December 7, 2022

Commissioner Loyzim
Department of Environmental Protection
17 State House Station
Augusta, Maine 04333-0017

RE: Stewardship Program for Packaging Law – Producer Exemptions.

Dear Commissioner Loyzim:

Thank you for the opportunity to provide comments regarding producer exemptions under the recently enacted Extended Producer Responsibility ("EPR") for Packaging Program.[1] These comments are submitted on behalf of Just Zero, a non-profit advocacy organization that works alongside communities, policy makers, scientists, educators, community groups, and others to implement just and equitable solutions to climate-damaging and toxic production, consumption, and waste disposal practices. Just Zero's goal is to help implement community-first zero waste systems with zero climate damaging emissions and zero toxic exposures.

Just Zero is committed to ensuring the success of Maine's first-in-the-nation EPR for Packaging Program. Therefore, Just Zero urges the Department of Environmental Protection (the "Department") to minimize exemptions. This includes both exemptions for individual producers, as well as exemptions for specific types of covered packaging. In general, Just Zero believes that all packaging that is currently collected by municipalities should be regulated under the EPR for Packaging Program.

Any exempted producers would still be selling packaging materials into the State of Maine. However, rather than being a part of the comprehensive EPR for Packaging Program, these producers would not be paying for the cost of managing the waste they create. Instead, the burden would fall on either participating producers or residents.

The same is true for exempt products and packaging materials. These materials will still be part of the municipal waste stream but will not be subject to fees. This is inequitable, and against the purpose of the EPR for Packaging Program. To the extent any special treatment is required to accommodate packaging that is subject to federal law and regulation, that should be addressed on a case-by-case basis through the fee provisions, rather than given an overarching exemption from the requirements of the program.

[1] 38 M.R.S. § 2146.

These comments focus on two important points relevant to the Department's rulemaking:

- First, nothing in the Federal Food, Drug, and Cosmetic Act ("FDCA") or the Poison Prevention Packaging Act of 1970 ("PPPA") preempts Maine from including packaging regulated under these federal laws from being included in Maine's EPR for Packaging Program; and,

- Second, the legislature did not intend to wholly exempt producers from all requirements of the law if just a portion of their business is selling perishable food using less than 15 tons of packaging material. Rather, the legislature intended only to exempt small farmers who exclusively sell perishable food using less than 15 tons of packaging material. Therefore, the Department should promulgate regulations that clarify this point, and are consistent with the legislature's intent.

I. Federal Law Does Not Preempt Maine from Regulating Packaging Under the EPR for Packaging Program.

As part of the rulemaking process, the Department must review packaging material that is subject to specific federal regulations to determine whether these materials should be excluded from the EPR for Packaging Program. Specifically, the Department must evaluate the following federal laws and regulations:

- Section 321 of the Federal Food, Drug, and Cosmetic Act and it's implementing regulations (21 C.F.R. §200, §300, and §800); and,
- The Poison Prevention and Packaging Act of 1970.

While these federal laws and regulations do impose specific requirements regarding how certain products are packaged and labeled, none of the requirements directly impact Maine's ability to include these products in the EPR for Packaging Program. Nothing preempts these products from state level regulation aimed at reducing packaging waste and increasing the recyclability of packaging. Therefore, packaging material subject to these federal laws and regulations should still be included in the program.

A. Overview of the Doctrine of Preemption

The Supremacy Clause of the United State's Constitution provides that federal law is "the supreme law of the land" notwithstanding any state law to the contrary.[2] This language has provided the foundation for the doctrine of federal preemption, through which federal law supersedes, and in some cases may invalidate, conflicting state laws. The Supreme Court has identified two general forms of preemption. The first, is express preemption – where a federal statute or regulation contains explicit language preempting state regulation.[3] The second, is

[2] U.S. CONST. art. VI, cl. 2.
[3] Gade v. Nat'l Solid Wastes Mgmt. Assn., 505 U.S. 88, 98 (1992).

implied preemption – where the structure and purpose of a federal law or regulation is viewed to have shown Congress's intent to bar state level regulation.[4]

Moreover, the Supreme Court has also further distinguished implied preemption by dividing it into two subcategories: field preemption and conflict preemption. Field preemption results when a federal law or regulation is intended to occupy the entire regulatory field in a manner that precludes supplementary state regulation.[5] Conflict preemption occurs either when compliance with both federal and state regulation is physically impossible, or where the state regulation creates an obstacle which prohibits compliance with the purposes of objectives of the federal regulation.[6]

When attempting to discern whether a federal regulation preempts state regulation, the Supreme Court has repeatedly held that Congress's intent when enacting the federal regulation is the "ultimate touchstone."[7] Congress's intent is generally understood primarily from the language of the statute. However, the Court will also consider the importance of the regulatory structure and the role the federal regulation is intended to play.[8] Moreover, the Court is generally reluctant to hold that federal law preempts state law unless it can find that preemption was "the clear and manifest purpose of Congress."[9]

B. Federal Packaging Regulations Do Not Expressly Preempt State Producer Responsibility Requirements

None of the federal regulations the Department is required to review during this rulemaking process expressly preempt state packaging regulation as it relates to increasing the recyclability or reducing the volume of packaging materials. While both the FDCA and the PPPA have express preemption components, neither of those laws expressly preempt states from regulating the recyclability and environmental impacts associated with product packaging.

FDCA – Including Implementing Regulations Under 21 C.F.R. § 200, § 300, and § 800.
While the FDCA does contain several express preemption provisions regarding food, medical devices, non-prescription drugs, and cosmetics, these provisions only apply to labeling and safety requirements, none of which impact the ability for the state to regulate these products under the EPR for Packaging Program.

For instance, the FDCA expressly prohibits states from imposing conflicting labeling requirements for food products.[10] These labeling requirements focus on ensuring that the packaging: (1) conveys the name of the product and the manufacturer that produced it; (2) does

[4] *Id.*
[5] *Id.*
[6] Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963).
[7] Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963)).
[8] Medtronic, Inc. v. Lohr, 518 U.S. 470, 486 (1996).
[9] See, e.g., De Buono v. NYSA-ILA Med. and Clinical Servs. Fund, 520 U.S. 806, 814 (1997).
[10] 21 U.S.C. § 343-1.

not include false or misleading information; (2) is made, formed, or filled in a manner as to not be misleading to consumers; and, (4) accurately expresses the quantity and weight of the products contained in the packaging.[11] None of these labeling requirements would prohibit a producer from compliance with the requirements of the EPR for Packaging Law or participation in the EPR for Packaging Program.

In terms of medical devices, the FDCA expressly preempts state regulations that address the safety or effectiveness of a medical device.[12] Importantly, most of these medical devices are disposed of in hospitals and doctors' offices and are not part of Maine's municipal waste stream and therefore would not be part of the EPR for Packaging Program. Moreover, the federal regulation only expressly preempts regulation regarding the medical device, not its packaging.[13] Thus, packaging material for medical devices regulated under the FDCA should not be exempt from the EPR for Packaging Program.

The FDCA also expressly preempts state-level regulation related to the sale and distribution of prescription drugs.[14] Specifically, the law preempts state regulations that control who can prescribe and distribute prescription drugs.[15] Additionally, the FDCA also requires all prescription drugs to comply with the requirements of the Fair Packaging and Labeling Act, which requires product labels to specify the identity of the product, the name of the producer, and the weight and quantity of the product.[16] These federal requirements do not impact Maine's ability to regulate prescription drug packaging in terms of packaging reduction or recyclability. Moreover, the FDCA contains language that exempts state-level regulations from being preempted so long as the state regulation exempts state regulation would not clause the drug to be in violation of any requirement or prohibition under federal law.[17] Therefore, packaging material for prescription drugs regulated under the FDCA should not be exempted from the EPR for Packaging Program.

Finally, the preemption provisions of the FDCA regarding cosmetics also only apply to the labeling requirements.[18] Additionally, the FDCA allows for state level-regulation that conflicts with the federal labeling requirements if the state can establish that the state-level regulation is necessary to (1) protect and important public interest that would otherwise be unprotected; (2) would not cause a cosmetic to be in violation of any applicable requirement under federal law; and, (3) would not unduly burden interstate commerce.[19] Therefore, Maine is not expressly preempted from including cosmetics regulated under the FDCA in the EPR for Packaging Program.

[11] 21 U.S.C. § 343.
[12] 21 U.S.C. § 360k.
[13] *Id.*
[14] 21 U.S.C. § 379-R.
[15] 21 U.S.C. § 353.
[16] See, 15 U.S.C. 1451 et seq.
[17] 21 U.S.C. § 379R(b)(1)(B).
[18] 21 U.S.C. § 379S.
[19] 21 U.S.C. § 379S(b).

Poison Prevention Packaging Act of 1970 ("PPPA").

The PPPA authorizes the Consumer Product Safety Commission to impose special packaging and labeling requirements for certain household substances that may pose a threat to children. Specifically, they can require these household substances to be contained in special packaging.[20] Special packaging is defined as packaging that is designed or constructed to be significantly difficult for children under the age of five to open, while still being relatively easy for most adults to open and properly use.[21] Additionally, the PPPA imposes special labeling and marketing requirements for products contained in special packaging.[22]

The PPPA does have express preemption language which prohibits states from establishing regulations which conflict with the requirements of the federal law.[23] However, the PPPA does allow for state level regulation if it would not cause a regulated household substance to be in violation of the special packaging and labeling requirements prescribed by the federal law.[24]

It is unlikely that a producer would be unable to either increase the recyclability or reduce the volume of special packaging while still complying with the requirements of the PPPA. For instance, reducing unnecessary and superfluous packaging or rightsizing the packaging is unlikely to impact the protections in place to restrict children from opening the packaging. Similarly, producers should be able to maintain compliance with the PPPA while switching to packaging from unrecyclable materials to materials that are readily recyclable in Maine.

To the extent that a producer believes that it cannot either increase the recyclability or reduce the volume of special packaging while still complying with the requirements of the PPPA, that producer should be responsible for applying for an exemption for that type of special packaging. Providing a blanket exemption through rulemaking will only result in the exclusion of special packaging that should be included in the EPR for Packaging Program.

C. Federal Laws and Regulations Do Not Implicitly Preempt State Producer Responsibility Requirements

Additionally, neither the FDCA nor the PPPA implicitly preempt state producer responsibility for packaging requirements. These laws primarily focus on providing consumer productions from misleading labeling, false product information, unlawful distribution, and in the case of the PPPA, packaging of hazardous household substances that are not properly packaged to limit depackaging by small children. They are not intended to occupy or conflict with regulations regarding waste management and recycling. Therefore, Maine is not preempted from including products covered by these federal regulations in the EPR for Packaging Program.

[20] 15 U.S.C.A. § 1473.
[21] 15 U.S.C.A. § 1471(4).
[22] 15 U.S.C.A. § 1473.
[23] 15 U.S.C.A. § 1476(a).
[24] *Id.*

FDCA – Including Implementing Regulations Under 21 C.F.R. Part 200, Part 300, and Part 800.
The Supreme Court has held that "Congress enacted the FDCA to bolster consumer protection against harmful products."[25] More specifically, the Court has held that, when viewing the FDCA "as a whole, it is evidence that one of the Act's core objectives is to ensure that any product regulated by the [Food and Drug Administration] is 'safe' and 'effective.'"[26] Lower courts have further articulated that the purpose of the FDCA is to "protect consumers from fraud and misrepresentation in the sale of food, drugs, and cosmetics."[27] This is unsurprising given that the law created the United States Food and Drug Administration and charged the newly created agency with ensuring that:

- Food is safe, sanitary, and properly labeled;
- Human and veterinary drugs are safe and effective;
- There are reasonable assurances as to the safety and effectiveness of medical devices; and,
- Cosmetics are safe and properly labeled.[28]

Therefore, it is clear that Congress's intention when passing the FDCA was to establish a regulatory program focused on ensuring the food, drugs, and cosmetics are safe for consumers. The law has no bearing on state authority to pass laws or regulations related to improving municipal recycling by requiring producers who sell, offer for sale, or distribute for sale products in packaging, to pay fees to cover the cost of managing the waste associated with their packaging. Moreover, it does not impact the authority of any state to require these producers to redesign their products in a manner that makes them less wasteful and more recyclable.

PPPA of 1970
Congress passed the PPPA in 1970 to supplement the Federal Hazardous Substance Act.[29] The PPPA was designed to provide consumers with an additional layer of protection from the hazards associated with household substances.[30] Specifically, by providing additional protection for children. In fact, the congressional history regarding the introduction of the act shows the legislation aims to ensure "adequate protection of children from accidental poisoning."[31] The courts have repeatedly held when interpreting the intent of the PPPA, and its preemption provisions, that the PPPA was passed to create uniform national labeling and packaging requirements for hazardous substances.[32]

Like the FDCA, when enacting the PPPA Congress did not intent to preempt the entire field of regulation. Instead, given the congressional history surrounding the passage of the PPPA,

[25] Wyeth v. Levine, 129 S.Ct. 1187, 1199, (U.S., 2009)
[26] Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 120 S.Ct. 1291, 1301, (U.S., 2000)
[27] See, Booker v. E.T. Browne Drug Co., Inc., 2021 WL 4340489, at *4 (S.D.N.Y., 2021),
[28] 21 U.S.C.A. § 393(b).
[29] Miles v. S.C. Johnson & Son, Inc., 2002 WL 31655188, at *5 (N.D.Ill.,2002).
[30] *Id.*
[31] *See,* H.R. REP. 91-1642 (1970).
[32] Miles v. S.C. Johnson & Son, Inc., 2002 WL 31655188, at *5 (N.D.Ill.,2002)

including the explicit preemption clause, it is clear that Congress was primarily focused on ensuring that special packaging is labeled and produced in a way that ensures protection against child poisoning. States still have the authority to regulate special packaging as it relates to environmental standards, including reducing the volume of packaging materials and increasing the recyclability of packaging, so long as the producers can continue to comply with the requirements of the federal law. Therefore, the Department should not impose a blanket exemption for all special packaging regulated under the PPPA.

Just Zero acknowledges that there may be instances where the requirements from special packaging under the PPPA limit the ability of the producer to significantly redesign the packaging in a manner that reduces the amount of packaging material or increases recyclability. These instances should be handled on a case-by-case basis. Specifically, if they arise, these instances can easily be considered as part of the fee-setting provisions of the program. The fees could be reduced given the limited ability of the producer to make significant changes to the packaging that would otherwise help reduce overall contributions to the program. Moreover, the burden should fall on the producer of the special packaging to make a compelling case for why the product cannot be designed more sustainability in light of the requirements of the PPPA.

This case-by-case basis approach is significantly more beneficial than allowing for complete exemption of the packaging. Through this approach, the producer would still have to report the amount and type of packaging sold, offered for sale, or distributed for sale, into the state, and would still be able to comply with other provision of the law like reducing toxicity in packaging.

II. The Department Should Not Provide a Blanket Exemption for Producers Who Sell "Perishable Food" Using 15 Tons of Packaging or Less.

Just Zero urges the Department to further clarify the purpose of the perishable foods exemption through rule to better align with the legislature's intent. As written, the perishable foods exemption could be interpreted as exempting any producer who sells perishable foods using less than 15 tons of packaging from all requirements of the law.[33]

For example, Amazon is expected to be one of the largest producers regulated under the EPR for Packaging Program. Amazon's packaging is used for a wide array of consumer products such as cosmetics, electronics, clothing, toys, books, pet supplies, and much more. Should Amazon also begin selling perishable food items using less than 15 tons of packaging in Maine, then it is possible the company's entire packaging portfolio would be completely exempted from regulation under the EPR for Packaging Program. This was not the legislature's intent. This exemption was a targeted political decision designed to give special consideration to small farmers that exclusively sell perishable food items. Just Zero urges the Department to promulgate regulations that clarify the purpose of this exemption.

[33] 38 M.R.S. § 2146(2)(D)

A. The Department Has The Authority To Clarify the Exemption Through Rulemaking

The Department has ample authority to promulgate regulations that clarify the legislature's intent regarding the perishable food exemption. When interpreting statutes in Maine, the primary rule is to determine and give effect to the intent of the legislature. To do this, the first step is for the agency to consider the plain meaning of the statutory language. If the meaning of the language is clear and unambiguous, the statute must be interpreted to mean exactly what it says.[34] If the plain meaning of the statutory language is ambiguous, the agency shall look beyond the plain meaning of the statute and examine other indicators of legislative intent, such as legislative history.[35] A statute is ambiguous if it is reasonably susceptible to different interpretations or could be interpreted in a way that renders the statute unenforceable or unworkable."[36] Importantly, the overall statutory purpose from which the specific language arises must be interpreted to achieve a "harmonious outcome."[37] Therefore, statutory language should not be interpreted to produce absurd, illogical, or inconsistent results.[38]

The plain language of the perishable food exemption is ambiguous. Interpreting the perishable food exemption to mean exactly what it says would result in enforcement that would significantly undermine the entire statutory purpose. The legislature enacted the first EPR for Packaging Program in the country to help address the economic and environmental impacts associated with the production, management, and disposal of packaging waste. The program was created to ensure that large corporations, which previously had no responsibility for the packaging waste associated with their products, took responsibility for dealing with this diverse and complicated waste stream. The program requires these companies to pay fees based on the amount of packaging material used to contain, protect, and deliver their products throughout the state. Allowing all producers who sell a small amount of perishable food to be completely exempt from all requirements of the law would significantly undermine the law's overarching purpose.

Moreover, the legislative history establishes that the perishable food exemption was not intended to provide complete exemption for the requirements of the law to producers who, among other products, also sell a small amount of perishable foods. When first introduced, the bill that would become the EPR for Packaging Law already had significant exemptions to protect small businesses, which remained in place. These exemptions include:

(1) 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;

[34] Coker v. City of Lewiston, 710 A.2d 909, 910 (ME. 1998)
[35] *Id.*
[36] Estate of Joyce v. Commercial Welding Co. 62, 55 A.3d 411 (ME. 2012).
[37] Coker v. City of Lewiston, 710 A.2d 909, 910 (ME. 1998)
[38] Temm v. S.D. Warren Co., 887 A.2d 39, 41 (ME. 2005).

(2) Small producers who sold or otherwise distributed less than one ton of packaging to consumers in Maine;
(3) 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; and,
(4) Any producer that is a non-profit organization.

The perishable food exemption was not included in the initial language of the bill. It was added at the end of the legislative session as a political compromise amid concerns about the impact the bill may have on small Maine farms. Given the array of other exemptions designed to protect small businesses and unique interests, as well as the history behind the amendment, it is clear that the legislature did not intend for the perishable food exemption to be applied so broadly.

Therefore, when promulgating the regulations to administer the perishable food exemption, the Department should ensure that the rules specify that only producers that *exclusively* sell perishable foods using less than 15 tons of packaging materials are exempt from the requirements of the law. This would clarify that large businesses that happen to sell perishable foods using less than 15 tons of packaging material along with other packaged goods do not qualify for the exemption and must report and pay for all their packaging.

III. Conclusion

Thank you for the opportunity to provide comments on this critical aspect of Maine's EPR for Packaging Program. Determining who is included and exempted from regulation is an important component of determining the scope and impact of the program. Just Zero looks forward to working with the Department and providing comments on the other substantive areas of rulemaking.

Respectfully submitted,

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State Policy Director
Just Zero