "known" would exempt every chemical from being listed as high concern due to inherent uncertainty in the realm of toxicology. Clearly the Legislature did not intend to write a statute that would have no effect. Rather, the criteria in establishing the Chemicals of High Concern list are further delineated in the unallocated language in Section 3 of PL 2007 c. 643, indicating that the Legislature intended a definition of "known" that is much broader than the commenters interpret it to be, and left room for the department and the Maine CDC to exercise their judgment in developing the list. The department and the Maine CDC interpreted the Legislature's intent to include endocrine disruptors and to use sources such as OSPAR and the European Commission's Priority list of endocrine disruptors as well as the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (CERHR)'s top three levels of concern for risks to reproduction.

The intent of the process laid out by the Legislature for developing the CHC list was to take advantage of other governments' work to quickly narrow the list over 80,000 chemicals in commercial use down to a smaller list of chemicals with potential to cause harm to children. This allowed the department to focus its limited resources on the smaller list and quickly move to reduce exposure.

In every case, prior to proposing a substance for designation as a priority chemical, the Maine CDC toxicologists will review the toxicity data to ensure that the initial designation by the source list was appropriate and supported by credible scientific evidence. Bisphenol A clearly demonstrates strong evidence of both endocrine disruption and reproductive toxicity.

The department stands by its determination that bisphenol A meets the requirements of designation on the Chemicals of High Concern list. In the judgment of the department and Maine CDC, OSPAR (The Convention for the Protection of the Marine Environment of the North-East), the European Commission and the US National Toxicology Program are all authoritative governmental entities. OSPAR is the mechanism by which fifteen Governments of the western coasts and catchments of Europe, together with the European Community, cooperate to protect the marine environment of the North-East Atlantic. The fifteen Governments are Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom. While OSPAR itself is not a government agency, its function as a mechanism that helps governments cooperate and provides those governments with monitoring and research tools and policy guidance is analogous to that of the World Health Organization, which is listed in PL 2007, c. 643, section 3.

OSPAR's list of Substances of Possible Concern was developed based on the ***inherent hazard*** *of those substances, regardless of whether OSPAR's primary focus is on the marine environment, rather than human health. Chemicals rise to the level of Priority Action in OSPAR based on that organization's internal ranking criteria. Maine DEP has a different set of criteria, and no requirement to rank chemicals, laid out by the Legislature in 38 MRSA §1694. Bisphenol A meets all six of those criteria (although it is only required to meet one).*

Furthermore, at least three members of the 124th Maine Legislature, including the Speaker of the House and the President of the Senate, testified or submitted comments in support of the department's proposed rule, indicating that designation of bisphenol A as a priority chemical was well within the intent of the Legislature in enacting the Toxic Chemicals in Children's Products law.

No change to the rule.

Risk-Based Prioritization

21. Comment: The commenter suggests that the department should undertake a risk-based prioritization to identify chemicals of highest concern through exposure, use, and hazard data relevant to the US

population and a "weight-of-evidence" approach to chemicals prioritization that evaluates authoritative information on hazard traits, and considers the most severe hazards first. (10)

Response: 38 MRSA §1694 gives the department the authority to designate a chemical of high concern as a priority chemical if it meets one of the six stipulated criteria. The application of these criteria does not necessitate ranking the chemicals on the CHC list, nor does the statute require the department to rank chemicals, as suggested by the commenter. The criteria given in the statute for designation of priority chemicals very specifically require only that chemicals be present in human blood, in the natural environment, in a consumer product, etc. A risk analysis is not required.

As stated in subsection 2(A) of 06-096 CMR Chapter 880, Regulation of Chemical Use in Children's Products, one of the purposes of designating priority chemicals is to facilitate gathering of information on the use of chemicals in consumer products, the extent to which children may be exposed and the safety and availability of alternatives. To require the department to conduct a risk analysis of every chemical on the CHC list in order to rank them would stand this process on its head, such that the department would need to have the very information it seeks in order to request that information from manufacturers. The lack of complete information should not be a barrier to designation; on the contrary, it may be a compelling factor in favor of designation.

No change to the rule.

Federal Action

22. Comment: The commenter asserts that while federal Food and Drug Administration (FDA) has taken the position that products currently on the market containing BPA are safe, the report from the FDA Science Board Subcommittee on Bisphenol A states: "Coupling together the available qualitative and quantitative information (including application of uncertainty factors) provides a sufficient scientific basis to conclude that the Margins of Safety defined by the FDA as "adequate" are, in fact, inadequate." (2)

23. Comment: The commenter points out that the US FDA has begun working with the food industry to reduce or eliminate BPA exposure. The commenter suggests that this important partnership should be encouraged to help reinforce the research efforts underway. The commenter contends that the Board's activity would undermine the authority of the FDA to effectively regulate the safety of food, including packaging. (11)

24. Comment: The commenter contends that the FDA's exact statement on January 10, 2010 is that research is going on about the uncertainties and the potential of BPA, but they specifically stated they are not recommending the change in the use of infant formula or foods as the benefits of a stable source of good nutrition far outweigh the possible risks. The commenter concludes that the FDA essentially said bisphenol A is safe for its intended use. (12)

25. Comment: The commenter suggests that if the Federal Food and Drug Administration considered BPA to be a health risk, that agency would take steps to address it. (17)

26. Comment: The commenter asserts Linda Birnbaum, director of the National Institute for Environmental Health Sciences, the primary federal agency studying the safety of BPA, said that people should avoid ingesting the chemical, especially pregnant women, infants and children. The commenter quotes Birnbaum as saying there are plenty of reasonable alternatives and that she has seen enough studies about its effects on human health and advises her children to avoid using food packaged in containers made with BPA and that consumers should be "absolutely" worried about BPA. (32)

27. Comment: The commenter suggests that, in light of the FDA's recent update on BPA and its efforts to further evaluate the chemical, the department's regulation of the chemical is premature. (39)

Response to comments 22-27: The FDA's update on Bisphenol A for Use in Food Contact Applications of January 2010 indicates that that agency does consider BPA a health risk. The FDA echoed the National Toxicology Program's statement on BPA, saying it has "some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children." The agency is carrying out a review in cooperation with other federal agencies to further develop knowledge concerning BPA risks. While that review takes place, the agency is taking steps to reduce human exposure to BPA in the food supply, including: supporting voluntary phase-out of BPA in baby bottles and feeding cups; facilitating the development of alternatives to BPA for the lining of formula cans; and supporting efforts to replace or minimize BPA in other food can linings. Additionally, FDA is supporting a shift to a more robust regulatory framework for oversight of BPA. The department commends the FDA's research and bisphenol A reduction efforts and looks forward to the results. However, the department's proposed rule in no way undermines, oversteps or in any other way interferes with efforts in this area. Rather, this rule is a complementary information gathering and exposure reduction effort that will likely, if anything, enhance FDA's ability to develop meaningful federal regulation. No change to the rule.

28. Comment: The commenter asserts that the proposed rule would be in direct conflict with the federal regulatory scheme. The commenter points out that only FDA has the authority to approve any alternatives to BPA for food contact applications and that FDA is considering alternatives, developing guidance on endocrine disruption pharmacokinetic data on BPA, developing the Chemical Evaluation Risk Estimation System to evaluate risks from exposure. (10)

The department does not propose to approve alternatives to BPA for food contact applications. What the department proposes to do with this rulemaking is to gather information on the extent of the use of BPA in infant food and formula packaging in Maine and the likelihood that children may be exposed from those uses. The department is requiring an alternatives assessment not for the purpose of approving any alternative for food contact applications, but rather to assess whether there are indeed alternatives available on the market, or under development that have a lower hazard or exposure profile than bisphenol A. If an alternative is already on the market, it has presumably gone through FDA's approval process. If an alternative is still in the development stages, it will obviously go through that same approval process prior to entering the market or being considered a safer alternative. Maine DEP is not US FDA and does not presume to serve that agency's function. No change to the rule.

BPA Regulation in Other Jurisdictions

29. Comment: The commenter asserts that all other governments found BPA safe for human health. (8)

30. Comment: The commenter asserts that BPA is well studied and regulated, and is safe for use as intended in food contact materials and that current exposure levels of BPA are safe for consumers and the environment as demonstrated by repeated testing and review by qualified experts and the history of over 60 years of commercial canned food safety. The commenter contends that repeated weight-of-the-evidence evaluations of all available scientific data and information by expert bodies around the world continue to show that BPA is safe for use as intended. The commenter cites assessments conducted by Food Standards Australia-New Zealand, Health Canada, the German Federal Institute for Risk Assessment, the US Food and Drug Administration, the European Food Safety Authority, the UK Food Standards Agency and the Japanese Ministry of Health, Labor and Welfare as agencies that have reaffirmed the safety of BPA and the commenter asserts that previous decisions to limit BPA use—Health Canada, Denmark—have been based on an "abundance of precaution" rather than evidence-based risk assessments. (10)

31. Comment: The commenter contends that the Obama Administration and the FDA say BPA is safe for current uses, and that the FDA's position on the safety of BPA concurs with the European Union, Canada, Australia, New Zealand, Japan and other public health bodies worldwide. (11)

32. Comment: The commenter concedes that Canada may list BPA in the near future as a CEPA (Canadian Environmental Protection Agency), but the Canadian Food Safety Authority has stated that at its current levels BPA is safe for infants and children. The commenter contends that the following agencies, states and countries have affirmed the safety of BPA: FDA, California Proposition 65, Germany, UK, New Zealand, EFSA and Japan. The commenter contends that Dr. Sue Barlow who is part of the European Food Safety Authority, stated that based on all of the studies it is the Authority's opinion that BPA is safe. (12)

33. Comment: The commenter contends that the FDA, the European Safety Association and the Japanese government have indicated that epoxy resins and polycarbonates are safe in their use in contact with food or beverages. The commenter takes issue with another commenter who noted that Health Canada recently issued a report that called into question the safety of BPA. The commenter states that Health Canada reaffirmed the safety of BPA in beverage containers and, when issuing the results of the recent survey, Health Canada concluded that the results "further confirm exposure to BPA from food and drink containers is very low and poses no health or safety concerns to the general population." (16)

34. Comment: The commenter contends that the FDA and the Department of Health and Human Services said earlier this year that if they though BPA was a health risk, they'd be taking regulatory steps to address it, but they are not. (17)

35. Comment: The commenter contends that the agency reviews cited by the opponents followed a process that limited the number of studies reviewed to a very small number, almost all of which had been funded by industry and had significant flaws. The commenter contends that in August Canada announced that they have rejected the American Chemistry Council's request to declare bisphenol A nontoxic and that the same week Sweden made a statement announcing it was taking steps to regulate BPA. (22)

36. Comment: The commenter contends that the Canadians just completed a bio-monitoring study that shows 90 to 95 percent of adults in Canada have BPA in their blood, and the levels were actually higher in teenagers than adults and that Canada is considering labeling BPA as a health threat to the general population, not just young children. Further, the commenter points out that BPA is banned in baby bottles in Canada as of March 2010 based on legislation initiated in 2008. Additionally, the commenter contends that the Canadian food safety organization actually said that due to the uncertainty raised in some animal studies related to the potential effects of low levels of BPA, the government of Canada is taking action to enhance the protection of infants and young children by recommending that the general principle of ALARA (as low as reasonably achievable), be applied to continued efforts on limiting BPA exposure from food packaging applications. (26)

37. Comment: The commenter contends that the following countries have taken steps to regulate bisphenol A in consumer products: the Danish government, together with the Danish People's Party, decided to invoke the principle of precaution and introduce a temporary national ban on bisphenol A in materials in contact with food for children aged 0 – 3 years; Germany advises manufacturers, importers, and users of bisphenol A to use alternative substances that pose less risk to human health and the environment in all areas of use that significantly contribute to exposure; the French Food Safety Agency (AFSSA) said consumers should be informed of the presence of bisphenol A in food containers and household utensils and recommended labeling system be introduced to warn

consumers not to heat these items for long and to "protect the most sensitive", namely babies and fetus, from the potential risks associated with BPA contamination, and the French Parliament acted to limit BPA in some uses; in California, both houses have passed protective BPA bans that are slightly different and they are working to resolve those minor differences and send legislation to Governor Schwarzenegger for his signature; Sweden has declared that if the EU does not act to protect its citizens from BPA it will act separately to do so; and Health Canada is moving forward with the regulatory steps necessary to declare bisphenol A toxic. (32)

Response to comments 30-38: The department acknowledges there has been a wide range of regulatory and policy responses to concern over bisphenol A between and even within governments. This disparity largely stems from the difference between risk-assessment-based chemical policy decision-making and hazard-based decision making. The law that established Maine's Toxic Chemicals in Children's Products program (38 MRSA §16-D) established a hazard-based chemical policy mechanism. This means that a chemical that has been designated as a known hazard by an authoritative governmental entity appears on the chemicals of high concern list published by the department in concurrence with the Maine CDC and can be designated as a priority chemical and regulated in children's products by demonstrating inherent hazard characteristics and exposure to children without necessitating a risk assessment or cost-benefit analysis. No change to the rule.

Health Effects of BPA

38. Comment: The commenter points out that two large and well-controlled studies of the possible health effects of BPA exposure on humans have been conducted, revealing positive correlations between urinary BPA concentrations and the prevalence of diabetes, heart disease and liver toxicity and that several smaller studies have found BPA associated with other health outcomes in women including obesity, endometrial hyperplasia, recurrent miscarriages, sterility, and polycystic ovarian syndrome. The commenter contends that animal studies indicate developmental exposure to environmentally relevant levels of BPA alters the development of the brain, the male and female reproductive tracts, the mammary gland and other organ systems and that BPA exposure in rats increases the incidence of prostate and mammary cancers in rodents. (2)

39. Comment: The commenter disputes the Maine CDC Justification of Concurrence document which states there is "no controversy" or that "consensus is that sufficient evidence exists..." that BPA causes adverse effects. The commenter refers the department to additional references pertaining to low dose effects of BPA: a 2009 article by Ryan et al demonstrating no effect from BPA on sexually dimorphic behavior, puberty, fertility and anatomy of female LE rats; the EU Joint Research Centre's Institute for Health and Consumer Protection report on "Bisphenol A and Baby Bottles: challenges and Perspectives;" and a 2010 article by Doerge et al in which the authors state that their "...observations imply that any toxicological effect observed in rats from early postnatal exposures to BPA could over-predict those possible for primates of the same age..." The commenter contends there is no human evidence to suggest that BPA causes selective reproductive toxicity. The commenter notes that a body of animal data from five reproductive toxicity studies indicates the most sensitive effect of BPA (the one that occurs at the lowest dose) is systemic toxicity. The commenter suggests that most of the studies that have examined endpoints indicative of reproductive toxicity employed unvalidated methodologies and have major limitations and inadequacies that make them either irrelevant to human exposures or inappropriate for human hazard identification. Therefore, the commenter asserts, listing BPA and the subsequent sales prohibition are unwarranted, would unnecessarily alarm Maine citizens, and would compromise the availability of safe, nutritious foods. (10)

40. Comment: The commenter contends that studies based on dermal injection are invalid because humans ingest food. The commenter asserts that as soon as BPA is put into the stomach, it is

converted into the glucoronide as it passes through the intestinal wall and as it goes through the liver, it's metabolized and excreted. (12)

41. The commenter contends that over 90 percent of government-funded studies find adverse effects of BPA at low levels while none of the industry-funded studies find adverse effects. The commenter asserts that when you look closely at the experiments that haven't found effects, you often find big flaws. The commenter cites the example of two recent studies done by the US EPA lab that reported no impacts on reproductive development in male and female rats exposed in the womb; however, the rats used were extremely insensitive to estrogen. The commenter states that often the big industry-funded studies use standardized assays, rather than more current approaches. The commenter contends that studies that inject BPA in their subjects are valid because we don't yet understand all of the routes of exposure to bisphenol A (e.g. dermal absorption from receipt paper) and that in terms of research on effects on fetuses, it doesn't matter how the BPA gets into the mom; if it's in the womb in unconjugated form, it's there whether it got there by pump or ingestion. (13)

42. Comment: The commenter contends that the legislature did not require the department to have conclusive proof of chemicals' health effects, but rather a preponderance of evidence. (18)

43. Comment: The commenter points out that children have developing organ systems that are meant to last a lifetime; they are not merely small adults, and they have brains, kidneys, livers, pancreases, hearts, lungs that are growing at an rapidly alarming rate. The commenter asserts that repeated exposure to toxins during this critical stage is detrimental to their growth and development and is causing direct damage to the structure and function of their cells and exposure to BPA in the womb during infancy or in childhood can set the stage for a lifetime of health problems in our most vulnerable populations. (19)

44. Comment: The commenter recommends that the Board follow the precautionary principle. The commenter states that because infants and young children do not have a voice, we have a moral imperative to speak on their behalf, and if we can't absolutely say there is no long-term risk to their development, then we have a moral obligation to protect them. (20)

45. Comment: The commenter points out that conditions of certainty rarely exists in the arcane world of toxicology, but the accumulating data from mostly animal studies has reached the point where it's appropriate to apply the precautionary principle and start restricting the use of BPA in children's products. (26)

Response to comments 38-45: The department understands that high doses of BPA are required to produce effects on the classic nuclear estrogen receptor and associated toxic endpoints. However, dozens of studies have documented adverse consequences of low-dose exposure in animal models on endpoints mediated through other mechanisms, such as cell membrane estrogen receptors. In addition, BPA produces effects on other systems, including the nervous and immune systems, and energy metabolic pathways (fat storage) that do not involve the estrogen receptor. Studies in humans have found associations between environmental BPA exposure and diabetes and heart disease in adults, as well as adverse behavioral outcomes as a consequence of in utero exposure. A just-published study found an association between BPA exposure and increased testosterone levels in men and changes in sex hormone binding globulin in pre-menopausal women. These results in the general human population suggest that BPA is exerting effects at levels of current exposure. No change to the rule.

Metabolism of BPA

46. Comment: The commenter suggests that BPA is not a health risk because infants and adults rapidly metabolize it. (8)

47. Comment: The commenter asserts the study on which contentions of rapid metabolism of BPA in the human body is based on a very small study that used a method of analysis that is ten times less sensitive than modern methods. The commenter asserts data from multiple studies by many different scientists establish clearly that most Americans have levels of BPA in their serum that are know to cause a wide range of adverse effects on experimental animals and also cause adverse effects in human cells. The commenter contends that almost two dozen studies have measured BPA—not the metabolized form, but the parent compound—in serum, showing that it can get where it causes harm. Additionally, the commenter points out that there are metabolic processes that take the glucoronated form of BPA and reconvert it to the parent form. The commenter asserts that through the classic mode of action initially studied in terms of endocrine disruption, BPA is a thousand to ten thousand times weaker than native estrogen; but for the last five years we've known that BPA works through another receptor on the surface of the cell membrane, and via that pathway it's just as powerful as the common human estrogen estradiol and can cause changes in human and rat cells at levels as low as less than a part per trillion. (13)

48. Comment: The commenter points out that children and fetuses are developing. There are developmental changes and processes happening in the body and if that process is disrupted, there is often not a chance for repair; there is a window that is crucial. The commenter contends that metabolism of BPA in neonates is a relatively meaningless element to toxicity. The commenter points out that metabolism does play a role, but the action within the human body is key. The commenter uses the example of a pharmaceutical that is excreted more quickly in infants and children than adults but is not used in those populations because it's presumed to be toxic to their developing cartilage. The commenter concludes that whether or not BPA is metabolized as fast as or faster or slower in children than adults is relatively meaningless, because what it's doing in the infant's body is what is important, and, the commenter asserts, bisphenol A is doing deleterious things to an infant's body when it's present. (21)

49. Comment: The commenter disputes suggestions by commenter #8 that BPA is metabolized similarly in newborns as well as adults and is unlikely to build up in the blood or tissues which seems to imply that because of metabolism, the chemical is completely eliminated from the body quickly and not available for systemic exposure. The commenter states that even if we accept the assertion that BPA is metabolized by infants as efficiently as adults, the commenter asserts that the implication that this prevents prolonged systemic exposure is erroneous because exposure to BPA can occur multiple times per day at each feeding where liquid formula, baby food, or breast milk that has BPA contamination is fed to the child. Assuming BPA has a half-life for elimination of approximately four to six hours—which is a matter of some controversy—there is potential for BPA to build up in the body and reach a "steady state" concentration, considering a typical two to three-hour feeding schedule for infants; this steady state concentration is the point at which equilibrium is achieved between exposure to BPA and elimination of the substance. Some studies suggest that the steady state achieved in infants is much greater than that for adults. Based on this steady state, it is likely that some BPA will be in the body constantly with the potential for systemic exposure. If you couple this with the many studies that show adverse effects of BPA at lower and lower levels of exposure, there is likely some potential for risk from BPA exposure to infants and newborns. (58)

Response to comments 46-49: It has been proposed that the fact that BPA is conjugated in the liver after ingestion (first-pass metabolism) and then presumably rapidly excreted in urine provides evidence that it does not present a hazard. However, conjugated BPA can be deconjugated in a number of tissues in the body, including the placenta. In addition, all the pathways of BPA exposure have not been identified and may include routes other than ingestion, thereby providing an opportunity for exposure of BPA to tissues without first-pass metabolism. A recent study in neonatal mice found no difference in plasma BPA levels following oral ingestion versus subcutaneous injection, suggestion that conjugation of BPA may not be efficient in young animals. Finally,

exposure of the general population to BPA is apparently constant based on the results of biomonitoring studies (see response to comment #50-51). Therefore, the only relevance of the half-life of BPA in the body is the potential for BPA levels to increase to some steady state concentration as a function of the relative half-life compared to the frequency of exposure. No change to the rule.

3(B) Criteria for designation

3(B)(1) Bisphenol A has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids.

50. Comment: The commenter states that since 1999, more than a dozen studies using a variety of different analytical techniques have measured free, unconjugated BPA concentrations in human serum at levels ranging from 0.2-20 ppb (ng/ml) serum. (2)

51. Comment: The commenter suggests that BPA is not found in human urine, but rather an inert metabolite is present. (8)

Response to comments 50-51: BPA has been detected in the majority of people in dozens of studies conducted around the world. Unconjugated BPA (the active form) has been detected in maternal blood, blood and tissue from umbilical cord, and breast milk. The US CDC reported detection of BPA in the urine of 93 percent of individuals in a study designed to be representative of the US population, suggestive of widespread exposure. The concentrations in children were higher than those in adults. Although the CDC study measured total BPA (conjugated and unconjugated), other studies have detected unconjugated BPA in urine, providing further evidence that all of the BPA is not being conjugated, or is being back-converted in the body to free BPA. The fact that BPA in urine is largely in the conjugated form is not evidence that the free form is not present in bodily tissues; in fact, there is substantial evidence to the contrary. No change to the rule.

3(B)(3) Bisphenol A has been found through monitoring to be present in fish, wildlife or the natural environment

52. Comment: The commenter points out that findings presented in March 2010 at the American Chemical Society's national symposium demonstrated that BPA has been detected in seawater samples and sand samples at levels that have endocrine activity at over 200 sites around the world and is believed to be related to the breaking down of plastic products in the marine environment. The commenter suggests the marine environment affects children and many susceptible populations; it's where a large amount of our food comes from. Additionally, the commenter posits that lobsters are another susceptible population that may be affected by BPA. (14)

Response: While the intent of the law and the rule is to protect the health of children and other vulnerable populations, the department appreciates that the benefits of removing hazards from consumer products can extend to other populations, including marine life. No change to the rule.

Section 4. Information Submission Required

4(A) Infant formula and baby food.

53. Comment: The commenters support the department's proposal to require reporting on BPA use in the packaging of foods and beverages marketed to children under age 3, and full assessment of safer alternatives to BPA for these uses. (The department received 129 emails with this statement).

Response: The department acknowledges the commenters' support. No change to the rule.

54. Comment: We appreciate the department's request to be updated on the number of products containing BPA and the status of finding alternatives to current packaging. However, some of the information requested in Section 4 could be considered proprietary and company-confidential. Proprietary information could not be shared, unless the department designated the submissions as confidential, did not disclose them to any other parties, and ensured they were not subject to release pursuant to a Freedom of Information submission. (63)

Response: Department rule 06-096 Chapter 880, Regulation of Chemical Use in Children's Products, section 3(F), provides for the handling of information to be claimed confidential in accordance with 38 MRSA §1310-B. Under section 1310-B, any records clearly marked as 'claimed confidential' on each page by the submitting party will be segregated. If the department receives a request for that information, the department will notify the submitter, who will then have 15 days to demonstrate that the information should not be disclosed because it is a trade secret or production, commercial or financial information, the disclosure of which would impair the competitive position of the submitter and would make available information not otherwise publicly available. No change to the rule.

55. Comment: The commenter contends that, because the first part of definition of "consumer product"—"'Consumer product' means any item sold for residential or commercial use, including any component parts and packaging"—includes the packaging of consumer product as an integral part of a consumer product, but the second section—"'Consumer product' does not include a food or beverage or an additive to a food or beverage…"—excludes any food, any beverage and any additive to a food or beverage. The commenter asserts that the purpose of the exclusion is to put beyond regulatory reach any food additive, including those from packaging, and thereby exclude from the statute and DEP regulatory purview concerns about food or beverages, and also what may appear in food or beverages, directly or indirectly, as an additive. (8)

Response: Title 38 MRSA §1697 (8) Food and Beverage Packaging makes clear that any restrictions on applicability of the law to food and beverage packaging do not apply to products "intentionally marketed or intended for the use of children under 3 years of age." No change to the rule.

56. Response: Given the conclusions of the FDA and other world food safety organizations, requiring local beverage distributors to file a report for every one of the products they sell in Maine in an aluminum can, simply because BPA is used as a liner in the can, would present an undue and unnecessary requirement. (16)

Response: The department does not propose to require local beverage distributors to file a report for the products they sell in Maine in an aluminum can. Aluminum beverage cans, unless they are intentionally marketed or intended for the use of children under three years of age are exempt from the requirements of 38 MRSA §16-D, and thus this chapter (please see section 1 (B)(2) of the proposed rule). No change to the rule.

4(B) Toys, childcare articles and tableware.

57. Comment: The commenter points out that no other state has banned BPA in toys. (9)

Response: The department is not proposing a ban on BPA use in toys with this rulemaking. Rather, it is seeking additional information to make an informed decision. No change to the rule.

58. Comment: The commenter asserts that requiring reporting for toys will not address any safety concern with regard to BPA exposure therefore, Section 4(B) should strike all references to toys with regard to reporting. (9)

As stated in subsection 2(A) of 06-096 CMR Chapter 880, Regulation of Chemical Use in Children's Products, one of the purposes of designating priority chemicals is to facilitate gathering of information on the use of chemicals in consumer products, the extent to which children may be exposed and the safety and availability of alternatives. The information gathered through section 4(B) of the rule will assist the department in assessing whether or not there is a health concern regarding toys containing bisphenol A. No change to the rule.

59. Comment: The commenters recommend that the request for information be limited only to toys intended to be placed in the mouth. (9, 39)

Response: While the department understands the commenter's desire to limit the burden on the affected manufacturers, the intent of the information request is to gather information that will give the department a greater understanding of the extent of the use of the priority chemical and the likelihood that children will be exposed. The broader scope of the children's toy definition will give the department a greater understanding of the extent to which the chemical is used in products children come into contact with; without the request for information, the department has no data to verify that BPA is only used in toys for older children. Additionally, it is possible that other avenues of exposure, including dermal contact, could be of concern with BPA. However, to assess the relevance of mouthing of toys, the department has added the following to section 4(B) of the proposed rule:

> *(3) A description of the product or products containing BPA, including the overall size of the product and/or the component of the product that contains BPA and whether the product or BPA-containing component of the product can be placed in the mouth. A toy can be placed in a child's mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the toy can only be licked, it is not able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth.*

Testing and *de minimus*

60. Comment: The commenter suggests that the department include a trigger level for reporting, and suggests 0.1% as that level. The commenter contends that a 0.1% (1,000 ppm) threshold was established as an appropriate level for classification and labeling purposes by the European Union's GHS program. Additionally, 0.1% is included as a relevant reporting threshold for articles in the EU REACH, Article 7 for reporting of substances in articles such as toys. The trigger would be established as the baseline above which reporting would be required and below which a company would not be required to report on BPA levels in toys. (9)

61. Comment: The commenter contends that the *de minimus* level proposed by commenter #9 would exempt all toys from the proposed reporting requirement. The commenter points out that, based on hearing testimony, free and detectable BPA occurs at around 1 part per million (ppm) in polycarbonate plastic, while the commenter proposes a *de minimus* level of 0.1%, or 1000 ppm. The commenter points out that, although polycarbonate plastic and epoxy resin only contain very small amounts of BPA once polymerized or cured, these materials remain a major ongoing source of BPA exposure as the BPA leaches out of the material over time. Further, the commenter stresses that BPA is biologically active at the parts per trillion level or lower once in the body. The commenter also stresses that referencing the REACH *de minimus* level of 0.1% is only relevant when addressing additive chemicals used in high concentrations, stating that in those cases the threshold will pick up intentional uses yet allow for incidental contamination to be exempt from regulation, but that such a

threshold would not work for BPA and other reactive chemicals that later leach out of the polymer or other transformed chemical matrix. The commenter proposes that, if the department and Board feel compelled to include a *de minimus* level it should be 0.1% for polycarbonate content, not BPA. (1)

62. Comment: The commenter suggests the inclusion of a trigger level for testing/reporting in the case of certain children's toys (but not food containers) is reasonable, if one can be readily ascertained. (58)

63. Comment: The department does not specify an analytical test method for determining concentration levels of BPA for reporting purposes. It is unclear how manufacturers will attempt to collect this information up stream in the supply chain and aggregate for components in the finished assembled product. For example, BPA used as a coating on printed circuit boards in a toy remote control car with a polycarbonate windshield containing BPA may be measured differently by suppliers of those components and the manufacturer would presumably then need to aggregate using the total weight of the entire toy. (39)

64. Comment: The commenter suggests that testing is not necessary to determine BPA content of products. Rather, the commenter contends a manufacturer only needs to know whether a part is made of polycarbonate plastic or contains BADGE based epoxy resin. The commenter asserts that manufacturers either already have this information or can readily obtain it from suppliers. The commenter concludes that if a toy contains either polycarbonate or epoxy, then it will be a source of BPA exposure to children and the environment. The commenter recommends that the department clarify the rule to refer to the presence of these materials as the reportable surrogate for the amount of BPA present in the product. (1)

Response to comments 61-65: The department shares the commenters' desire to minimize the reporting burden to the regulated community. However, the department believes that instituting a reporting threshold would force businesses into an expensive testing scenario that may not be within reach of some small businesses, and the department does not at this time have the information necessary to set a scientifically-valid threshold level; simply replicating the level used by another jurisdiction for unrelated compounds may not be the best course of action for addressing exposure to bisphenol A. Furthermore, it has been shown that BPA leaches out of polycarbonate plastic over time through hydrolysis and other processes. Therefore the amount of unreacted BPA in a children's product at the time of manufacture or sale may not represent the true likelihood of exposure of children to BPA over the lifetime of the product. To make reporting easier for manufacturers and avoid underreporting of BPA, the department proposes to use polycarbonate plastic and epoxy resin as a surrogate for bisphenol a and has amended sections 4(B)(5) and 4(B)(6)to read:

> *(5) The amount of bisphenol A in each unit of the product, or the amount of polycarbonate plastic or epoxy resin (percent by weight) in each unit of the product;*
>
> *(6) The function of bisphenol A (or polycarbonate plastic/epoxy resin) in the product; and*

With the addition of this language, the department does not propose to designate either polycarbonate plastic or epoxy resin as a priority chemical. Rather, the department seeks to minimize the regulatory burden and cost of compliance for manufacturers of the products subject to the requirements of the proposed rule by allowing them to report on presence of these materials as a proxy for bisphenol A, rather than test their products for the measured level of bisphenol A. The department acknowledges that in the case in which a manufacturer is unable to obtain information regarding the constituents of its raw materials from a supplier, testing may become necessary. However the department maintains that it does not have necessary information needed to establish an appropriate reporting threshold at this time. No change to the rule.

Other Product Categories

65. Comment: The commenters recommend that the department require usage reporting and alternatives assessments for food packaging for toddlers and epoxy-based floor coatings that contain intentionally-added BPA. (1,5)

Response: The department appreciates the commenters directing its attention to these other product categories that had not been considered for this rulemaking. The department will look into publicly available information on these products and determine whether a future request information is warranted. No change to the rule.

Section 5. Sales prohibition of children's products containing bisphenol A

66. Comment: The commenter points out that the department uses the term "children's product" in the title of the proposed rule and section 5(C)(1) and 5(E), whereas the term "consumer product" appears in section 5(B), while sections 5(A) and 5(D) do not use either term. The commenter asks the department to clarify whether the use or lack of use of specific terms is intentional. The commenter contends that the inconsistency in use of these terms is ambiguous and frustrating and could prevent compliance and enforcement of the regulation. (8)

Response: The use of "consumer product" rather than "children's product" in subsection 5(B) of the proposed rule was an inadvertent oversight in the development of the rule and the inconsistency has been remedied by the deletion of that subsection based on other comments (see response to comments #88-89). The absence of either term in subsections 5(A) and 5(D) is intentional, as section 5 applies only to a specific subset of children's products—reusable food and beverage containers. The proposed rule does not presume to extend the sales prohibition in section 5 to all children's products that contain bisphenol A. No additional change to the rule.

Support for sales prohibition of reusable food and beverage containers containing bisphenol A

67. Comment: The commenters express support for the sales prohibition of BPA in reusable food and beverage containers. (1- 6, 13-16, 19-37, 40-62. In addition to the individually-listed commenters, the department received, 305 emails, 40 faxes, 59 letters and a petition with 852 signatures supporting the proposal).

68. Comment: The commenter supports a ban of bisphenol A from consumer products, particularly those products used by pregnant women, infants and children. (2)

Response to comments 67-68: The department acknowledges the commenters' support. No change to the rule.

Opposition to sales prohibition on reusable food and beverage containers containing bisphenol A

69. Comment: The commenter points out that the statutory definition of "consumer product" in the Toxic Chemicals Law specifically does not include "a food or beverage or an additive to a food or beverage…" The commenter asserts that consumer products made from polycarbonate plastic or epoxy resins are thus excluded from the definition of "consumer product" to the extent that they are regulated as a "food additive" under to federal, Food, Drug and Cosmetics Act. The commenter quotes the definition of "food additive" from the Act as, "[T]he intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of or otherwise affecting the characteristics of any food (including any substance intended for the use in the producing, manufacturing, packaging, processing, preparing, treating, packaging, transporting, or holding food…." The commenter asserts that reusable food or beverage containers such as baby

bottles, sports water bottles, spill-proof cups or thermoses made from polycarbonate plastic are excluded from the regulation because polycarbonate plastic is regulated by the FDA as a food additive, based on the definition of "Food Additive" in 21 CFR Part 170.3, "A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container." (8)

Response: When a definition is not provided in statute, standard practice is to defer to the dictionary definition. In this case, the dictionary definition of "additive" is "a substance added in small amounts to alter it." This definition cannot be construed in any way to encompass a food or beverage container. While the definition of food additive quoted by the commenter may be useful for the FDA's regulatory purposes, applying such a definition to products such as baby bottles and sippy cups that contain a priority chemical would thwart the intent of the legislature, which, as stated in the declaration of policy in 38 MRSA §1692, is "to reduce exposure of children and other vulnerable populations to chemicals of high concern by substituting safer alternatives when feasible." No change to the rule.

70. Comment: The commenter contends that the immediate sales prohibition on reusable food and beverage containers skips step 3 (collection and review of data on the priority chemical in children's products) and step 4 (collection and review of data on the availability of safer alternatives), in the five-step process of implementing the law that the department has articulated in the past. The commenter asserts that in not first collecting the necessary and appropriate data on exposures and alternatives the department's proposal of a sales prohibition is inconsistent with statute and precludes the department from consideration of information that would inform its decision making on the prohibition. The commenter points out that the department does not explain why it is not seeking information on reusable food and beverage containers in the Basis Statement. The commenter concludes that the department lacks information on all other reusable food and beverage containers that are not "infant bottles, toddler cups and reusable sports water bottles." The commenter contends that information gathered during the comment period pertaining to this rulemaking is not a substitute for thoughtful analysis of necessary information contemplated by the legislature before a ban is proposed and for analysis of information that would be submitted to the department in response to an information-gathering rule. (8)

Response: 38 MRSA §1695(3) states, "The commissioner may waive all or part of the notification requirement under subsection 1 for one or more specified uses of a priority chemical if the commissioner determines that substantially equivalent information is already publicly available...." Because readily available information indicates that polycarbonate plastic reusable food and beverage containers do contain bisphenol A and that children are exposed to bisphenol A through distribution of this product, and because one or more states have adopted a sales prohibition on the same product category (Connecticut and Vermont), allowing for the presumption of the availability of safer alternatives, the Board is statutorily empowered to proceed directly to a sales prohibition. Requiring reporting from manufacturers on information already available would be an unnecessary regulatory burden on those entities. No change to the rule.

Other product categories

Food and Beverage Containers

71. Comment: The commenter asserts that, while BPA is used in making the linings of "two-piece" cans (i.e., soft drink cans) to date have not been found to contain any BPA when tested by the US Food and Drug administration in off-the-shelf product examination and that studies in New Zealand and the United Kingdom have not detected BPA in soft drinks. (16)

Response: The department does not propose to address BPA used in soft drink cans with this rulemaking, as these products are exempt from the requirements of 38 MRSA §16-D, and thus this chapter (see section 1(B)(2) of the proposed rule). No change to the rule.

72. Comment: The commenters recommend that the board prohibit the sale of infant formula and baby food packaging and packaging of food marketed to children under three years of age that contains intentionally-added bisphenol A. (1-7, 17, 22, 27, 28, 30, 32, 35, 40, 47, 48, 52, 55, 56, 59, 61, 62. In addition to the individually-listed commenters, the department received 129 emails from citizens asking that the board include baby food and formula packaging in the sales prohibition).

73. Comment: The commenter states that the Board should exercise its authority to prohibit the sale of cans, jars or plastic containers used to store infant formula and baby food. The commenter asserts the necessary criteria have been met: i.e., children are exposed to bisphenol A from formula and baby food and safer alternatives are available. The commenter points out that because BPA-containing baby food and formula containers have been banned in other states, the Board may presume that safer alternatives are available. Further, the commenter provides a press release indicating the General Mills Corporation will replace the packaging of its Muir Glenn line of canned tomato products with BPA-free alternative. Additionally, the commenter provides a portion of a BPA alternatives assessment conducted by Pure Strategies for an unnamed client, and states the report concludes that safer alternatives to BPA are commercially available for the epoxy-based coatings of food and beverage cans. The commenter states that the study found that of 12 alternative coatings evaluated, two commercially used alternatives passed all screens for human health and the environment, economic affordability, and technical performance (although concerns were raised about what chemicals were used to make the primer covered by the alternative in use or the adhesive used to attach the coating). The commenter recommends that the department revise the proposed rule to add a sales prohibition on containers with epoxy based linings that leach BPA for infant formula, baby food and toddler food, consistent with the board's legal authority to regulate food packaging when intended for use by or intentionally marketed to children younger than three. (1)

Response to comments 72-73: The department appreciates the commenter providing the partial alternatives assessment. The assessment, however, reaffirms the department's previous assertion that not enough is known about alternatives to BPA use in food packaging to warrant a sales prohibition at this time. The authors of the assessment reviewed 12 possible coating technologies, based on admittedly inferred information because the nature of the chemical composition and monomer is largely unknown and held closely by manufacturers as trade secrets. All but one of the coatings reviewed by the researchers failed the human health and screen. A passing evaluation for the coating that did not fail, Toray PET Lamination, depended on what type of adhesive is used to laminate the product to the can. Two other coating technologies, Oleo Resin and DAREX polyester, had slightly more encouraging scores of "likely fail" due to lack of information on the chemical composition of these technologies. Further, the oleoresinous coatings are intended for sulfur containing foods and do not work with highly acidic foods. The can technologies that outright failed the human health screen did so because they contained materials with a known carcinogen (formaldehyde) or other human health concerns (PVC). While the board has the authority to presume that safer alternatives exist when a product containing a priority chemical has been banned in another state, the board is not required to exercise that authority. With so much uncertainty regarding the safety and availability of alternative can coating products, and the possible other recourse of trading in completely recyclable materials (glass and metal) for plastics that contain unknown (to the department at this time) additives, the department maintains its position that the prudent course of action is to seek further information about available alternatives and assess their safety relative to BPA-containing epoxy resins. No change to the rule.

74. Comment: The commenter asserts that: BPA is a necessary component of epoxy resin coatings in cans; it serves a critical function in protecting the integrity of certain metal packaging components; and can coatings are necessary to protect public health from corrosion of the metal can and the introduction of microorganisms that may cause spoilage or illness. The commenter contends there are no alternatives to BPA for certain foods such as highly acidic baby formula. Additionally, the commenter states that although all of the major coating and can manufacturers are working continually to research and develop new coating chemistries for commercial food applications, epoxy coatings containing BPA still have unparalleled performance across a wide range of parameters, including toughness, adhesion, formability and resistance under high-temperature processing conditions. (10)

75. Comment: The commenter asserts that an unwarranted listing or restriction on food and beverage cans could greatly disrupt the manufacture of metal cans and significantly reduce the availability of food and beverage products in Maine, and hinder consumer ability to find nutritious, valuable and shelf stable foods and beverages. Because adequate alternatives to BPA-based epoxy can coatings are not currently available for most metal packaging, actions such as this board's listing could severely impact a wide range of canned and other packaged food, including glass, from fruits and vegetables to soft drinks and juice. The commenter asserts the listing, banning or restrictions on canned foods that are not supported by appropriate scientific studies could scare consumers away from these important and affordable sources of nutrition. (11)

76. Comment: The commenter asserts bisphenol A is an essential component of epoxy resin coatings that are used in metal food packaging The commenter contends the epoxies allow the can to go through the can making operation, the filling operation, transportation to and from the filler, transportation to the grocery store, and then back to your home where it's stored; and during that process it's banged around, dented, kicked, but that epoxies are flexible enough that they don't crack when the can is dented. The commenter states that the cans are resistant enough chemically to the food to prevent the container from eroding and allowing microbiological flora or fauna to get into the food. (12)

77. Comment: The commenter references 38 MRSA §1697, section 8, which states a container or a packaging for a food or beverage product is exempt from the requirements of this chapter unless that product is intentionally marketed or intended for the use of children under three years of age, and contends the language was expressly used to ensure the department could address bisphenol A in infant formula and baby food under the law. (35)

78. Comment: The commenter encourages the department to work with other agencies to help move this work forward. Helping Maine's specialty food processors to begin using alternatives to BPA through the support of the Maine Department of Agriculture and the Maine Technology Institute would be a way to create a clear message that the State will continue to lead on this issue. (51)

79. Comment: The commenter disputes another commenter's statement that cans with BPA free lining (such as Eden beans) do not have a stable shelf life. The commenter checked a can of the beans, which was good until 2013, and found that all Eden canned beans have a 3 year shelf life. The commenter points out the Eden Foods website states that even though the BPA-free cans cost 14% more than the BPA containing cans, this company has refused to use BPA-containing cans when an alternative exists. (53)

80. Comment: The commenter contends that an alternative exists to polycarbonate made with BPA: copolyester. In fact, some coffee preparation equipment and coffee containers are now fabricated from co-polyester instead of polycarbonate because of consumer concerns about the risk of BPA. (56)

81. Comment: The commenter states that while there are some types of infant formula packaging not made with BPA, there are some types, such as metal cans, which do require the use of BPA, and, to date, there have been no alternatives for metal infant formula packaging approved by the FDA. Nevertheless, while the scientific evidence continues to support the safety of BPA, the infant formula industry is partnering with the food packaging industry to minimize trace levels of BPA that may be contained in current packaging and with the FDA to aggressively research and identify possible alternatives to current packaging. Each of these steps takes time. Switching to alternative packaging is not a simple process and could take years. Just as packaging suppliers must work with regulators to identify, certify and make commercially available alternatives to the current epoxy-lined metal cans, the infant formula industry must also go through a number of steps to ensure that any new packaging materials continue to provide at least the same level of quality and safety provided by our current packaging. This process includes a formal submission to the FDA for approval of a new food contact use for any potential alternatives and could involve a significant level of dialogue with the FDA, over an extended period of time, whic is not guaranteed to end in the approval of an alternative package. Any consideration of regulating infant formula products containing BPA should take this information into consideration and recognize that the outcome could be the provision of infant formula to Maine consumers is limited, absent an FDA-approved alternative. (63)

82. Comment: The commenter believes a prohibition of certain products, including infant formula, containing BPA is not justified based on the currently available science and is not in the interest of Maine infants and caregivers, as it would reduce the availability of infant formula products currently available in the State. Scientific consensus on the safety of BPA does not exist, and current evidence does not support a prohibition on food and beverage containers. (63)

83. Comment: The commenter contends that despite reports to the contrary, the simple fact is there is no readily available, suitable alternative to epoxy-based can coatings that meets the essential safety and performance requirements for the broadest spectrum of foods now packaged in metal containers. There are some alternatives currently being used, but only for certain niche markets. These alternative coatings are not suitable for the wide range of food and beverages currently on the market. Among the most publicized non-BPA coatings are baked-on oleoresinous enamel and polyethylene terephthalate (PET) laminate technology. Currently used only for nonaggressive food products, such as dried beans, baked-on oleoresinous enamel is a limited use coating technology and is not viable for other food or beverage items. Though often cited as the BPA alternative of choice in the media, the baked-on oleoresinous enamel represents only a small fraction of the overall canned vegetable market because of its limited performance. Another alternative, PET laminate technology, involves the application of PET plastic inside the metal container. It is used in Japan, primarily for hot beverage containers sold in vending machines. About 40% of the food can market in Japan uses the PET laminate technology, but a significant portion of that 40% still requires the use of an epoxy coating with BPA as an adhesive to affix the laminate to the metal. In fact, most container specifications typically incorporate a combination of coatings and nearly all specifications utilize an epoxy resin material in some capacity. (64)

Response to comments 74-83: The department is not proposing a sales prohibition on infant formula and baby food packaging, at this time for the reasons stated in response to comments #72-73,. No change to the rule.

Toys, childcare articles and tableware

84. Comment: The commenters recommend that the board adopt a sales prohibition on toys, childcare articles and tableware that contain BPA. (1, 5)

85. Comment: The commenter contends that the information regarding alternatives to polycarbonate plastic included in the Pure Strategies alternatives assessment (see comment #74) would suffice to replace other applications of BPA-polycarbonate plastic used in toys, child care articles and table

ware and recommends that the department revise the proposed rule to add a sales prohibition on polycarbonate plastic, which is made from and leaches BPA, for use in toys, child care articles and tableware. (1)

Response to comments #84-85: While the department finds the information on the wide range of options for polycarbonate plastics that have been developed for use in food and beverage containers encouraging in terms of possible alternatives for the material's use in toys, tableware and childcare items, it would be precipitous to move directly to a sales prohibition at this time without first understanding the extent to which these products are made of polycarbonate plastic and the likelihood that children are exposed to BPA from these sources. No change to the rule.

Thermal paper

86. Comment: The commenters recommend that the department's proposal include a ban on the use of BPA in cash register receipts. (42, 43)

Response: The definition of "consumer product" in 38 MRSA §1691(8) specifically excludes paper, prohibiting the department from regulating priority chemicals in paper. No change to the rule.

All consumer products

87. Comment: The commenter recommends that the department immediately ban BPA in all consumer products sold in Maine for which there is a safer alternative available. (30. In addition to the listed commenter, the department received 59 letters asking the board to ban BPA use in all consumer products).

Response: Prior to prohibiting sales of children's products containing bisphenol A, the department must first gain an understanding of those products. The Information Submission in section 4 of the proposed rule is intended to provide the department with the necessary data to inform the department's decisions in the future regarding the likelihood of exposure for those product categories. No change to the rule.

Section 5(B) Labeling

88. Comment: The commenter contends that if the department adopts a "BPA-free" labeling requirement, manufacturers would not label or market products containing bisphenol A, even as an impurity, to avoid any claims of mislabeling. The commenter contends that the department lacks the authority to adopt a labeling requirement; it is inappropriate to place the burden of complying with the labeling requirement on the manufacturers and distributors of products made from materials assumed to be safer; and "BPA-free" is undefined in the proposed rule. The commenter recommends removing the requirement from the proposal. (8)

89. Comment: Section 5(B) would require all products subject to a sales prohibition to be clearly labeled as "BPA-Free." However, because the regulations neither define the term "BPA-Free" nor provide a methodology to attain "BPA-Free" status, this requirement is infeasible and could not be fulfilled. (63)

Response to comments 88-89: While the department maintains it has the authority to adopt labeling requirements, and has done so in other rules (e.g., 06-096 CMR Chapter 152 Control of Volatile Organic Compounds in Consumer Products section 6), the department agrees with the commenters that the difficulties of applying and enforcing the proposed requirement outweigh any possible benefit and has deleted section 5(B) from the proposed rule.

5(D) Compliance Plan Required

90. Comment: The commenter contends the proposed notification to wholesalers and retailers is broad and compliance is impossible because manufacturers do not have any idea who the retailers are, and would frequently not be in a position to notify them. At most, the commenter contends, a manufacturer would only know with any certainty the persons to whom it directly sells its products for further distribution. (8)

Response: Notification by manufacturers to retailers is required by 38 MRSA §1696(4), which states, "Responsibility. A manufacturer or distributor of a children's product containing a priority chemical shall notify persons that offer the product for sale or distribution in the State of the requirements of this Chapter." No change to the rule.

91. Comment: Notification requirements for manufacturers should be incorporated into compliance plans filed with the department. In many instances, retailers will be notifying their suppliers of this obligation to provide notification back to retailers. If this can be satisfied as an option in filing a compliance plan with the department, it will reduce the administrative burden of recordkeeping. (39)

Response: The department finds this a reasonable suggestion and has deleted section 5(C) and incorporated the requirements into the Compliance Plan (now section 5(B)) as follows:

B. Compliance plan required. *The manufacturer of a reusable food or beverage container subject to the sales prohibition of subsection A shall file, or cause all of its distributors to file, a compliance plan with the department no later than 180 days prior to the effective date of a sales prohibition under this section, unless the manufacturer receives a time extension in writing from the department. The compliance plan must:*

(1) Identify the manufacturer's products subject to the sales prohibition;

(2) Specify whether compliance will be achieved by discontinuing the sale of the children's product in Maine or by substituting a safer alternative in the product; ~~*and*~~

(3) If compliance is achieved by substitution of a safer alternative in the product, identify the safer alternative and the timetable for substitution.; and

(4) Confirm that the manufacturer has notified all persons that offer the product for sale or distribution in Maine of the sales prohibition, as required by 38 MRSA §1696(4).

(a)Confirmation shall include a copy of the notice and a list of the persons to whom it was sent.

(b)A retailer is exempt from the sales prohibition requirements of this section if the manufacturer failed to notify the wholesaler and retailer in accordance with this subsection, and the department did not notify the retailer of the sales prohibition.

General Comments

Fiscal Impact

92. Comment: The commenter contends the department did not perform an evaluation and estimation of the fiscal impact of the proposed rule and has not considered the costs of the rule on small businesses as required by the Maine Administrative Procedures Act. The commenter points out that no fiscal impact information appears in the Basis Statement or Memorandum to the Board, and the fact sheet only includes a general description of fiscal impact with no calculation of quantity or impact. (8)

Response: The department is mindful of its duty to ensure that rules minimize adverse impacts to small business, and of the obligation to prepare the Economic Impact Statement required under 5 MRSA §8052(5-A) prior to the adoption of any proposed rule that may have an adverse impact on small businesses and has appended an economic impact statement to the board packet. The intent of this requirement is to "reduce any economic burdens through flexible or simplified reporting requirements and ... to reduce burdens through flexible or simplified timetables." The department's search did not yield any small businesses in Maine that manufacture any of the products to which the rule applies, and retailers are exempt from the requirements of the rule, unless they knowingly sell products which fall under the sales prohibition. The department anticipates the reporting costs to small manufacturers to be minimal and, likewise, anticipates costs to small retailers in leftover inventory of unsalable products at the time the sales prohibition goes into effect to be minimal as well. The development of an alternatives assessment could prove to be a more significant cost, although the department provides opportunities for minimizing those costs.

The intent of establishing rulemaking as the process by which priority chemicals are designated was, in part, to ensure "that chemical manufacturers and other interested parties are notified of a department proposal to designate a priority chemical, and have the opportunity to provide comments that will assist the department in deciding whether to proceed with a designation," as stated in the basis statement of adopted 06-096 Chapter 880, Regulation of Chemicals in Children's Products. One of the purposes of this rulemaking proceeding is to seek information bearing on the fiscal impacts to small business or others. The MAPA rulemaking process, guarantees that small businesses and other potentially affected parties have the opportunity to provide the department with information, comments and concerns bearing on the impact of the rule. The department received comments from a number of small business owners during the public comment period. None provided evidence or estimates of potential adverse economic impacts; rather all support the department's proposal.

No change to the rule.

93. Comment: The commenter contends Maine wholesalers and retailers are among the Maine small businesses likely to be affected by the proposed sales ban and that among the likely fiscal impacts will be inevitable confusion in the distribution chain, among retailers and among consumers. The commenter suggests the proposed rule will impact commerce, and may fall disproportionately on businesses in Maine, and on smaller businesses. (8)

Response: The department asserts that the fiscal impacts of the proposed rule will fall mainly on manufacturers of reusable food or beverage containers containing bisphenol A and, to a lesser extent, on manufacturers of those products for which the department requires reporting. The department's search did not yield any information about Maine-based businesses, large or small, that manufacture the subject products and no such business has stepped forward to comment during the rulemaking process.

The department does not expect the implementation of the proposed sales prohibition to pose any significant fiscal consequences for retailers. The Maine Legislature included a number of provisions in the underlying statute to avoid any such consequences, including a requirement that manufacturers and distributors of bisphenol A-containing reusable food and beverage containers notify retailers and wholesalers of the sales prohibition, a requirement that the board specify an effective date for the sales prohibition of at least 12 months after the notice of proposed rule is published, in part to give retailers and wholesalers time to sell-through their inventory of bisphenol A containing reusable

containers; and a provision exempting retailers from enforcement action unless they knowingly sell a product subject to the ban after having been notified of the ban by the manufacturer, distributor or the State..

The department's experience with the administration of product sales bans under Maine's mercury product laws suggest that compliance with those bans has not posed a financial hardship for retailers and wholesalers. In addition, the department heard from several hundred consumers during the public comment period who urged the department to move forward with the proposal without delay.

No change to the rule.

94. Comment: The commenter points out that the health and economic costs of childhood diseases related to toxic chemical exposure in Maine are estimated to be at least $380 million every year. Nurses and families see first hand how children and families struggle and suffer with such diseases. Given there are safer alternatives to BPA for most uses, the risk it poses to children's health and the associate healthcare costs make its continued use inexcusable. (19)

95. Comment: The commenter suggests that some, especially those who profit in some way from the use of BPA, may want to express concern about the cost of shifting from BPA to safer alternatives but the commenter wants the department place higher concern on health and education costs, both the financial and the personal, caused by chemicals like BPA, costs that go on for years. This proposed rule to phase out BPA in certain products is about health, families business, innovation and it's about what it will cost to educate our children in future years, 10, 20, 30 years out. (23)

Response to comments 94-95: The department acknowledges that healthcare and special education can prove costly for families and communities. No change to the rule.

Worker Health

96. Comment: The commenter states that eliminating BPA from consumer products wherever possible will protect workers, improve children's health and position Maine's economy for the future. (24)

97. Comment: The commenter asserts that when harmful chemicals like BPA's use is restricted downstream in consumer products, it has the action of protecting upstream workers who manufacture those products. The commenter cites a recent study in china that has shown that Chinese workers after one to two years' exposure to BPA have had reproductive effects in not being able to reproduce. The commenter contends that workers and their families have a right to be safe from these chemicals, BPA, in our homes, and no worker or any family member should be exposed to a dangerous chemical, whether it's on the factory floor, the breakroom, the living room or in the food or drink containers that workers or their children use. (31)

Response to comments 97-98: While the intent of the law and the rule is to protect the health of children and other vulnerable populations, the department appreciates that the benefits of removing hazards from consumer products can extend to other populations, including workers. No change to the rule.

Routine Technical/Major Substantive

98. Comment: The commenter recommends that the department specify which elements of the rule are "minor routine" and which are "major substantive" so the public and interested parties may track the progress and timing of the rule, its potential obligations and the state's rulemaking procedures. (8)

Response: Sections 1 through 4 of the proposed rule are routine technical; section 5 is major substantive. No change to the rule.

ADDITIONAL COMMENTS

On October 7, 2010, the Board of Environmental Protection held a workshop to discuss the proposed rule and comments received. At that workshop, the board recommended that the department amend section 4(A) of the proposed rule to require manufacturers of baby food and formula packaged in containers containing intentionally-added bisphenol A to submit an alternatives assessment to the department. The department posted the revised proposed rule to a public comment period to solicit comments regarding the proposed changes to section 4(A). Some parties provided comments outside the scope of the additional comment period; those comments are addressed in the appropriate topic areas above.

Comments on the proposed changes to section 4(A)

99. Comment: The department received 64 comments asking the department to: "-Formalize the Strengthened rule to include packaging for baby food and infant formula without delay -Follow the example set by other states in phasing BPA out of baby food and infant formula packaging -Set strict deadlines by which manufacturers must conduct and submit alternatives assessments."

    Response: The department acknowledges the commenters' support. The results of the alternatives assessment will inform the department's next steps, if any, in regard to regulating this chemical. The department has proposed a deadline of January 1, 2012 for the assessment. No change to the rule.

100. Comment: The commenter supports the department's desire to protect Maine infants and young children from potentially harmful chemicals. However the commenter opposes the proposed prohibition and has concerns regarding specific requirements for infant formula manufacturers. Specifically, the commenter states the effective dates in section 4 are not clear and it appears the information required to be reported regarding certain products containing bisphenol A must be provided six months prior to the information regarding alternatives assessments. (63)

    Response: The department included the differing dates of compliance deliberately. The statute requires reporting on basic chemical information "no later than 180 days after a priority chemical is identified." Because the department elected to use rulemaking as the process by which priority chemicals are identified to ensure maximum participation by interested parties and the public, the date a priority chemical is "identified" is the effective date of the rule (i.e.,, five days after the adopted rule has been filed with the Secretary of State's Office). Recognizing that the alternatives assessment process involves more data gathering and analysis than the basic chemical reporting and would thus take more time, the department proposed a longer period of time in which to fulfill that requirement. Chapter 880 provides for the commissioner to grant an extension of data submission deadlines if the commissioner determines that more time is needed to comply with the information request. No change to the rule.

101. The commenter concludes that because there are no viable alternatives to current infant formula packaging containing trace levels of bisphenol A, the commenter requests that the department delay its regulations until the FDA has completed its review of BPA. (63)

    Response: The department looks forward to FDA's review of bisphenol A and will consider that agency's conclusions in tandem with the product use and alternatives assessment data collected upon promulgation of this rule before considering any further action with regard to BPA. No change to the rule.

102. Comment: The commenter supports the need for careful and deliberate assessment on alternative packaging options. However, the commenter contends the department's proposal is inappropriate, unrealistic, unworkable and unnecessary because the proposal essentially requires baby food and infant formula manufacturers to conduct extensive life-cycle risk assessment for alternatives to bisphenol A and such assessments require the involvement of professional experts in exposure estimation, toxicology, environmental fate, epidemiology, and other scientific study areas, which would necessitate hiring outside consultants to compile or develop data, complete an evaluation of the data and generate the required assessment report. (64)

Response: While the department acknowledges the proposed assessment is somewhat extensive, for the most part it does not require new research. The alternatives assessment requirements referenced in section 4(A)(2) of the proposed rule refer to 06-096 CMR Chapter 880 section 3(B)(3). Under that section, the data requirements identified in subparagraphs (a), (b) and (c) are all information manufacturers should currently possess, or be able to obtain from their packaging suppliers. Data required in (d) and (f) should be obtainable from a literature search of PubMed or other databases of peer reviewed journal articles. Only subparagraph (e), which requires an evaluation of hazard characteristics of potential alternatives, could be construed as new research. The department acknowledges that although the data may be readily available to manufacturers, it will require a certain amount of staff time to compile and analyze the information. However, the Legislature, in placing the requirement for manufacturers to develop alternatives assessments in 38 MRSA §1698(2) deliberately placed the financial burden of assessing alternatives onto those who manufacture products that contain the priority chemical, rather than on the public. Furthermore, manufacturers can significantly reduce the costs and staffing requirements of developing alternatives assessments by relying on information submitted on behalf of the manufacturer by a trade association, chemical manufacturer or other third party, as stated in the NOTE after section 4(B) of the proposed rule. No change to the rule.

103. The commenter asserts that even if manufacturers had resources to conduct such an assessment, they cannot, by law, offer an alternative for food packaging that has not been assessed by the FDA. The commenter points out that if the FDA has already conducted an assessment, it makes no sense for manufacturers to conduct another for Maine's purposes. (64)

Response: The department's proposal does not require manufacturers to offer packaging that has not been approved by the FDA. As far as the department is aware, the FDA has not conducted an alternatives assessment on BPA. However, if the FDA has data on particular packaging alternatives, the manufacturer should include that information as part of its assessment. No change to the rule.

104. The commenter contends there is no readily available, suitable alternative to epoxy-based can coatings meeting the essential safety and performance requirements afforded by bisphenol A epoxy resins. The commenter asserts the metal packaging industry continues to develop the next generation of coatings; however the amount of time required to get a new product to market would extend well beyond the January 12, 2012 deadline contemplated in the proposal. The commenter asserts coating development can take one to three years, with trials and testing taking more than two additional years and additional time required for commercialization. (64)

Response: The proposed language does not contemplate that manufacturers undertake original research and development to produce all-new products; the alternatives assessment language in 06-096 CMR Chapter 880 (which the proposed language references) explicitly requires manufacturers to provide information on "specific chemical and non-chemical alternatives considered in lieu of the priority chemical" and "known emerging chemical and non-chemical alternatives to use of the priority chemical." Such an assessment would include the kinds of alternative packaging products currently on shelves, such as the plastic containers in which some brands of formula and baby food are sold. Further, the department's proposed language does not require that an alternative be in

place on January 12, 2012, but rather that the assessment be submitted to the department by that date. No change to the rule.

105. The commenter states that because new food packaging technologies will not be available by the January 12, 2012 deadline, the only options available to manufacturers are those coating materials already approved by FDA, including vinyl, acrylic, polyester, and oleoresin. The commenter contends that like bisphenol A, these coatings will also migrate materials into food products and pose limitations such as imparting odor or taste to the food product, less flexibility, inability to withstand high temperatures and compromised shelf life. The commenter states that if the department chooses to ignore the stated limitations and proceed with these materials as alternatives, a full assessment of these materials would take years. (64)

Response: It is exactly the kind of information stated by the commenter which the department seeks in requiring the alternatives assessment. However, the alternatives assessment would provide actual data regarding the performance and potential hazards and exposure routes posed by these materials, rather than hearsay. The department reiterates that the January 12, 2012 deadline is the date on which the alternatives assessment is due to the department; it is not a date by which alternatives must be available on the market. Furthermore, because the alternatives assessments will be carried out by baby food and formula packaging, they will likely weigh a wider range of packaging products, rather than merely epoxy-coated cans. If an alternatives assessment cannot be completed by the date required in the proposed rule, a manufacturer my request an extension of the deadline. No change to the rule.

106. Comment: The commenter contends that infant formula and baby food manufacturers, by themselves, are in no position to submit alternatives analysis work plans for potential alternatives to BPA in epoxy-lined cans, as they rely on their packaging suppliers to provide them with these materials. The commenter asserts the baby food and infant formula manufacturers' expertise is with manufacturing of baby food and infant formula, not with the packaging that contains them and it is highly unlikely that within the food packaging context a baby food or infant formula manufacturer by itself will possess the necessary knowledge and expertise to identify appropriate alternatives to BPA and evaluate their safety, effectiveness, and compatibility within the packaging material matrix. (10)

Response: The department recognizes the difficulties posed by a baby food manufacturer assessing the design and composition of a metal can, glass jar or plastic container, however, the law that established Maine's Safer Chemicals in Children's Products program, 38 MRSA §1691, defines "manufacturer" as the "person who manufactures a final consumer product," not the supplier of the package, materials, components or chemical constituents, and so it is to those manufacturers of final consumer products (in this case, infant formula and baby food manufacturers) to whom the law, and subsequently this rule, applies. Furthermore, the department anticipates that manufacturers of baby food or formula will play an active role in selecting the packaging materials it uses for their products, and as large industrial consumers of the packaging manufacturers' products, have a considerable amount of sway in driving the design and composition of those product, even if they are not necessarily privy to the chemical composition of those products. As acknowledged in the department's response to comment #102, some outside expertise may be required to compile and analyze the information required for an alternatives assessment. However, as stated in that same response, the Legislature, in placing the requirement for manufacturers to develop alternatives assessments in 38 MRSA §1698(2) deliberately placed the financial burden of assessing alternatives onto those who manufacture products that contain the priority chemical, rather than on the public. No change to the rule.

107. Comment: The commenters point out that some of the information requested in section 4 of the proposed rule, especially in the new sub-section regarding alternatives assessments, is proprietary and

company-confidential. The commenters express concern that the section does not specify where the collected information will be kept. (10, 64)

Response: All information collected will be managed according to state law and department policy regarding confidential record, as noted in 06-096 Chapter 880, Regulation of Chemical Use in Children's Products, the rule implementing Maine's Safer Chemicals in Children's Products law— Section 3(F):

> ***Data protection.*** *Records containing chemical use information of the type listed in subsection A above are presumptively public records under Maine's Freedom of Access Act ("FOAA"), 1 MRSA §401 et seq. Any records submitted to the department pursuant to this chapter that the submitting party believes are not subject to disclosure under FOAA must be clearly marked as "claimed confidential." Any request to the department under FOAA seeking records submitted under this chapter and marked as "claimed confidential" will be processed in accordance with 38 MRSA §1310-B, subsection 2.*
>
> *This subsection does not authorize a manufacturer or distributor to refuse to disclose to the department information required under this chapter.*
>
> *NOTE: The requirement to disclose information on the use of and exposure to priority chemicals in children's products is fundamental to the effective study and control of those chemicals, and is a key feature of the law on Toxic Chemicals in Children's Products. The public release of chemical use information submitted to the department pursuant to this requirement furthers the purpose of the law by providing consumers with more complete information on the products available to them and encourages the development of safer alternatives. However, records submitted to the department under this chapter that are either confidential by statute or otherwise exempt from the definition of "public records" set forth in 1 MRSA §402 are not subject to public disclosure.*

No change to the rule.

108. Comment: The commenters request that the board hold a hearing regarding the revised alternatives assessment language to allow interested parties to make comments on the proposal. (8, 9, 11, 63, 64)

Response: The Maine Administrative Procedures Act (MAPA), 5 MRSA §8052(5) provides that,

> *A rule may not be adopted unless the adopted rule is consistent with the terms of the proposed rule, except to the extent that the agency determines that it is necessary to address concerns raised in comments about the proposed rule, or specific findings are made supporting changes to the proposed rule.... If an agency determines that a rule that the agency intends to adopt is substantially different from the proposed rule,* ***the agency shall request comments from the public concerning the changes from the proposed rule.*** *The agency may not adopt the rule for a period of 30 days from the date comments are requested pursuant to this paragraph," [emphasis added].*

A hearing was held on this rule on August 19, 2010 and a public comment period ran through August 30, 2010. Pursuant to the MAPA requirements, the department provided an additional period for submission of public comments concerning a proposed change to section 4(A) of the rule. The purpose of the proposed change is to allow the department to gather data to resolve whether safer alternatives to bisphenol A exist so that the department can make an informed recommendation to the board. Holding a second hearing is highly unusual and would generally only take place when there is credible conflicting technical information regarding a statutory criterion and a public hearing would assist the board in understanding the evidence related to whether or not the statutory criterion

will be met. The commenters' request for a public hearing did not indicate that such a conflict regarding statutory criterion relating to alternatives assessments exists, nor how such a perceived conflict would be resolved through a public hearing.

Written comments are a part of the public record and interested parties have an opportunity to give testimony on comments received during rulemaking or proposed changes to the rule during the meeting at which the board will vote on adoption of the rule.

No change to the rule.

Comments on other proposed changes to the rule

109. Comment: The commenter objects to the department's revised definition of toys as overly broad and contends that BPA-containing polycarbonate plastic plays an important safety role in those products and contends that exposure to bisphenol A would not occur from most toys. (8)

Response: Because the governing statute of this program was intended to protect children from exposure to toxic chemicals, it would be disingenuous of the department to ignore the use of those chemicals in toys, which are products with which children are in regular contact. Only through gathering information on the use of the chemical in those products, including the safety features that the polycarbonate plastic imparts, can the department begin to assess whether those products are a concern for children or not, including whether there is exposure to bisphenol A from those products, either through ingestion or dermal absorption. In the current informational void, there is no way anyone can weigh the safety benefits imparted by the material against any potential hazard it may pose. No change to the rule.

110. Comment: The commenter objects to the revisions to section 5(B), Compliance Plan Required because the proposed language in sections 5(B)(4)(a) and (b) was not authorized in the statute and because the retailer exemption does not belong in the compliance plan section. (8)

Response: The intent of rulemaking is to create more detailed regulations to implement the broad policy mandates set by the Legislature through the passage of laws. The department moved the language in question regarding retailer notification, to which there was not objection during the initial comment period (August 19,through August 30, 2010), to the compliance plan section at the request of a commenter who argued, quite reasonably, that it would make sense and reduce the burdens on the regulatory community by combining the two. No change to the rule.