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Refillable Personal-Care Packaging: Experts Discuss Contamination Risks, Liability, MoCRA Compliance

by Eileen Francis

Personal-care companies navigating a growing patchwork of state recycling laws are exploring refillable packaging options, but there are serious concerns and questions to consider before embarking down this potentially risky path, experts said at IBA's Supply Chain & Sustainability Conference.

Refillable/reusable personal-care product packaging is of growing interest to consumers as well as US brands working to comply with a rising number of state recycling laws; however, limitations in current manufacturing practices and complex regulatory considerations make refillable personal-care models challenging and fraught with potential risks, experts say.

In a panel titled "Reuse & Refill: Progress and Pitfalls for Indie Beauty" at the Independent Beauty Association's Supply Chain & Sustainability Conference on 1-2 November, participants noted that cosmetics companies face a growing number of extended producer responsibility (EPR) and other laws to address plastic pollution in states and municipalities around the US.

Akemi Ooka, IBA's head of global supply chain resources, pointed specifically to California's source reduction requirements for single-use packaging – which does not include reusable packaging – under the Plastics Pollution Prevention and Packaging Producer Responsibility Act, <u>SB 54</u>, signed into law in July 2022. (Also see "<u>US State Laws To Address Packaging Waste Are Cosmetics Industry's Newest Patchwork Problem</u>" - HBW Insight, 29 Nov, 2023.)

"While it sounds like it might be straightforward to do reuse and refill, it's actually very complex, and it's a particularly tricky area for the beauty industry," Ooka said.

For refillable packaging to be an advisable approach for most beauty and personal-care brands

and manufacturers, Richie Rubin, executive VP of Garcoa Laboratories, Inc., suggested "there needs to be some serious innovation in the form of industrial hygiene specific to reusing these products."

Refillable design approaches allow the consumer to reuse a container multiple times rather than dispose of it after a single use. Examples include replacement cartridges that can be popped in place of an empty cartridge within the product; refill packets purchased in stores that can be poured into the original bottle; and "on-the-go" models wherein consumers take empty containers to stores to refill them at an on-site machine or drop off their original packaging and pick up a pre-filled package that has undergone cleaning.

Calabasas, Calif.-based Garcoa provides controlled label, private label and contract manufacturing for companies in the cosmetics, over-the-counter health, and household cleaning product sectors. The family/women-owned company bills itself as a full-service creative agency in addition to a leader in custom package development (including reusable), quality assurance and regulatory.

Garcoa says it is "focused on evolving past landfill-bound packaging in favor of materials with a net neutral or positive impact on the Earth. We love partnering with brands and organizations that drive environmental projects," the company's website says.

According to Rubin, Garcoa has "very robust" internal policies for cleaning equipment "with a certain type of sanitizer that kills any microbe, and we also perform biofilm removals to remove any micro risk from the environment," he said.

Further, "We've invested millions of dollars into [reverse osmosis deionization] water systems at each one of our facilities because ultimately they will drive the business," he said, noting that often in US Food and Drug Administration facility inspections, product contamination is a result of the water source.

Finally, Rubin said Garcoa tests every formula it manufactures using United States Pharmacopeia methods – USP <61> and USP <62> – to ensure against microbial contamination.

In his view, most personal-care brands that manufacture do not have the infrastructure and training necessary to clean used packaging in a way that avoids contamination.

"Would a refill station at a retailer count as a manufacturing or



filling site under MoCRA? Would they be required to implement GMP protocols to ensure safety, quality and sanitation?"

There is also the issue of what happens in a consumer's home or the retail environment.

Consumers purchasing product refills to pour into empty containers do not have the ability to ensure against, or test for, contamination at home. Compared with the contamination prevention measures taken at facilities like Garcoa's, "people in the general public just aren't doing this; now talk about doing this at scale with refill containers. It's going to present a real challenge in terms of really trying to create that circular economy," Rubin said.

Simone Swafford, CEO and founder of boutique regulatory agency Vogue Regulatory, also worries about product refills in retail settings where employees may not have sufficient training, and "that can cause a product to become adulterated really, really quickly," she said.

For now, Rubin recommends against pursuing reusable packaging for products applied to the body, with some exceptions such as hand soap. For light household cleaning products, refillable packaging could be a viable option, he said.

Even so, companies should ensure that any reusable packaging model is truly a sustainable solution and not just a gimmick.

"Something that doesn't get talked up a lot is just the waste that goes into making some of these refill units," he said. "There's a lot of secondary and tertiary packaging associated with these products, a lot of utilized components and packages that are from various part so the world. So there's a lot of waste in terms of bringing those products to the United States, or at least to us in order to refill them. It's just important to think about the entire supply chain."

He further noted that brands do not always do a great job of communicating to consumers how many times they need to refill a primary package to reduce the carbon footprint. "Look, the reality is in the US we're very bad at recycling."

Regulatory Perils

Further complicating matters for companies interested in reusable packaging is today's complex regulatory environment. Swafford said "a confluence of factors" in state and federal regulations may hamper personal-care companies' ability to pursue refillable or reusable packaging.

First, she noted many commonly used preservatives are "on the chopping block" under state legislation proposed or enacted, such as Washington State's <u>HB 1047</u>, signed into law in May, which prohibits the manufacture, sale or distribution of cosmetic products containing formaldehyde donors beginning 1 January 2026. (Also see "<u>Cosmetics Industry's Preservatives Crisis Grows More Dire Under New Washington State Law</u>" - HBW Insight, 25 May, 2023.)

The depletion of industry's preservative palette makes reusable packaging all the hairier, she said.



SIMONE SWAFFORD, VOGUE REGULATORY

that the small size of many refill units could present issues for labeling required by the Modernization of Cosmetics Regulation Act (MoCRA), including the contact information for a responsible person and the identification of fragrance allergens. (Also see "Compliance Clock Starts Ticking Under Historic Modernization of Cosmetic Regulations Act" - HBW Insight, 3 Jan, 2023.)

"Is the information on cartridge contents visible and accessible in case of an adverse event? Are lot numbers readily accessible to consumers so that they can

Brands may well decide that the "safest way" to protect their formulas is through the use of sealed cartridges or pouches. "That makes the most sense, but from a logistical standpoint, it really is counter to the spirit or counterproductive" to these state pollution prevention laws, she said. "Because if you're now introducing a new cartridge, it's a new product, right? Are you going to put that product by itself on the shelf, or is it now going to come in a secondary carton?"

Further, Swafford noted that labeling must be considered for both primary and secondary packages.

Ooka expanded on that point in a 4 December email to *HBW Insight*. She said marketers must keep in mind

'Refillable' Claims Dicey As Well

"Refillable" claims, similar to "recyclable" claims, are litigation targets and should only be made if the product has a refill system in place, says Rachel Gartner, counsel in the New York office of McDermott Will & Emery.

"The complexities around a refill reusable program are significant," said Gartner at the IBA conference.

<u>Cosmetics Companies Need In Their AE</u>
<u>Reporting Systems</u>" - HBW Insight, 3 Oct, 2023.)

She said there could be situations where, due to state-level ingredient bans or other reasons, a company has to reformulate, and original containers with original labeling are being refilled with that new formulation. That could be problematic from a regulatory compliance standpoint.

She added that marketers developing refill programs must also consider good manufacturing practices compliance and how exactly a refiller would be covered by MoCRA. "Would a refill station at a retailer count as a manufacturing or filling site under MoCRA? Would they be required to implement GMP protocols to ensure safety, quality and sanitation?"

Plaintiffs' Bar Is Watching

The responsible person listed on cosmetic product labels is required by MoCRA to report serious adverse events to the FDA within 15 business days. Swafford noted, "If a consumer refills a product in a way that introduces microbial contamination, it's what they did, right? But they call the brand, and now there's an adverse event report. This poses an interesting situation, because the brand didn't cause that, but at the end of the day, it's still their brand, they're part of their responsibility. They're the responsible person, they own it, they can't separate themselves or distance themselves from that."

And who assumes responsibility in the

Companies can promote a product as capable of refill or reuse. But whether there's actually an infrastructure in place to facilitate the refill – that is a separate analysis and does play into the ability to substantiate that claim, said Gartner.

Gartner identified refillable claims in addition to "recyclable" and "clean/non-toxic" claims as "litigation watch-out" statements.

"Unless you're providing the consumer with a comprehensive system that enables the refill or reuse of the product, you should avoid making that claim," she concluded.

Refillable claims are addressed under the Federal Trade Commission's Guides for the Use of Environmental Marketing Claims (16 CFR 260.14), or "Green Guides," last updated in 2012. The FTC collected comments through April 2023 on the need for an update to the guides, and industry now awaits word of next steps. (Also see "FTC Considers Adding 'Organic' and 'Sustainable' Guidance In Environmental Claims Update" - HBW Insight, 15 Dec, 2022.)

The guides state it is "deceptive to misrepresent, directly or by implication, that a package is refillable" and that a marketer "must not make an unqualified refillable claim unless the marketer provides the means for refilling the package. The marketer may either provide a system for the collection and refill of the package or offer for sale a product that consumer can purchase to refill the original

event that product must be recalled?

Swafford suggested that brands consider safety data exchange agreements or similar contracts with retailer partners involved in refilling their containers to define quality responsibilities – ie, "who's responsible for what in the event of A, B, C or D happening."

She added, "I think these are the questions that brands, retailers, and just about every stakeholder that's impacted by this really need to start thinking about. How do we manage risk? And just really start thinking about it from that point and working backwards."

package."

The guides provide an example in which a container is labeled "refillable three times," and the manufacturer has the capability to refill returned containers and show the container will withstand being refilled at least three times. "The manufacturer, however, has established no collection program. The unqualified claim is deceptive because there is no means to return the container to the manufacturer for refill," the guides say.

Swafford raised a final point of concern beyond regulatory compliance that makes the United States dodgier for refillable packaging programs than, say, the United Kingdom.

"We're a highly litigious country," she pointed out. "So if a consumer – whether or not it's their fault or whether it happened at the retail level – gets some sort of adverse event or reaction from a product that gets contaminated, you have a plaintiffs' bar that's actively watching and actively monitoring the beauty industry for anything that they can sue."

In a survey of more than 1,100 consumers conducted by consumer insights platform Suzy, Inc., 44% of respondents said they try to use reusable products and packaging instead of single-use plastic in order to be more sustainable, while 49% of consumers said they prioritize refillable/reusable packaging when they shop.

Environmental advocacy groups are helping to drive demand for refillable packaging. Last year, Greenpeace released a report urging companies to phase out single-use plastic and aim for 50% reusable packaging by 2030.

Canadian start-up bareLUXE Skincare, which markets refillable face oil serums, set out to understand why consumer uptake of refillable products has been relatively limited despite growing global emphasis on sustainability. The firm found in a study published 7 June that close to 80% of 154 survey respondents rated sustainability as important in shopping decisions, though only 23% indicated they currently used refillable skin care products. The most cited reason for not using the products was difficulty finding available options. (Also see "bareLUXE"

<u>Probes Consumer Demand For Sustainable Packaging, Low Uptake Of Refillables</u>" - HBW Insight, 9 Jun, 2023.)