SUPPLEMENTAL BASIS STATEMENT

CHAPTER 883
DESIGNATION OF THE CHEMICAL CLASS NONYLPHENOL AND NONYLPHENOL ETHOXYLATES A PRIORITY CHEMICAL

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COMMENTS

Section 3. Designation of the chemical class nonylphenol and nonylphenol ethoxylates as a priority chemical

1. Comment: The commenters support the designation of the chemical class nonylphenol and nonylphenol ethoxylates as a priority chemical. (1-10, 21-24)

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

2. Comment: The commenters oppose the designation of the chemical class nonylphenol and nonylphenol ethoxylates as a priority chemical. (11-20)

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

3. Comment: The commenter asserts that under the governing statute, the department and the board do have clear authority to designate classes of chemicals as priority chemicals. (9)

   Response: The department concurs. No change to the rule.

4. Comment: The commenter points out that nonylphenol and nonylphenol ethoxylates are being lumped together in one class of compounds when they are actually unique chemical substances with very different properties. The commenter states that nonylphenol is a chemical intermediate and its commercial purpose is as a starting material for conversion into other chemical substances. The commenter points out that, based on a literature survey, among the product categories listed in the proposed rule there is one application where nonylphenol is used by itself. The commenter adds that NP is a chemical that is intended to be handled by professionals or under conditions where children should not come into contact with the raw product. The commenter stresses that his company in no way advocates exposure to nonylphenol by any persons in an uncontrolled scenario. The commenter also points out that nonylphenol is not the only degradation product of nonylphenol ethoxylates, but that in an aerobic system, the main biodegradation product on nonylphenol ethoxylates are carbon dioxide and water. (13)

   Response: The department acknowledges the distinction between nonylphenol and nonylphenol ethoxylates, as clearly described in the Basis Statement. However, in 38 MRSA §1691, "Chemical" is defined as "a substance with a distinct molecular composition or a group of structurally related substances and includes the breakdown products of the substances or substances that form through decomposition, degradation or metabolism." Nonylphenol and nonylphenol ethoxylates are structurally related, and the primary degradation products of nonylphenol ethoxylates in waste water treatment plants are the more persistent and more toxic shorter-chained NPEs as well as NP. Further, the US EPA has concluded that in mammals, NPEs metabolize to NP. For these reasons, NP and NPE together meet the statutory definition of "chemical." No change to the rule.

5. Comment: The commenter expresses confusion at the process by which the department chose to designate NPE as a priority from among the 1750 compounds on the list of chemicals of high concern. (14)

   Response: When selecting compounds for designation as a priority chemical, the department followed the process laid out by the Legislature in the Toxic Chemicals in Children's Products law. Specifically, the department selected chemicals from the chemicals of high concern list that meet at least one of the criteria in 38 MRSA §1694. In the case of nonylphenol and nonylphenol ethoxylates, these chemicals meet five out of the six criteria, which to the department indicates that this class of chemicals is a strong candidate for selection as priority chemicals. However, the department would welcome recommendations of other chemicals the commenter considers appropriate candidates for designation. No change to the rule.

Human Health Risk of NP/NPE

6. Comment: The commenter contends that continued use of nonylphenol and nonylphenol ethoxylates unnecessarily exposes children, adults and wildlife to chemicals which are both PBTs and endocrine disruptors. The commenter states that NP and NPEs have a wide variety of toxic effects as demonstrated by numerous field and lab studies of aquatic organisms as well as lab studies to correlate exposure with potential health effects in humans and that the chief concern is endocrine disruption. (1)

7. Comment: The commenter contends that the presence of NPEs in cleaning agents is of particular concern because NPEs will be in both higher volume and higher concentration than in other industrial or commercial application products, that humans are brought both directly (when using cleaners and degreasers) and indirectly (through residual detergent) into contact with this endocrine disruptor; and that 100% of the diluted and waste detergents are passed either directly into the ground water or waste water stream. Even if the substance is removed in the sewage treatment process, it is then delivered to agricultural settings in the form of solid sludge resulting in a high probability that it will make it into our food in low, but steady doses. (4)

8. Comment: The commenter asserts that the results of studies which reveal that NP produced estrogen mimicking effects and interfered with processes which play a critical role in pregnancy, particularly during development of the placenta and implantation of the conceptus, raise concern about the effects of exposure to NP on the maintenance of pregnancy. The commenter suggests that these findings and similar findings from animal studies suggest that applying the precautionary principle to policy decisions on NP and NPEs may be in order. The commenter states that under the principle, policy makers have a responsibility to protect the public from exposure to harm when scientific inquiry suggests a possible risk exists, particularly in the absence of proof to the contrary. The commenter asserts that science suggests NP and NPEs may be harmful to human health and there is no scientific proof that NP and NPEs are safe for humans; therefore, the doctors and nurses of PSR Maine believe it would be prudent to enact policies which protect humans from exposure to NP and NPEs. (6)

9. Comment: The commenter contends that NP and NPE are of serious concern to women and girls because they mimic hormones by interacting with estrogen receptors. The commenter

asserts that not only have these effects been demonstrated in fish and rats, they have been found in human breast tumor cells. The commenter points out that women are more likely to be diagnosed with breast cancer than any other cancer and it is the second leading cause of cancer death, after lung cancer. The commenter also points out that NP and NPE are used in household cleaning products as well as cosmetic and personal care products, both categories of products with which women and girls regularly come into contact. (7)

10. Comment: The commenter asserts that NP has been shown to affect reproductive health in wildlife, including feminization, reduction of viable embryos and physically deformed or dual reproductive organs, and has caused increased cell division in rat uterus lining and enlarged uteruses in juvenile rats. The commenter states that these results support the commenter's concern about human health risks. (8)

11. Comment: The commenter asserts it is well established that this class of chemicals is harmful to children based on scientific evidence compiled by credible government entities. (9)

12. Comment: The commenter contends that peer-reviewed research findings published in authoritative science journals indicate nonylphenol is a strong endocrine disrupting compound that threatens healthy pregnancies and the immune system and to which humans are routinely exposed. The commenter references studies which demonstrate: maternal exposure to the endocrine disruptor nonylphenol during pregnancy increases the risk of implantation failure, pregnancy loss or other complications due to causing an unbalanced cytokine network at the maternal-fetal interface; nonylphenol is an endocrine disruptor that is an estrogen receptor agonist and an androgen receptor antagonist and which inhibits aromatase activity (which converts testosterone to estrogen). Nonylphenol also increased aryl hydrocarbon receptor activity which is involved in the synthesis of steroid and the metabolism of steroids and xenobiotic compounds. Nonylphenol had the highest relative potency as an endocrine disruption of the 4 chemicals tested, which also included bisphenol A, bisphenol A dimethyacrylate and octylphenol; humans are widely exposed to nonylphenol as documented by biomonitoring of a random sampling of Americans. A majority of urine samples contained detectable amounts of nonylphenol. The 95th percentile showed an average of 1.59 ug/L (parts per billion) of nonylphenol in the sample; and nonylphenol is an endocrine disrupting chemical which interferes with the regulation of the function of human dendritic cells, which are a frontline immunoregualtory cell type in contact with the environment. Nonylphenol was shown to increase expression of tumor-necrosis factor alpha and decrease production of lipopolysaccharide-induced interleukin-10, which are both regulatory cytokines important in the pro- and anti-inflammatory processes. (10)

13. Comment: The commenter contends that scientists have known about the estrogenic properties of nonylphenol for decades, and more recently have found that these chemicals impact many hormone-sensitive pathways in lab animals and cell cultures. The commenter points out that nonylphenol has shown up in our waterways and drinking water supplies and that children are likely exposed to nonylphenol through the environment, and measurable levels have been detected in human breast milk. (21)

14. Comment: The commenter contends that scientific literature indicates environmental concentrations of nonylphenol can have an effect on the human placenta, and has been shown

to cross the placenta barrier and inhibit immune function, which raises concerns about maternal exposure to the chemical during pregnancy and what effects it may have on offspring. (22)

15. Comment: The commenter contends that studies have shown that NP and NPEs are toxic to the health of aquatic organisms and there are potential effects in humans. The commenter points out that the US in 2006 produced 100 to 500 million pounds of NP, or between one third of a pound to more than 1.5 pounds of NP per person living in the US. (24)

    Response to comments 6-15: The department agrees with the commenters' concerns regarding the potential health effects of nonylphenol. No change to the rule.

16. Comment: The commenter contends estrogen activity is not endocrine disruption, and that while NP does display estrogenic activity in screening studies, the real test of whether a compound is an endocrine disruptor is not the screening test but in robust multigenerational rat studies that look at adverse effects that are mediated by hormones. The commenter asserts that NP only shows adverse effects in whole animals at extraordinarily high doses. The commenter adds that because both EPA's Endocrine Screening and Testing Advisory Committee and the International Programme on Chemical Safety's definitions of endocrine disruptor include the phrase "causes adverse effects" in the organism, chemicals showing some endocrine modulation are not endocrine disruptors and should not be considered to be such. The commenter also contends that multi-generational rat studies show no reproductive or developmental effects from exposure to NP. The commenter suggests that the studies referenced in the Maine Department of Health and Human Services, Center for Disease Control and Prevention (Maine CDC), concurrence document are for the most part screening studies that test for endocrine activity, not endocrine disruption, report spurious effects not duplicated in other more robust studies or were non-guideline studies that, while interesting for academic purposes, do not contribute or stand up to the weight-of-evidence regarding the toxicological properties of NP. The commenter provided a list of the studies cited by the Maine CDC with comments as to why each does not support a conclusion of endocrine disruption. (11)

17. Comment: The commenter makes a distinction between "endocrine active" or "estrogenic" chemicals and "endocrine disruptors" and contends that only through a careful consideration of the effects of chemicals on reproduction, development and growth, among other processes, on an intact whole organism can one begin to assess the possibility of endocrine disruption. The commenter further asserts that screening assays provide information about the potential of a chemical to interact with the endocrine systems but are not sufficient to conclude the chemical is an endocrine disruptor and only through testing in whole animals can one determine if endocrine disruption and the accompanying adverse effects are occurring. (12)

    Response to comments 16-17: The department and the Maine CDC disagree with the commenters' distinction between "endocrine disruptor" and "estrogenic" or "endocrine active" chemical. The Endocrine Society defines endocrine disruptor as "a compound…which, through environmental or inappropriate developmental exposures, alters the hormonal and homeostatic systems that enable the organism to communicate with and respond to its environment." If a chemical is on a pathway that affects estrogen, endocrine disruption will eventually happen. Furthermore, multigenerational studies of NP (such as

the "Three-Generation Study of Dietary para-*Nonylphenol in CD Sprague-Dawley Rats" by Tyl et al, published in* Toxicological Sciences *in 2006) have used the same strain of rats that have come under criticism in their use in bisphenol A studies because of their extreme insensitivity to estrogen. Finally, there is evidence of deleterious effects in whole animals, including a recent paper which found that NP exposure during embryo organogenesis period induces neurobehavioral development alternation and nerve development delay, resulting in reduction in learning and memory capacity of male F1 rats and disrupted the reproductive development in the male offspring of rats and growth development in fetal rats ("Toxic Effects of Gestational Exposure to Nonylphenol on F1 Male Rats" by Jie et al published in* Birth Defects Research (Part B) *89:418-428. October 2010). No Change to the rule.*

18. Comment: The commenter objects to the Maine CDC's concurrence document for the following reasons: Most of the studies cited as evidence of endocrine disruption in the document provide screening data suggestive of possible endocrine-mediated effects, rather than the more conclusive and biologically relevant information from obtained definitive tests; the document cites a number of standard assays as providing evidence of NP/NPE estrogenicity, but with few exceptions none of the studies cited by Maine CDC is contained in EPA's battery of validated screens to detect endocrine activity and should not be considered "standard assays." Referencing one study cited by Maine CDC regarding NP's effects on placental tissue, which was rejected by EPA in its evaluation of NP, the commenter states that reliance on unvalidated screens by CDC to make speculative or conclusive statements that NP/NPE are endocrine disruptors is inappropriate given the international convention that screens cannot be relied upon and the availability of other whole animal and multi-generational rat studies conducted on NP according to protocols viewed as valid for characterizing endocrine disruption by EDSTAC. In contrast, the commenter points out that in its comprehensive review of hazard data and use and non-occupational exposure data for pesticide use of NPE and toxicological data for NP, US EPA concluded none of the studies reviewed showed adverse effects on reproductive function, no developmental toxicity was seen in rats and mice and there was no concern for increased sensitivity to infants and children from NPEs. (12)

Response: When reviewing toxicological data, government agencies often rely on standard assays or studies that follow "good laboratory practice" (GLP). This is a way of standardizing research methods for contract laboratories developed by the US EPA (and in Europe, OECD) in response to fraudulent practices committed by these labs. Good laboratory practice is not a guarantee of reliability or validity, as has been demonstrated in reviews of the flawed studies used by both FDA and the European Union in their assessments of the safety of BPA. Government organizations often reject government funded studies performed by research institutions (rather than contract laboratories) which adhere to the extremely high standards set by the organizations funding the research (e.g., National Institutes of Health), undergo a rigorous peer-review process prior to publication, focus on more sensitive endpoints than the GLP studies are capable of, and often are supplemented by subsequent studies that extend the research in the initial study. GLP is merely a recordkeeping requirement and has no specifications on quality of research design, skills of technicians, sensitivity of assays or whether methods employed are the most up-to-date. Furthermore, US EPA has recently altered its stance on NP and NPE and has outlined a number of steps the agency intends to take to both support voluntary phase-out of NP and

NPE and initiate regulatory controls under TSCA, on the basis of potential human health effects.

Risk Assessment and International Regulations

19. Comment: The commenter contends that regulatory agencies around the world have already taken action to restrict NP and NPEs. The commenter asserts that, based on the evidence of harm to humans and wildlife, the European Union has virtually eliminated all uses of NP and NPEs and Canada has taken action to reduce the use of these chemicals by 95% across all sectors from 2003-2010. The commenter suggests the US has become the dumping ground for toxic chemicals that have been phased out in other parts of the world. (1)

20. Comment: The commenter contends that risk assessment is the most scientifically defensible and broadly accepted methodology to prioritize chemicals for regulatory action. The commenter asserts that by reviewing relevant human risk assessments, DEP could ensure that those CHC chemicals most likely to cause harm to children would be addressed first. The commenter refers to the following findings of government risk assessments: EPA's assessment of the human safety of NPEs for their use as inert ingredients in pesticide formulations concluded no concern for increased sensitivity to infants and children from NPEs; a Canadian risk assessment of NP/NPE concluded no danger to human health from environmental exposures, including from ambient and indoor air, drinking water, foodstuffs and the use of consumer products; and the European Commission risk assessment on NP concluded no concern for human health. (11)

21. Comment: The commenter contends that the department's basis statement supporting the designation of NP and NPE was not sufficiently robust in that it did not include results of risk assessments carried out by EPA, Canada, and the European Commission. (14)

22. Comment: The commenters contend that nonylphenol and nonylphenol ethoxylates do not pose a human health or a children's health risk. (14, 18)

23. Comment: The commenter contends that any previous regulation of phase-out of NP or NPE by industry or other governments has related to aquatic toxicity and not human health concerns. (18)

24. Comment: The commenter asserts that science does not support the designation of NP/NPE as a priority chemical given that state, federal and international entities have concluded that they are not a concern for human health, including US EPA's assessment of NPE use as inert ingredients in pesticides in 2006, Canada's assessment of NP and NPE in 2001, the European Union risk assessment for NP and NPE in 2002, and Washington and Oregon which both concluded NP is not a PBT. (20)

Response to comments 19-24: After carefully considering the above comments, the department finds that there is no new evidence to reverse the department's conclusion that NP and NPE clearly meet the statutory criteria for designation as a priority chemical under 38 MRSA §1694; that this designation is an appropriate use of department resources; and that designation is necessary for the department to gather complete information on current use and risk posed by NP and NPE, including its breakdown products, in children's

products. This ability to gather complete information is necessary for the department to make an informed decision regarding the need for and methods of reducing children's exposure to NP and NPE in Children's products. Under 38 MRSA §1694 sub-§ 3, manufacturers have the ability to supply detailed risk information for department consideration before the department proposes risk reduction strategies.

The Toxic Chemicals in Children's Products statute does not require the department to assess the risk posed by priority chemicals. Rather, the statute requires only that the chemical be present on the Chemicals of High Concern List and meet one of six other criteria. Nonylphenol and nonylphenol ethoxylates meet five of the six criteria, indicating that children and other vulnerable populations are likely to be exposed to this chemical which has inherent hazard characteristics. This reflects a shift from risk-based chemicals management policy to a hazard-based policy.

The department acknowledges that information regarding chemical hazard traits is continually being updated. For instance, in its most recent assessment of NP and NPE (Nonylphenol and Nonylphenol Ethoxylates Action Plan, August 18, 2010), the US EPA concludes that "NP and certain oligomeric NPEs are highly toxic to aquatic organisms, are moderately bioaccumulative in mollusks, are persistent in the aquatic environment and accumulate in soils and sediments." EPA further states that, "Exposure is a result of the presence of NPE and NPEs in detergents, agricultural and indoor pesticides, food packaging and cosmetics. These are potentially products of concern for women and children." EPA proposes a number of steps, including supporting the voluntary phase-out of NP and NPEs in certain sectors, and regulatory measures that would require testing and notice to EPA prior to use of NP and NPEs (test rule and significant new use rule). The department contends that the proposed rule is not out of step with EPAs latest assessment of this class of chemicals and proposed actions to address those chemicals. No change to the rule.

3(A) Presence of NP/NPE on the Chemicals of High Concern list

25. Comment: The commenter asserts that the department listed nonylphenol and nonylphenol ethoxylates as a chemical of high concern simply because they are listed on the OSPAR list of Chemicals for Priority Action as persistent, bioaccumulative and toxic (PBT) and an endocrine disruptor. The commenter asserts that the mission of the OSPAR Commission is the protect the marine environment of the Northeast Atlantic and that the OSPAR document on NP/NPE does not cite human health concerns as a reason for listing them for Chemicals for Priority Action and contains the following statement: "Regarding consumers, no risk is expected." The commenter also points out that the OSPAR categorization of NP/NPE as a PBT is not consistent with other more recent governmental PBT assessments, such as those conducted by the European Union, Environment Canada, Washington State and Oregon, which concluded that NP/NPE are not persistent or bioaccumulative. The commenter contends that the process and basis for listing NP and NPE on the Chemicals of High concern list is flawed and the chemicals should be removed from the CHC list because NP and NPE are not persistent or bioaccumulative and more relevant government assessments should supersede the OSPAR categorization of these compounds as PBT. (11)

26. Comment: The commenter contends that NP should be removed from the CHC list because it does not meet the criteria for high concern for human exposure on the European Commission Endocrine Disruptor Program Category 1 Endocrine Disruptor list and. Further,

the commenter points out that NPE is not listed on the EC Category 1 list. The commenter also asserts that because the chemicals on the Endocrine Disruptor list have not undergone any type of risk assessment and the list is not regarded as final and unchangeable as chemicals may be added or removed in response to developments in scientific knowledge or changes in chemical use pattern, the use of the Endocrine Disruptor list is questionable. (11)

27. Comment: The commenter objects to the citation of the European Commission Endocrine Disruptor Program list as support for including NP and NPE on the chemicals of high concern list, because NPE is not listed on the EC Category 1 list and NP does not meet the EDP criteria for high concern for human exposure. Further, the commenter points out that the chemicals on the EDP list have not undergone any risk assessment and the list itself is fungible, in that chemicals can be added or deleted, and therefore NP and NPE should be removed from the CHC list. (20)

Response to comments 25-27: The department, in consultation with a toxicologist from the Maine CDC developed and published a list of chemicals of high concern (CHC list), as directed by the Legislature in 38 MRSA§1693. This list, as well as a background document that describes the sources for the chemicals listed, is available on the Department of Environmental Protection's website at http://www.maine.gov/dep/oc/safechem/highconcern/.

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 of over 80,000 chemicals in commercial use down to a smaller list of chemicals with the 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 light of the department's ability to move forward with this rulemaking now, and the threats to children's health documented for nonylphenol and nonylphenol ethoxylates in the public record for this rulemaking, it appears that the screening system worked exactly as intended by the legislature.

The department does not ignore the Legislature's directive to confine the list to "known" sources of hazard. However, the Legislature further defines what it means by "known" in the legislation that established the Toxic Chemicals in Children's Products law, PL 2007 c. 643 Section 3. Under that section, the Legislature listed about ten examples of existing chemical lists that the department "may consider" in developing Maine's Chemicals of High Concern List. Categories the Legislature recommends the department use in developing its list include, for example, chemicals "reasonably anticipated to be a human carcinogen" as well as those "known to be a human carcinogen" by the US Department of Health and Human Services.

The majority of the source lists used in developing the CHC list came from those outlined in section 3 of the enacting legislation. However, the Legislature did not limit the department's options to just the suggested lists. Additional source lists were consulted where deemed appropriate in the judgment of the Maine CDC toxicologist who advised the department. A discussion of the department's and the Maine CDC's basis for drawing on the specific lists referenced by the commenters follows:

OSPAR. *The Convention for the Protection of the Marine Environment of the North-East Atlantic (the 'OSPAR Convention') 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 the United Kingdom. While OSPAR itself is not a governmental 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.

While the original purpose of OSPAR (and its predecessors, the Oslo Convention and the Paris Convention) was to identify threats to the maritime area, one of the operating principles of the OSPAR Commission is the precautionary principle, by which "...preventive measures are to be taken when there are reasonable grounds for concern that human activities may bring about ***hazards to human health****, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea..." [emphasis added]. OSPAR has conducted considerable work to identify chemicals of concern to the North-East Atlantic. In 2002, OSPAR established a list of 310 chemicals or chemical groups of possible concern which consists mainly of PBT chemicals with a few endocrine disruptors included. OSPAR further identified a shorter list of 50 chemicals or chemical groups which require priority action. The List of Substances of Possible Concern consists of the substances which have been selected on the basis of their intrinsic hazardous properties (e.g., PBT or endocrine disruptor). All of the chemicals or chemical groups from both the list of substances of possible concern and the list of chemicals for priority action were included in the Maine's CHC list.*

European Commission (EC). *The mission of the EC is to promote the general interest of the European Union. It presents proposals for European law, oversees implementation of treaties and European law and carries out common policies. The EC conducts work on a wide range of environmental issues and has established several databases which address chemical specific issues undertaken by the EC to address chemical safety.*

On December 20, 1999, the EC adopted a Communication on a Community Strategy for Endocrine Disrupters – a range of substances suspected of interfering with the hormone systems of humans and wildlife. The strategy focuses on man-made substances, including chemicals and synthetic hormones, which may harm health and cause cancer, behavioral changes and reproductive abnormalities.

The European Commission established a Priority List of endocrine disruptors by first reviewing evidence of endocrine disruption for "suspected endocrine disruptors." Those that either showed evidence of persistence in the environment or are produced at high production volumes were further reviewed for strength of case for endocrine disruption and assigned to one of three categories, with Category 1 being chemicals that showed evidence of endocrine disruption activity in at least one intact animal. Category 1 chemicals were further reviewed for the likelihood that either humans or wildlife are actually exposed to the chemical and ranked from High (humans or wildlife expected to be exposed) to Low (neither humans nor wildlife expected to be exposed). Nonylphenol appears on the list as a Category 1 Endocrine Disruptor with a medium likelihood of exposure to wildlife.

The department stresses that the CHC list is merely a starting point—a way of narrowing down the tens of thousands of chemicals in commerce to a more manageable number. In all cases, the department and the Maine CDC will review supporting evidence and toxicological and exposure information for any chemical considered for designation as a priority chemical. The toxicological literature on nonylphenol is a cause for concern regarding potential impacts to children. The fact that it has shown up through biomonitoring in human bodily fluids and tissues and through sampling in the home environment causes the department to suspect that humans are indeed exposed to this chemical. Based on the information gathered through this rulemaking, the department will be better equipped to assess whether children are exposed to nonylphenol through the use of products listed in section 4(A) of the proposed rule. No change to the rule.

3(B) Criteria for designation.

28. Comment: The commenter asserts that the criteria for designation of this class of chemicals as a priority chemical have clearly and fully been met and that the basis for that designation has been well-documented. (9)

    Response: The department concurs. No change to the rule.

29. Comment: The commenter points out that because we are able to detect anything at almost any level, parts per trillion, we will find anything in our bodies and just because a chemical or chemicals are found in our bodies does not mean that it is causing harm. (14)

    Response: In drafting the guiding statute for the Safer Chemicals in Children's Products Program, the Maine Legislature considered the most prudent course of action to minimize exposure to chemicals that concentrate in human blood and tissue, especially for children and other vulnerable populations. This was due, in part, to a concern regarding the number and levels of numerous industrial chemicals in the fluids and tissues ofhumans, our poor understanding of the health effects posed by individual chemicals let alone chemical mixtures, and the known impact at low doses of some chemicals such as certain dioxins and drugs. No change to the rule.

Section 4. Information Submission Required

Exposure of children to NP and NPE

30. Comment: The commenter contends that governmental exposure and risk assessments conducted in Canada and the European Union have concluded that measured exposure of children to NP and NPE in home and preschool settings is extremely low with high margins of safety. The commenter notes that the use NPEs in detergents and household cleaning products has significantly decreased and its use in personal care products has never been significant, and that exposure from NPE used in home maintenance products is expected to be minimal. The commenter summarized governmental assessments and exposure studies which support the conclusion that NP and NPE do not represent a significant exposure or risk to consumers or children in Maine. (11)

    Response: The department finds the commenter's information regarding minimal exposure to children to be encouraging, however, the fact that NP is found in human bodily fluids and

tissues indicates that humans are indeed exposed to the chemical. The department looks forward to confirmation of the minimal use of NPE in the proposed product categories through full and complete disclosures by manufacturers, which are only possible after promulgation of this rule. No change to the rule.

4(A) Product Categories

31. Comment: The commenter states that as the goal of the law is to keep chemicals of greatest concern from affecting children, the commenter has a hard time understanding how the proposed categories are some of the most likely to affect children as they are not generally understood to be children's products nor are they marketed to children. The commenter's concern is that the rule "applies to manufacturers of children's products containing intentionally-added nonylphenol or nonylphenol ethoxylates that are manufactured, sold, offered for sale or distributed for sale in Maine." The commenter urges the board to look closely at the definitions of children's products in the rule and adopt the definition of children's toy and childcare article from the federal Consumer Product Safety Improvement Act (CPSIA). In addition, the commenter suggests that the department be consistent with federal law by designating application to products intended for children ages three years or younger and limiting the scope to those toys that can be placed in the mouth under the federal definition. (17)

Response: While the Department strives to be consistent with federal regulatory programs whenever possible, narrowing the universe of regulated products in this case to those regulated under CPSIA would be inconsistent with the department's legislative charge. The Maine Legislature recognized that children contact more than toys or childcare articles and broadly defined "children's product" in 38 MRSA §16-D as "a consumer product intended for use by children, such as baby products, toys, car seats, personal care products and clothing, and ***any consumer product containing a chemical of high concern that when used or disposed of will likely result in a child's or fetus's being exposed to that chemical****." [emphasis added] The Legislature did not define "child" in statute, so the department, in 06-096 CMR Chapter 880, adopted the regulatory definition of "child" or "children" meaning "a person who has not attained the age of 18 years." The department promulgated this definition because children live in homes, attend daycares and schools, go into commercial establishments, ingest food, breathe air, and drink water, so they continually come into contact with products beyond the narrow group regulated under CPSIA (those "specifically intended for or marketed to children, intended as toys or intended to be mouthed"). Furthermore, children do not cease growth and development at age three; significant physical, mental and hormonal changes continue through the teen years and even into the early twenties, making them susceptible to health impacts from low doses of some chemicals. Further, the Maine Legislature's definition of "children's product" encompasses exposure of a fetus, meaning that the department must also consider the exposures of pregnant women. All three categories of products proposed in this rule meet the Legislature's definition of "children's product" in that the use or disposal of any of the stated products could potentially result in a child or fetus being exposed to NPE through coming into contact with fabrics or surfaces that have been cleaned with NPE-containing products, through use of NPE-containing personal care products or contact with an adult that has used such products, and through living in a home where NPE-containing maintenance products are used. No change to the rule.*

4(A)(1) Household and commercial cleaning products

32. Comment: The commenter contends that NPE and NPEs have been virtually eliminated from the consumer product marketplace because of readily-available, performance-comparable and cost-effective safer alternatives. The commenter points to EPA's Safer Detergents Stewardship Initiative under which more than 70 leading companies have pledged to eliminate NP and NPEs from their products, including Colgate-Palmolive, SC Johnson and Son, Procter and Gamble, Unilever, Rochester Midland, Clorox and 3M. The commenter also points out that the world's largest retailer, Walmart, issued a directive to all of its vendors more than four years ago to get out of NP and NPEs. (1)

    Response: The department appreciates the commenter's information regarding concentrations of NPE in cleaning products and anticipates full and complete information on its usage from the information that will be submitted by manufacturers following promulgation of this rule. No change to the rule.

33. Comment: The commenter asserts that eighty percent of all use of NPE is in cleaning products, and that concentrations of NPE are very high in those products. (4)

    Response: The department appreciates the commenter's information regarding concentrations of NPE in cleaning products and anticipates more information on its usage from the information that will be submitted by manufacturers. No change to the rule.

Availability, efficacy and cost of alternative chemicals in cleaning products

34. Comment: The commenter contends that cleaning products free of harmful chemicals work just as well, if not better, and they are better for your health and the environment. The commenter asserts all businesses want to sell products that are safe for kids and families but they, like parents and other consumers, are left in the dark about what chemicals are in products and whether they are safe. (3)

35. Comment: The commenter states that his cleaning product manufacturing company conducted a complete review of all their chemicals in the early nineties and systematically eliminated all use of NPEs, finding safer substitutes. The commenter's company now manufactures more than 500 products, 150 to 200 of them carry third-party green certification, and not one of them carries NPE or any APEs (alkylphenol ethoxylates). The commenter asserts that safer alternatives are definitely available and the commenter's company has employed those alternatives very effectively, and because of the revolutions that have taken place in the cleaning industry they have found ways to conduct the same cleaning with almost no chemicals. For example, the commenter states that they can take plain water, split the hydrogen and oxygen apart from one another, add an electric charge to it, turn it into a natural detergent, allow it to do its job, bring it back into the wastewater stream and because it is unstable, it forms back into water again and all you have is dirty water. Additionally, the commenter asserts that with the advent of microfiber cloths that capture 96 to 98 percent of all soil and bio load off of any hard surface with no detergent at all, items that would have had NPE in the past, such as glass cleaner, no longer need NPE. The commenter provides an additional example of a program for health care cleaning that involves microfiber cloths in conjunction with natural acids, not unlike vinegar, with detergent not unlike baking soda. (4)

36. Comment: The commenter contends that at least one hospital in Maine—Maine General—has eliminated NP and NPEs from its cleaning regimen. (6)

37. Comment: The commenter asserts that safer alternatives to this class of chemicals are readily available and widely in use at comparable costs. (9)

38. Comment: The commenter contends that replacing NPE is not a "drop-in" process and alternative formulations may have higher concentrations of surfactants, and require the addition of other ingredients, in an attempt to achieve performance or technical function comparable to NPE. The commenter cites a Consumer Reports analysis that demonstrates that detergents based on NPEs are on average half the cost of alternative detergents. (11)

39. Comment: The commenter contends that, as a manufacturer they test all the alternative surfactants for their performance ability and have yet to see one perform as well as NPE and that consumers have to use four to five times the amount of material manufactured with the safer alternatives, therefore exposing the environment to more pollution instead of less. The commenter contends that the cleaning products industry is not prepared with the proper replacements for NPE at this time because the alternatives are inferior and more of a risk of polluting than protecting the environment. (19)

40. Comment: The commenter asserts that alcohol ethoxylate, the alternative to NPE, is more than 100 times safer, and that the European Union and Canada have already taken significant steps to eliminate or drastically reduce the use of NP. (24)

Response to comments 34-40: The department finds the information on the wide availability and efficacy of alternatives to NPE in cleaning products both interesting and encouraging. However, the information obtained through the information request proposed in the rule will target more specifically why these alternatives do not meet the needs of manufacturers still using NPE in their products. No change to the rule.

4(A)(2) Personal Care Products

41. Comment: The commenter contends that the personal care products industry has generally phased out the use of NP/NPE in its consumer products, however, the commenter points out that cosmetics ingredients are already stringently assessed for adverse human health and safety impacts. The commenter contends that the Cosmetic Ingredient Review Expert panel is an independent, industry-funded panel of scientific experts that regularly assesses the safety of numerous cosmetic ingredients and publishes its findings. The commenter states that the Expert Panel reviewed nonylphenol ethoxylate and found it to be safe as used in cosmetics. The commenter recommends that the department exempt cosmetic ingredients that have been reviewed by CIR and found to be safe from being designated as priority chemicals or acknowledge CIR as an authoritative body and consider CIR's safety studies and findings prior to designating any priority chemicals. (20)

Response: The department appreciates that the industry has largely phased out NP and NPE and looks forward to confirmation of this statement from the information submitted in response to the proposed rule. The department also appreciates the information regarding the CIR safety studies and will take this information into consideration when further

evaluating NP and NPE once the information from manufacturers has been received, and when evaluating other chemicals in the future. No change to the rule.

4(A)(3) Home maintenance Products

42. Comment: The commenter states that NPE is used in a diverse number of formulated products, prior regulatory action in EU and Canada has spurred use/risk reduction in many industries, and some uses are likely to remain. The commenter contends that use of NPE in paint is not expressly restricted in the EU and Canada. The commenter stresses that uses of NPE in paint are primarily centered around various waterborne finishes as an alternative to (arguably) more hazardous VOCs and HAPs. Despite this environmental benefit, the commenter acknowledges the need for continued evaluation of NPE substitutes. Additionally, the commenter states that NP is sometimes used as part of the curing agent formulation to dry the paint film and that the basic chemistry is that these curing agents react with the epoxy resin to create a cross-linked vehicle matrix and should be bound with the film. For the most part this substance is used in 100% solid epoxy flooring materials. The commenter contends that when NPEs are used in paints, there are risk reduction practices that operate to limit exposure, and that many of these, such as hazard and precautionary labeling, are quite specific and are frequently modified as needed to reflect new and expanded hazard information. The commenter points out that the most notable physiochemical attribute of NPE is its low vapor pressure which translates into a low exposure potential and that in one known indoor air quality study, the sources and pathways of exposure identified did not include NPE used in paint. (16)

    Response: The department appreciates this additional information about NPE use in paints and coatings. It is exactly this kind of information relating to the use of a chemical and the reasons it is formulated in a product as well as the likelihood of children becoming exposed from a product that the department seeks from all applicable manufacturers through this rulemaking. Understanding of the extent of NPE use in home maintenance products including paints and coatings along with physiochemical properties that may affect exposure as well as its use as a substitute for more hazardous ingredients, such as the VOCs and HAPs referenced by the commenter, will help the department make informed decisions when contemplating whether or how to proceed with regulation of this chemical. However, the department maintains that the more specific information required through this proposed rule from all subject manufacturers is necessary for evaluating options. No change to the rule.

4(B) Information Required

43. Comment: The commenter requests the DEP to expeditiously review the information collected under section 4. (1)

    Response: The department intends to review the submitted information as expeditiously as resources allow. No change to the rule.

44. Comment: The commenter contends that it is appropriate and reasonable to establish a series of reporting requirements so that department staff and the public can find out where NP and NPEs are used in consumer products, to further educate the marketplace about the importance of moving away from these chemicals and get further voluntary forward progress. The commenter asserts that we need the information that the proposed rule will

generate through the reporting requirements to characterize benefits that may be gained from further action on NP and NPEs. (10)

Response: The department concurs. No change to the rule.

45. Comment: The commenter expresses concern about the hardship placed on Maine companies which will be obligated to spend time and resources simply to figure out whether they use a priority chemical even if it turns out that they don't actually use one, as well as the expense of having to determine exposure to children of a product's use and investigation of the possibility of reformulating and proving the safety of an alternative. The commenter asserts that this scheme is expensive and will put Maine companies at a competitive disadvantage and will not result in a safer environment. (14)

46. Comment: The commenter asserts that it could be difficult for Maine businesses to figure out if they are using or even selling a product that contains NP/NPE and other future priority chemicals. (15)

Response to comments 45-46: The information requested in the proposed rule would apply to all manufacturers of the listed product categories, not just Maine manufacturers and therefore should not impose any competitive disadvantage on Maine manufacturers. Further, consumers are coming to expect a manufacturer to know what chemicals that company uses in products it sends into the marketplace. Such knowledge would allow manufacturers to proactively seek alternatives to any Chemical of High Concern, regardless of its status in the department's process of designating priority chemicals, which would place those businesses at a distinct advantage in this age of consumer awareness of health effects of chemicals and desire to use products that a produced sustainably. Finally, since the rule will create a level playing field in which all companies must comply, establish a predictable process, and produce an informed risk-based decision by a neutral third party, the rule will remove any economic advantage for companies that fail to protect children from chemicals in their products. No change to the rule.

47. Comment: The commenter contends that rule will impose significant reporting requirements and will force companies to pay for the redesign of certain products and the ongoing administrative costs associated with compliance would be significant. (15)

Response: The department is committed to minimizing the resources companies must employ to comply with the rule and the Safer Chemicals in Children's Products Act. The program seeks to have both protective standards for children and the least burdensome process for demonstrating that the standards are met. The department acknowledges that there will be some one-time costs associated with the reporting requirements of the proposed rule, but does not anticipate those costs to be as significant as manufactures fear. The reporting requirement is a one-time requirement to assist the department in determining the extent of the use of the priority chemical in Maine and the likelihood that children may be exposed from those uses. This requirement is necessary, and a requirement of the statute, because historically, when the department has attempted to regulate the use of hazardous chemicals in consumer products, manufacturers were not always forthcoming with information about all of the uses of the targeted chemical. Nothing in the proposed rule compels redesign of

any products since a ban on use of the chemical is not included in the rule. No change to the rule.

48. Comment: The commenter contends that to complete the information that would be requested by Maine DEP will require manpower by the industry and then require manpower by DEP to review the information and that to impose an additional monetary burden on the industry and the agency in these economic times is unwarranted and unreasonable. (18)

    Response: The reporting requirement proposed in this rule is a one-time requirement. While the department acknowledges there will be some costs associated with submitting this information to the department and with the department recouping its own costs under the process laid out in 06-096 CMR Chapter 881, the department has no reason to believe that these costs will be significant in comparison with other operating costs or revenues of the manufacturers of these products. Further, businesses can reduce the reporting burden and costs to both the manufacturers and the department by relying on information submitted on the businesses behalf by a trade association, chemical manufacturer or other third party as allowed under 06-096 CMR Chapter 880 Section 3(E). Finally, the department believes that the cost is outweighed by the benefits from reduced health impacts to children and increased confidence in the consuming public. No change to the rule.

Additional comments

Nonoxynol-9

49. Comment: The commenter states that the NP-based product nonoxynol-9 was touted as a way of preventing HIV and other STIs in the 1980's, but that in the late 1990's, studies showed that not only did nonoxynol-9 not kill HIV and other viruses as suspected, but its abrasive properties actually increased the likelihood of spreading viruses. The commenter supports the use of nonoxynol-9 as a spermicide for the prevention of pregnancy, but highlights the need for a safer substitute than a pesticide to kill sperm when pregnancy is not the desired outcome. (8)

    Response: The department shares the commenter's concerns, however, the use of NP in spermicide use falls outside of the scope of the department's proposal. No change to the rule.

Uncertainty

50. Comment: The commenter expresses concern that a Maine business making a product today does not know if the compound it uses to make a product will be designated as a priority chemical in the future, creating uncertainty and inhibiting Maine businesses' ability to plan for the future, remain competitive and keep or create jobs in the state. (14)

    Response: While it is true that almost any of the compounds on the chemicals of high concern list could be a future candidate for designation as a priority chemical (excluding those used exclusively as drugs or biologics or which are regulated as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act), the process of designating a priority chemical through rulemaking, which is both a lengthy process and a process through which individual Maine businesses have the opportunity to comment and express specific concerns about how the proposed rule may affect them, along with the 180 day time frame for

manufacturers to report information, should allow Maine businesses ample time to plan for the future. Any further regulation, of which none is proposed with this rulemaking, would include additional time for manufacturers to meet the requirements and would allow for extensions if necessary. No change to the rule.

Federal Role

51. Comment: The commenter contends that it is the role of the federal government to regulate the use of chemicals in the products and market in the US through reform of the federal Toxic Substances Control Act. (14)

    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 their citizens. Concurrently with the implementation of the Toxic Chemicals in Children's Products Act, 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 in order to regulate the most problematic chemicals in commerce, protects 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.

Use Restriction and Sales Prohibition

52. Comment: The commenter recommends that the department consider adopting use restrictions on nonylphenol and nonylphenol ethoxylates in commercial laundry detergents to mirror the voluntary phase out agreement between US EPA and the Textile Rental Services Association of America. (1)

    Response: At this time, the department does not have enough information regarding the usage of NP/NPE in products, including industrial laundry detergents, to propose usage restrictions recommended by the commenter. No change to the rule.

53. Comment: The commenter supports a full ban on NP and NPE if analysis shows it is no longer being used, to codify a market shift away from these chemicals. (7)

54. Comment: The commenter contends that the marketplace has already moved away from NP and NPE in household and commercial laundry detergents. The commenter points out that under US EPA's Design for the Environment Program Safer Detergents Stewardship Initiative, more than 70 companies have already eliminated or pledged to eliminate NP and NPEs from their products, and that includes major international manufacturers. Further, the commenter points out that the Textile Rental Services Association of America, which is the trade association representing 98 percent of industrial laundry facilities, has claimed that over

the last five years the industry's use of NPE has declined by approximately 75 percent and the association has formally committed to US EPA to phase out remaining uses over the next few years, and that a mandatory phase out of NPE is possible by the end of 2014. Based on this voluntary commitment of industry to phase out use of NPE in household and industrial detergent, the commenter recommends that it would be a better use of the department's resources to not collect a lot more information, but to codify what the market is already doing. (9)

55. Comment: The commenter opposes a ban on NPE and states that if NPE is banned in the state it will force the commenter to manufacture more expensive, less effective, lower quality products and try to compete against manufacturers in other states who do not face the same restrictions. (19)

Response to comments 53-55: The department supports the market shift away from NP and NPE and looks forward to receiving information that confirms this shift. The department does not propose to ban NP and NPE with this rulemaking. The department's proposal is intended as a request for complete information to assess the extent of use of NP/NPE in children's products manufactured, distributed and sold in Maine and the likelihood that children may be exposed from those uses. The department needs this information to make an informed decision regarding any need to prohibit sales of products containing NP/NPE, which would be done through a future rule change. No change to the rule.

Fiscal Impact

56. Comment: The commenter contends that the department has not produced the required estimate of fiscal impact of the rule as required by the Maine Administrative Procedures Act, nor considered impacts and costs on small businesses. The commenter asserts that the fiscal statement in the department's fact sheet does not include any type of estimate of the fiscal impact of the proposed regulation, and that an "estimate" of impact is not the same thing as a brief, general, qualitative description in the fact sheet. The commenter submits that a reasonable estimate in compliance with the MAPA would include an approximate quantitative calculation of the fiscal impact on all potentially impacted parties. (11)

Response: The department disagrees with the suggestion that the MAPA requires agencies to quantify their estimates of fiscal impact; there are no words to that effect in the statute. Moreover, agencies are unlikely to be in position to attach a dollar value to fiscal impact estimates without access to propriety information from affected parties. The affected manufacturers and their representative organizations presumably have access to the particularized information needed to prepare such a calculation whereas the department does not. Nor does the MAPA require the department to perform such a calculation.

The department's obligation is to consider the fiscal impact of the rules it adopts—by including an estimate of fiscal impact on the rulemaking fact sheet, and to assist the regulated community and general public in understanding how a rule may affect them. The department has described these impacts generally in the Chapter 883 rulemaking fact sheet. The estimate identifies who is likely to incur costs if chapter 883 is adopted—manufacturers and distributors of products containing nonylphenol and nonylphenol ethoxylates—and the nature of those costs—compiling and submitting information requested by the. The fact sheet description fulfills the letter and purpose of the MAPA requirements by assisting the regulated community and public in understanding how the proposed rule may affect them so

that they do not miss the opportunity to provide the department with comments during the public comment period.

The MAPA rulemaking process guarantees affected parties and other interested persons the opportunity to provide fiscal impact data. If the affected parties had a different understanding of the fiscal impact or have facts bearing on fiscal impact that the department does not have, they had the opportunity transmit that information to the department for consideration so that the agency can refine its fiscal impact estimate as appropriate and revise the rule if warranted. No commenters provided specific information or suggestions upon which the department can rely to revise the fiscal impact estimate or revise the rule in ways that might reduce its impact.

No change to the rule.

Market Forces

57. Comment: The commenter suggests that market forces—such as EPA's Design for the Environment and a Safer Detergents Stewardship Initiative—should take care of products that contain NP/NPE and that people have the right to make a choice.

Response: The department fully supports the market-based reduction in use of NP and NPE over recent years. With the information reported as a result of this proposed rulemaking, the department anticipates having a complete understanding of how effective this program has been, and if there is any residual risk to children that should be addressed. We disagree, with the assertion that consumers currently have the choice to avoid products containing NP/NPE, since consumers have no way of knowing if the products they purchase contain NP or NPE. No change to the rule.