



December 8, 2022

Commissioner Loyzim,

The Natural Resources Council of Maine (NRCM) is committed to ensuring the success of Maine's Extended Producer Responsibility (EPR) for Packaging program established in [MRS Title 38 §2146](#). Thank you for the opportunity to participate in this first of five Department rulemaking topic areas, regarding *producer exemptions* as they are related to perishable food in section 2D, and federally regulated packaging in section 13D of the statute.

We feel strongly that exemptions adversely impact the management and fairness of any EPR program; however, we also believe it's prudent to have reasonable exemptions or special consideration for certain producers or specific types of products and packaging based on established criteria and explicit rationale as to the operational or public health reasons behind the exemption.

In general, we believe that any packaging that is currently being collected by municipalities should remain in the EPR system, unless the material is best managed separately under a different program. If any special treatment is to be granted regarding federal regulations that limit the recyclability or use of recycled materials for a particular type of package, then that should be addressed through reductions in fees, not exemptions.

Exemptions adversely impact the management and fairness of the program

Any exempted producers would still be selling packaging materials into Maine's communities but leaving the responsibility of paying for management of this material to either the participating producers or municipal taxpayers. This is inequitable, and contrary to the fundamental rationale behind EPR. Further, we believe exemptions should be considered with caution and should be very limited in scope because:

- Exemptions add administrative complications for the stewardship organization; because producers should only be accountable for obligated materials, significant auditing is required to account for exempted materials collected by municipalities.
- Exemptions benefit producers of exempted materials, creating an unlevel marketplace.
- Exemptions make performance measurement challenging (e.g., recovery rate/collection rate) as there is not full reporting of the material sold and significant work is required to audit material collected.

Maine's EPR law already exempts certain materials and producers, including:

- Small producers who realized less than \$5 million in annual gross revenue for the first three years of the program, and less than \$2 million in annual gross revenue after the third year; or small producers who sold or otherwise distributed less than one ton of packaging to consumers in Maine;

- Producers who realized more than 50% of the total gross revenue in the prior calendar year from the sale of goods they acquired through insurance salvages, closeouts, bankruptcies, and liquidations;
- Producers of perishable food and frozen wild Maine blueberries who sold or otherwise distributed 15 tons or less in packaging materials to consumers in Maine (we will describe our recommendations for rulemaking regarding this particular producer exemption below);
- Any producer who is also a nonprofit 501(C)(3) organization;
- Any packaging that is intended to provide long-term storage for at least five years;
- Packaging that is already being collected through an existing EPR program in Maine including beverage containers that are subject to Maine’s bottle bill; and
- Architectural paint cans collected by Maine’s Paintcare program.

In the absence of a very detailed, costly, regular auditing exercise, we will have no way to know how much exempted material this will amount to in the EPR system since reporting is not required. We do not support adding more exemptions, largely for this reason. In contrast, we urge the Department to request that the Stewardship Organization seek out the exempted producers and ask them to voluntarily report estimates of the amount of material, or to be voluntary stewards, so that we gain a more accurate and fair packaging stewardship program.

The existing exemptions were added to the law for various reasons ranging from operational to political, but none that consider recyclability or ability to reduce packaging, which is the basis for considering federally regulated packaging exemptions by major substantive rule. This highlights the lack of consistent rationale for granting exemptions in the program. As such, we urge the Department to consider defining criteria to be used in determining whether an exemption is appropriate under the EPR law as part of the routine technical rulemaking process.

Perishable Food, Section 2D

We urge the Department to further specify this exemption through rule, to better align with the intent of the statute. The intent of this exemption was political in nature and intended to give special consideration to small farmers and food producers who sell less than 15 tons of packaging material along with their perishable food (or frozen wild blueberries) to Maine consumers each year. Our concern is that the way it reads could imply that the producer is *entirely exempted* from the law, if just a portion of their business is selling perishable food to Maine’s consumers and is under the 15-ton threshold, which was clearly was not the intent.

Most small farmers will already be exempt by virtue of falling under the “small producer” exemption threshold. But, in the context of larger businesses that happens to sell fewer than 15 tons of *perishable food* along with other packaged goods in Maine, it should be clear that they do not qualify for this exemption, and that they must report and pay into the EPR program for *all* of their packaging, even if they sell perishable foods.

Federally Regulated Products, section 13D

The statute directs the Department to review packaging materials associated with certain federally regulated products to determine if they should qualify for an exemption by major substantive rule, meaning that the exemptions would need to be approved by the Legislature. In making the determination, the Department must consider if the packaging associated with these products *is unable to be recycled or reduced* because of federal regulations.

Regardless of what these regulated products are and why they must be packaged a certain way, NRCM believes that the producers should have to participate in the program by reporting and paying fees and not receive a blanket exemption. It's very important for the operation and fairness of the entire program to limit exemptions unless there is a compelling operational or public health reason to exempt them.

Since the Department must consider the recyclability and ability to reduce the amount of packaging in its review, we strongly believe that special consideration should be given to these materials in the fee-setting portion of the program instead of being completely exempted. These producers should have to report the amount and type of packaging and make a compelling case why they can't possibly use more sustainable packaging options, and only then be able to qualify for a reduction in fees only for necessary additional packaging that they must add by law, for instance.

That said, we would like to review the four specific federally regulated product categories identified in the statute and discuss the breadth of the products and materials in question. It is important to note that, to the best of our knowledge, these materials and producers are not exempt in any of the EPR for Packaging programs that are operating outside of the United States.

- (1) *“Material that is used for the containment, protection, delivery, presentation or distribution of a drug, as that term is defined under Section 321 of the federal Food, Drug, and Cosmetic Act, as regulated by the United States Food and Drug Administration under the federal Food, Drug, and Cosmetic Act or as collected under a stewardship program in the State that has been approved for operation by the department and has been established to collect and dispose of such drugs, including, but not limited to, prescription and nonprescription drugs, drugs in medical devices and combination products, branded and generic drugs and drugs for veterinary use”*

Discussion: Maine's drug take-back stewardship program only applies to the drugs, and not the packaging of the covered drugs, so that material should still be included in the EPR for Packaging program. In [section 3\(D\) of that law](#), the stewardship organization is compelled to encourage consumers to separate their unused drugs from the packaging.

Furthermore, Maine's drug take-back program does not apply to substances classified as regulated drugs, which include but are not limited to vitamins or supplements, cosmetics, soaps, laundry detergent, bleach, shampoo, household cleaning products, sunscreen, toothpaste, lip balm, anti-perspirant and other personal care products, and more. This amounts to a large portion of Maine's waste stream. The federal regulations do not affect the amount of or recyclability of these products, and even if they did, there is no

compelling operational or public health reason why the obliged producers of any of those packaged products should be exempted from Maine's EPR for Packaging law.

Any ophthalmic preparation and dispensers such as eye cups and eyedroppers may need to use a minimum amount of packaging material to meet their purpose, but that same argument could be made for any type of packaging. We also recognize that the FDA requires a certain amount of labeling on packaging that could limit the producer's ability to reduce the packaging. **NRCM believes that it would be more appropriate to address the issues of ophthalmic products and any additional packaging required to meet FDA labeling guidelines through the fee setting portion of the program rather than through blanket exemptions; such products could be eligible for reduced fees.**

(2) *“Material that is a medical device or a biological product, or is used for the containment, protection, delivery, presentation or distribution of a medical device or a biological product, as regulated by the United States Food and Drug Administration under 21 Code of Federal Regulations, Parts 200, 300 and 800”*

Discussion: Many of the medical devices listed are found in hospitals and doctors' offices and are not part of Maine's municipal waste stream so they would not be a part of Maine's EPR program. A large [searchable database of medical devices](#) can be found on the FDA website.¹ Some examples of “medical devices and biological products” that could be found in homes from the search include: bandages, condoms, contact lenses, dental floss, humidifiers, menstrual products, pregnancy tests, thermometers, and toothbrushes. There is no compelling operational or public health reason why the obliged producers of any of those packaged products should be exempted from Maine's EPR for Packaging law.

(3) *“Material that is used for the containment, protection, delivery, presentation or distribution of an over-the-counter human drug product for which tamper-evident packaging is required, as regulated by the United States Food and Drug Administration under 21 Code of Federal Regulations, Section 211.132”*

Discussion: This is redundant to the drug exemption consideration in Section 1 above, since all over-the-counter drugs require tamper-evident packaging. This would essentially exempt most everything in the pharmacy sections of Maine's convenience and grocery stores. Many of these products are excessively packaged, are disruptive to Maine's recycling streams, and often contain outer packaging in addition to the regulated package described above (such as paperboard boxes around tamper-evident bottles). The large producers of these products should

¹ Medical Device Definition: <https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device>

not be allowed to leave the burden of managing this large quantity of materials to Maine's taxpayers or the other obligated producers.

(4) *“Material that is used for the containment, protection, delivery, presentation or distribution of a substance regulated by the United States Consumer Product Safety Commission pursuant to the federal Poison Prevention Packaging Act of 1970 for which special packaging is required under 16 Code of Federal Regulations, Part1700”*

Discussion: We acknowledge the need to provide child-proof packaging designed to protect the health and safety of children especially, but inclusion of these materials in the EPR for Packaging law will not impact that level of safety at all. Exclusion of this extensive list of materials would only work to financially benefit the producers of drugs and toxic chemicals, while leaving the burden of managing the materials on Maine's municipalities and taxpayers. Further, we don't believe that the federal regulations affect the amount or recyclability of the packaging materials; but if they do, then this issue should be addressed through the fee setting rather than a blanket exemption.

Exemptions by major substantive rule should not impact the implementation timeline

Further, we urge the Department to amend the [schedule for implementation of this program](#) to remove reference to major substantive rulemaking for exemptions. We do not support any exemptions by major substantive rule, but, if that happens then the implementation of the EPR for Packaging program can happen concurrently with any major substantive rulemaking activity. Major substantive rulemaking will only determine what packaging producers are exempt from requirements to pay fees to the stewardship organization. The request for proposal for the stewardship organization, and selection and organization of that entity, can be underway at the same time as the submittal of major substantive rules to the Legislature since the exemptions in question do not impact that process.

There will be producers who enter and leave the program over the lifetime of the program for various reasons. And, if major substantive rulemaking adoption changes the fee amounts at any point in time, the stewardship organization could address the situation through debits or credits, as needed.

Thank you for the opportunity to provide comments on this important aspect of Maine's EPR for Packaging program. We look forward to working with the Department and providing comments on the other four topic areas, including: municipal reimbursement; recyclability, auditing, and program performance; education and investment; and payments and reporting.

Sincerely,

Sarah Nichols
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Natural Resources Council of Maine