



american cleaning institute®

May 20, 2024

Maine Department of Environmental Protection
Packaging EPR Implementation Team,

Topic: Exemption Request - Federally-Regulated Packaging Material.

ACI appreciates the opportunity to provide a packaging material exemption request for packaging regulated by the packaging stewardship program. The American Cleaning Institute (ACI) – the association for detergent and cleaning product manufacturers – has a vested interest in ensuring packaging such as that which is encompassed by this law does not become waste. That is why we have a goal to eliminate all cleaning product packaging waste by 2040 and are already making great strides in creating more recyclable packaging, reducing our packaging usage, incorporating more recycled content into the packaging we do introduce to market, and transitioning to reusable and refillable applications.

Our comments focus on topical antiseptics used in community and healthcare settings, and soaps in healthcare settings. These products are regulated by the U.S. Food and Drug Administration (FDA) as Over-the-Counter (OTC) non-prescription drugs. The FDA and Center for Disease Control and Prevention (CDC) have both shared guidance that advise not refilling these packages to protect product integrity and human health.

The new extended producer responsibility (EPR) program for packaging correctly directs the Department of Environmental Protection to review packaging covered by federal law that should be excluded from the definition of packaging material. One of the criteria for such an exemption includes regulation that causes a “significantly diminished ability to reduce volume...this includes transitions to reusable and refillable packaging material.” Dispensers are commonly used to dispense product in high-traffic areas. These dispensers hold packaged product that can be recycled when emptied but are not designed to be refilled or “topped-off.” We therefore request exemption from the provisions of this law through the authority granted to the Department for antiseptics used in community and healthcare settings, and soaps in healthcare settings.

Some health and safety concerns that need to be recognized that hinder the ability to transition to reuse and refill applications include:

- Lot codes and expiration dates may not accurately reflect the product inside the package;
- Product stability and efficacy may be impacted if products are mixed;
- Labeling and product information on the packaging may not be representative of what has been refilled; and
- Product integrity may be impacted by repeated packaging use.

Specifically, the FDA and CDC state the following.

U.S. Food & Drug Administration: [Q&A for Consumers | Hand Sanitizers and COVID-19](#)

Q. Should empty or partially empty containers of hand sanitizer (e.g., pump bottles, wall-mounted dispensers) be refilled or “topped off”?

A. FDA does not recommend refilling empty or partially empty containers of hand sanitizer. The safety of refilling or “topping off” used containers of hand sanitizer has not been well-studied. Potential safety risks that may be associated with refilling or “topping off” containers of hand sanitizer include accidental contamination, mixing of different hand sanitizer products leading to irritant effects, reduced potency from the evaporation of alcohol, and loss of stability. In addition, accurate product labeling, including the drug facts label, should always be readily viewable at the time of use.

Centers for Disease Control and Prevention: [Clinical Safety: Hand Hygiene for Healthcare Workers](#)

[Alcohol-Based Hand Sanitizer] (ABHS) is an FDA-regulated over-the-counter product that should be stored and dispensed in an effective and safe manner.

The safety of refilling or "topping off" containers of ABHS such as pump bottles, pocket-sized dispenser bottles and single-use wall-mounted dispensers of ABHS is not well studied. Safety risks associated with refilling or "topping off" containers of ABHS include:

- Accidental contamination.
- Reduced effectiveness from alcohol evaporation.
- Irritant effects from mixing formulations.

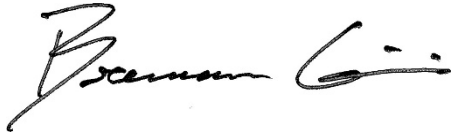
Therefore, refilling or "topping off" ABHS dispensers should only be considered in accordance with manufacturer's guidance and FDA regulations.

Refilling or "topping off" containers of liquid soap has been associated with outbreaks of pathogenic bacteria. Soap should not be added to partially empty soap dispensers. ([Guideline for Hand Hygiene in Healthcare Settings](#))

We believe these to be valid concerns that the Department should recognize to qualify this OTC drug packaging category as exempted. Other consumer goods products may share similar health and safety complications when attempting to incorporate reuse/refill systems.

We would like to reiterate that ACI members support efforts to reduce packaging waste. We hope the Department will contemplate ACI input on this law and related issues during this rulemaking process. ACI looks forward to providing necessary input regarding the performance of our products and packaging to achieve desired policy goals.

Sincerely,

A handwritten signature in black ink, appearing to read "Brennan Georgianni". The signature is fluid and cursive, with the first name "Brennan" being larger and more prominent than the last name "Georgianni".

Brennan Georgianni
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