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How New Laws Could Tighten FDA Regulation Of Cosmetics

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2022 may finally be the year that the effort to modernize safety standards in the U.S. for cosmetics and other personal care products, which has been ongoing since 2013, comes to fruition.

If so, the new cosmetics standards will further focus a spotlight on the safety of perfluoroalkyl or polyfluoroalkyl substances, or PFAS, in cosmetics — and on the safety of other cosmetic ingredients as well.

On Dec. 14, 2021, during a U.S. Senate hearing to consider Robert Califf's nomination to serve as the next commissioner of the U.S. Food and Drug Administration, Sen. Patty Murray, D-Wash., the chair of the Senate Health, Education, Labor, and Pensions Committee, hinted that cosmetics reform may happen in 2022 with the Cures 2.0 Act. This legislation includes the FDA's user fee reauthorization, which must pass by September.

Significantly, cosmetics reform could also come in the form of S. 2100, the Personal Care Products Safety Act, which Sen. Dianne Feinstein, D-Calif., introduced in June 2021. If S. 2100 is enacted, it would direct the FDA to issue a proposed rule to ban the use of intentionally added PFAS in cosmetics within six months of the passage of the act.[1]

S. 2100, if enacted, would also modernize federal oversight of cosmetics by (1) requiring cosmetics companies to register with the FDA, comply with good manufacturing practices and report serious adverse events, among other things, and (2) requiring the FDA to review the safety of five cosmetics ingredients or nonfunctional constituents annually.

At this point, many in the cosmetics industry are very familiar with S. 2100, given that different iterations of the bill have been introduced in the last three Congresses — and they are very familiar with the public health and environmental concerns associated with PFAS, as well.

PFAS have been associated with a number of health-related issues — including kidney cancer — and they have been referred to as "forever chemicals" because they do not break down easily.

In some instances, according to the FDA, PFAS are intentionally added to lotions, cleaners, nail polish, shaving cream, foundation, lipstick, eyeliner, eyeshadow and mascara. But in other instances, PFAS are unintentionally present in cosmetics, as a result of raw material impurities, or due to the breakdown of other ingredients that form PFAS.

PFAS in cosmetics have been in the spotlight before. Last year, California, Maryland and Maine all made headlines by enacting laws aimed at minimizing exposure to PFAS.

California's law specifically bans the manufacture, sale and distribution of cosmetics to which any one of 13 PFAS or their salts have been intentionally added. The California law becomes effective in January 2025.

Maryland's law is similar, and it becomes effective on the same date. Similar bills are pending in other states.

Notably, Maine's law is even more sweeping: It prohibits the sale of and distribution of all products to which PFAS has been intentionally added, subject to limited exceptions; that prohibition becomes effective in January 2030. Maine's law also imposes certain reporting requirements, which take effect in January 2023.

Even more urgently, California has another law, effective as of Jan. 1 of this year, that imposes continuous reporting requirements for fragrances and flavors in cosmetics that are "identified as causing cancer or reproductive toxicity." Roughly 100 PFAS appear on the list of substances that trigger these reporting requirements.

In addition, in the European Union, several PFAS are already prohibited from cosmetics, through Annex III of the Cosmetics Regulation 1223/2009. More generally, certain PFAS are regulated under the EU's Registration, Evaluation, Authorization and Restriction of Chemicals, or REACH, regulation.

And more regulation is likely to come. For example, in the Chemical Strategy for Sustainability, issued in October 2020, the European Commission pledged to ban all uses of all PFAS unless the use is proven essential for society, and that objective seems to be shared by member states.

In August 2021, five EU countries submitted a restriction proposal for all PFAS to the European Chemicals Agency, which, if adopted, could reduce the manufacture, distribution and use of PFAS through REACH by 2025. Moreover, the ongoing revision of the EU Cosmetics Regulation will likely lead to more restrictions — or even a ban — on PFAS in cosmetic products. A related legislative proposal is expected by the end of 2022.

Given the concerns about PFAS, many cosmetics companies long ago publicly committed to eliminating PFAS from their products, and many others are working on reformulation. In addition, many in the industry have been working with the nonprofit Environmental Working Group to support the prohibition of certain PFAS from use in cosmetics.

Nonetheless, as discussed further below, if S. 2100 were enacted, the focus on PFAS, and other potentially concerning ingredients and nonfunctional constituents in cosmetics, is likely to intensify. Below, we provide an overview of S. 2100, and recommend best practices for industry.

S. 2100: The Personal Care Products Act

The FDA began working with industry and public interest groups in 2013 on a proposed legislative framework that would modernize cosmetics oversight. From the beginning, the effort was targeted at requiring companies manufacturing cosmetics to register with the FDA, comply with good manufacturing practices and report serious adverse events.

In addition, the initial framework contemplated providing the FDA with authority to mandate recalls of cosmetics products, and requiring the agency to review the safety of certain cosmetic substances. The negotiations between the FDA and industry, however, stalled due to controversial elements in the framework, including preemption, and the triggers for adverse event reporting.

In 2015, Feinstein introduced the first iteration of the Personal Care Products Safety Act, S. 1014, which contained many of the same provisions contemplated in the FDA's negotiation with industry. Although S. 1014 was never enacted, Feinstein has introduced similar bills in each successive Congress — e.g., S. 1113, on May 11, 2017, during the 115th Congress, and S. 726, on March 7, 2019, during the 116th Congress.

Feinstein introduced the most recent iteration, S. 2100, on June 17, 2021, and that bill is still pending. Notably, according to a press release from Feinstein, the bill has broad support from industry, physician associations and watchdog groups such as the Environmental Working Group.

S. 2100, if enacted, would, among other things:

- Give the FDA new basic regulatory tools to enhance cosmetics oversight;
- Require the agency to review the safety of five ingredients or nonfunctional constituents annually;
- Require the agency to issue a proposed rule, no later than six months after the date the legislation is enacted, that would ban the use of intentionally added PFAS in cosmetics; and
- Contain a limited preemption provision.

Each of these four elements are discussed in more detail below.

Regulatory Tools

S. 2100 would require cosmetics companies — e.g., brand owners that are manufacturers, entities whose names appear on cosmetics labels, and contract manufacturers — to register all of their facilities with the FDA annually, and to pay a registration fee.

Each registration would contain the following information, among other things: (1) an ingredient list for all cosmetics products manufactured or processed in the registered facility; and (2) written assurance that each cosmetic product manufactured or processed in the registered facility has been substantiated for safety or carries a requisite warning.

If enacted, the bill would also require compliance with good manufacturing practices. Currently, in the U.S., compliance with good manufacturing practices is voluntary.

S. 2100 would additionally require adverse event reporting. Specifically, it would mandate adverse event reporting to the FDA for "serious adverse events" not later than 15 days after information concerning the serious adverse event has been received, and for other "adverse events" in an annual report.

A "serious adverse event," as defined in the legislation, is one that results in (1) death, (2) a life-threatening experience, (3) inpatient hospitalization, (4) a persistent or significant disability or incapacity, (5) a congenital anomaly or birth defect, (6) significant disfigurement (e.g., serious and persistent rashes or infections and significant hair loss), or (7) the need for a medical or surgical intervention to prevent one of the aforementioned outcomes, based on appropriate medical judgment.

Finally, S. 2100 would give the FDA mandatory recall authority over cosmetics. Currently, all cosmetics recalls are voluntary, although the FDA can ask cosmetics companies to conduct them.

Annual Ingredient/Nonfunctional Constituent Safety Reviews

S. 2100 would require the FDA to review five cosmetics ingredients or nonfunctional constituents for safety each year. Typically, the agency would select ingredients or constituents from a list determined in consultation with the cosmetics industry and consumer and health groups.

But the FDA could also review any other ingredient or constituent not on that list, on its own initiative. As part of each review, the agency would open a docket to solicit data and public comments.

After reviewing the relevant information — assuming there is adequate evidence to make a safety finding — the FDA would issue a proposed administrative order deeming the ingredient or nonfunctional constituent to be: (1) safe in cosmetic products under specified conditions of use or tolerances, (2) safe in cosmetic products without the need for specified conditions of use or tolerances, or (3) not safe in cosmetic products.

The agency would then open up a docket for public comment on the proposed administrative order, review the comments and issue a final administrative order.

Notably, in the event that there is inadequate evidence upon which the FDA can make a safety determination, the bill would allow it to solicit additional data from interested persons for another 30-day period, and then again, if necessary, for an additional time period not to exceed 18 months.

If there is still insufficient information upon which FDA can make a safety determination, the agency would then issue an order making a determination that the ingredient or nonfunctional constituent has not been shown to be safe in cosmetics.

Ban on PFAS

S. 2100, if enacted, would require the FDA to issue a proposed rule, not later than six months after the legislation is enacted, banning the use of intentionally added PFAS in cosmetics.

Preemption

The preemption provision in S. 2100 is very detailed. Among other things, it provides that:

> No State or political subdivision of a State may establish or continue in effect any requirement for cosmetics other than a requirement that is in full effect and implemented on the date of enactment [of S. 2100 with respect to] registration, good manufacturing practices, mandatory recalls, or adverse event reporting, [or] the safety of a cosmetic ingredient or non-functional constituent that is the subject of a final order [unless the State/local requirement is more restrictive than the final order].

In addition, S. 2100 provides that, if enacted, nothing in the legislation, nor any

> standard, rule, requirement, regulation, adverse event report, safety assessment, safety determination, scientific assessment, or order issued or implemented pursuant to such [Act], shall be construed to modify or otherwise affect, preempt, or displace any cause of action or State or Federal law creating a remedy for civil relief or criminal cause of action, whether statutory or based in common law.

Takeaways and Best Practices

If the past is prologue, and cosmetics reform legislation does not pass this year, the FDA, states, public interest groups and the media are still likely to continue to focus on the safety of PFAS and other substances in cosmetics.

And if S. 2100 or similar legislation is enacted this year, scrutiny regarding the safety of substances in cosmetics, including PFAS, will intensify. The enactment of cosmetics reform legislation, associated rulemaking related to PFAS, and the review of the safety of other cosmetics substances, as well as related regulatory dockets, will inevitably attract more attention.

In this new paradigm, cosmetics companies will want to:

- Carefully monitor federal and state legislation in this space;
- Accurately identify (1) all of their cosmetics products that contain PFAS that are intentionally added, (2) all of their cosmetics products that contain PFAS that are unintentionally present, in case, for example, such products become subject to new federal or state requirements, and (3) all cosmetics products that contain reportable or other potentially controversial substances;
- Ensure that they are aware of state and federal reporting requirements related to PFAS and other potentially controversial cosmetics substances;
- Identify alternatives for any identified PFAS ingredients;
- Consider how manufacturing and waste disposal practices may be affected by the increased scrutiny on cosmetic substances;
- Consider whether provisions related to controversial substances in contracts with contract manufacturers or suppliers could better protect the company; and
- Consider voluntary compliance with good manufacturing practices.

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[1] See also S. 2047 and H.R. 3990, both titled "No PFAS in Cosmetics Act," containing similar provisions.