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Cosmetics Industry Awaits FDA's Allergen List While Working To Inform GMP Rulemaking

by Eileen Francis

The Independent Beauty Association does not yet have insight into what ingredients will be listed in the US FDA's proposed rulemaking for cosmetic allergen labeling – due by 29 June – but is optimistic the agency will consult industry when it comes to setting the compliance timeline. Meanwhile, industry stakeholders are pushing for international harmonization in the agency's cosmetic GMPs rulemaking.

It is not yet known what allergens will have to be labeled on cosmetic products under a coming proposed rule from the US Food and Drug Administration, but the Independent Beauty Association is hopeful the agency will accommodate the sell-through of existing products and establish a reasonable timeline for updating labels.

At IBA's 10 April Cosmetic Convergence Symposium, VP of technical-regulatory affairs Meredith Petillo acknowledged members' anxiety, with little insight to date as to what will be contained in the proposed rulemaking for cosmetic allergen labeling, which the Modernization of Cosmetic Regulations Act requires by 29 June.

Once the proposed rule is released and the public comment period ends, a final rulemaking will be due in 180 days. MoCRA, enacted in late 2022, directs the FDA to consider international, state and local requirements for allergen disclosure in its proposal and, ultimately, to set a deadline for labeling compliance.

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"We have a lot of members reaching out to ask about what's on the list. We don't have the list yet [but] we do know that FDA is obviously very aware of the original EU list and the extended allergen list that the industry currently is working to implement," said Petillo, referring to California's Cosmetic Fragrance and Flavor Ingredient Right to Know Act (CFFIRKA).

Under CFFIRKA, companies are required to report to the state department of health their use of fragrance and flavor ingredients that appear on nearly two-dozen chemical lists from authoritative bodies in the state, the US and Europe. One of those lists includes Annex III (restricted substances) of the EU's Cosmetic products Regulation, which initially contained 25 fragrance allergens that must be labeled on product packaging. In July 2023, the EU Commission amended the CPR to include an additional 56 fragrance allergens subject to required labeling, including menthol, vanillin and terpinolene. (Also see "*EU To Expand Fragrance Allergen Labeling With Implications For California's 'Right To Know'*" - HBW Insight, 7 Oct, 2022.)

The CFFIRKA was enacted in 2020, and manufacturers of cosmetic products sold in California were required to begin reporting use of fragrance and flavor ingredients in early 2022. (Also see "*California's Fragrance 'Right To Know' Act Kicks In With Important Questions Unresolved*" - HBW Insight, 20 Jan, 2022.)

'Reasonable Accommodations' Likely

Addressing prospects for a transition period for the sale of old-label products before rolling out new labels, Petillo noted, "We have not been hearing much of anything about market withdrawal of products. So I don't know that would be their intention." She expects "some reasonable accommodations" for moving products with old labels off shelf.

IBA President and CEO Don Frey said he thinks FDA will be reasonable in setting the deadline for new labeling compliance given its history of consulting industry on deadlines. "They do reach out and ask kind of what are realistic timelines, especially when labeling is involved. They know it takes some time to do those things," Frey said.

"We will continue to work with FDA and make sure that we try to guarantee adequate time for implementation," he said. "Because it's not something you can prep for now, not until you know that list of allergens."

Frey pointed out that IBA and the Personal Care Products Council (PCPC), following the lead of the Fragrance Creators Association (FCA), were able to persuade the California Department of Public Health to delay the compliance deadline for reporting requirements under CFFIRKA.

Initially, California provided a six-month grace period for reporting after the effective date of a list revision adding a new ingredient. California recently announced its timing is now aligned with the European Commission's compliance framework for new fragrance allergen labeling requirements, which provides three years (by 31 July 2026) for new labels to be applied, while non-compliant products have five years (by 31 July 2028) before they need to be pulled from the market.

"We're not always able to affect timing or regulations, but when there are concerted efforts and we have some facts to bring to bear, we can frequently influence these things," Frey said, giving most of the credit of persuading the department to FCA. "That was a great win for the industry."

Internationally Harmonized GMPs Sought

IBA is also in discussions with FDA about its efforts toward a proposed rule for good manufacturing practices (GMPs) for cosmetic facilities that the agency is required to issue by 29 December 2024. A final rule is due a year later.

Currently, the FDA only provides draft guidance to cosmetic companies on GMPs. Not legally enforceable, the guidance incorporates elements of *ISO 22716:2007* and addresses facility and equipment requirements, personnel hygiene and training, raw material sourcing and control, and quality control procedures, among other aspects.

FDA is in the process of analyzing that ISO standard along with other proposals that have been submitted, Petillo said, adding that nothing is yet publicly available.

"The industry standards that were currently in place before the implementation of MoCRA are great places to start exploring gap analysis and areas where businesses may need to be focusing in anticipation of seeing the proposed rule later this year," she said.

Frey says IBA is encouraging FDA to develop GMPs that will align with those of global partners. "One of the things we feel is most important is that whatever the FDA comes up with, that it works well with the guidelines that are used around the world," particularly within the EU, "so that people can continue to be able to make one batch of product and split the batch to be able to be used both domestically as well as internationally and have the same kind of paperwork."

He added, "Hopefully we will get to a place that doesn't require a separate set of books, if you will, for US domestic products versus international products."

In June 2023, the FDA held a virtual “listening session,” where it solicited input from stakeholders on GMPs. While many stakeholders favored the ISO standard, others pushed the US national standard *NSF/ANSI 455-3*. Attendees also encouraged FDA to only take regulatory action for GMP violations when they are safety-related and not when they are minor, technical violations. (Also see "*MoCRA Check-In: Postscript To My Three Minutes At US FDA's Cosmetics GMP ‘Listening Session’*" - HBW Insight, 7 Jun, 2023.)