

# How is the regulation of toxic chemicals in cosmetics emerging in US states?

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Matthew Lawson and Steve Siros from law firm Jenner & Block takes a look at the current legislative map at state and federal level



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According to an alert published in February 2022 by the environmental health organisation Safer States, at least 32 US states have promulgated, or are in the process of promulgating, legislation to regulate "emerging contaminants" in various media.

While much of this legislation has focused on addressing the risks in groundwater, including PFASs and 1,4-dioxane, a secondary and increasingly significant focus has been on the regulation of the same contaminants in cosmetics and personal care products.

Four states – California, Maryland, Maine and New York – have spearheaded efforts through recently enacted legislation. New York's law took effect on 1 January, while laws in California and Maryland are set to take effect in 2025, and in Maine by 2030.

Now that the regulatory floodgates have opened, more states are likely to follow and promulgate regulations that either ban or significantly restrict the use of perand polyfluoroalkyl substances and other emerging contaminants in cosmetics and personal care products. Moreover, as further discussed below, increased federal regulation is likely in the not-too-distant future.

# **Federal regulation**

At the federal level, chemical substances in consumer products are primarily regulated under either TSCA or the Federal Food, Drug, and Cosmetic Act (FD&C Act).

While TSCA broadly regulates any chemical substance that is actively utilised in interstate commerce, chemicals may be exempt from TSCA when they are used in products that are directly regulated by other federal statutes. Such products include cosmetics regulated by the FD&C Act, which are defined as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance".

The definition of cosmetics in the FD&C Act is far-reaching and encompasses many personal care products, such as:

- skin moisturisers;
- perfumes;
- · lipsticks;
- fingernail polishes;
- eye and facial makeup preparations; shampoos;

- permanent waves;
- hair colours;
- toothpastes; and

Therefore, even if the EPA determines – pursuant to its authority under TSCA – that a specific chemical presents an unreasonable risk to public health or the environment under certain use conditions, its subsequent regulation or prohibition of the chemical will not extend to the substance's use in a cosmetic product.

For example, the agency is currently conducting TSCA risk evaluations for several chemicals that have been used in personal care products, including formaldehyde, 1,4-dioxane, diisodecyl phthalate (DIDP), diisononyl phthalate (DINP) and dibutyl phthalate (DBP). However, its scoping documents expressly acknowledge that uses of these chemicals in cosmetic products "fall under the regulatory purview" of the US Food and Drug Administration (FDA) and are therefore excluded from its risk evaluations and any subsequent TSCA regulation.

This is because cosmetic products and their ingredients are primarily regulated under the FD&C Act, which prohibits manufacturers and importers from "introdu[cing] into interstate commerce any ... cosmetic that is adulterated or misbranded".

Pursuant to this authority, the FDA requires that cosmetic products produced for retail distribution list their ingredients – except where they are incidental and present at insignificant levels – on the product's label. In addition, manufacturers and importers are prohibited from introducing into commerce any cosmetic product that contains a "deleterious substance which may render [the product] injurious to users under the conditions of use prescribed in the labelling".

However, organisations such as Safer States claim that these requirements are not stringent enough to ensure the safety of cosmetic products because the FDA generally does not require registration or preapproval of chemicals used in them, and the agency lacks the authority to require specific safety testing or demand a product recall where it believes a potential health hazard exists.

Organisations such as Safer States claim that these requirements are not stringent enough to ensure the safety of cosmetic products because the FDA generally does not require registration or preapproval of chemicals used in them While there have been numerous efforts over the years to update the FD&C Act, the law has remained substantially unchanged since its original enactment more than 80 years ago. Most recently, in June 2021, Senators Dianne Feinstein (D-Calif) and Susan Collins (R-Maine) introduced the Personal Care Products Safety Act, legislation that would overhaul the FDA's regulatory authority over cosmetic products. Under the proposed bill, companies would be required to register their cosmetic products with the FDA and disclose the ingredients prior to placing their products into commerce. In addition, companies would have to inform the FDA of any serious adverse events (such as infections that require medical treatment) resulting from the use of their products. They would have to do this within 15 days of the reported event and submit annual reports to the agency identifying all reported adverse health events (including less serious reactions, such as rashes) on an annual basis.

A second bill, the Toxic-Free Beauty Act of 2021, introduced by Congresswoman Jan Schakowsky (D-IL) in October 2021, proposes an outright ban on 11 chemicals, including mercury, formaldehyde and PFASs, from beauty and personal care products sold in the US. The ban would match current prohibitions in place for similar products sold within the EU.

Both bills are currently in committees in the Senate and House, respectively. Whether either of the newly proposed bills will fare better than previous efforts to modify federal regulation over cosmetic products remains to be seen.

Newly enacted and anticipated future state legislation While the regulation of chemicals in cosmetic and personal care products has traditionally been left to the FDA, a few states have historically enacted legislation targeting substances in personal care products, particularly for personal care products that are marketed at children. Examples include:

- California in 2005, the state enacted the Safe Cosmetics Act, which requires manufacturers to inform the state of any cosmetic product sold within California that contains an ingredient known to the state to cause cancer or birth defects;
- Minnesota in 2013, the state enacted HB 458, which bans the use of formaldehyde in personal care products intended for use by children under the age of eight; and
- Washington in 2008, the state adopted the Children's Safe Product Act, which requires manufacturers of children's products – including personal care products – to report to the state if their product contains a chemical of high concern to children.

In recent years, a growing number of states have expressed interest in directly regulating chemicals in all types of cosmetic and personal care products sold within their jurisdictions. Beginning in 2019, state regulation of these chemicals took a significant step forward as New York signed into law a new bill regulating the presence of 1,4-dioxane in consumer products. This was followed shortly after by similar bills in Maryland, Maine and California (see box for summary).

#### **Bill summary**

New York – on 9 December 2019, Governor Cuomo signed into law New York Senate Bill 4389-B/A.6295-A. This made New York the first and only state to set a maximum contaminant limit of 1,4-dioxane in consumer products. While there are no direct consumer uses of the compound, it may be present in cosmetics and personal care products as a byproduct of the manufacturing process. New York's legislation, which takes effect on 31 December 2022, prohibits the sale of personal care products containing more than 2ppm of 1,4-dioxane and the sale of cosmetic products containing more than 10ppm of 1,4-dioxane;

California – on 30 September 2020, Governor Newsom signed into law the Toxic-Free Cosmetics Act, California Assembly Bill 2762, banning the intentional use of 24 chemicals, including mercury, formaldehyde and certain types of PFASs, from being used in cosmetic products sold in California. The legislation is set to take effect in 2025 and will mark one of the first state laws to prohibit the use of these chemicals in cosmetic products;

Maryland – on 30 May 2021, Maryland's General Assembly passed House Bill 0643 prohibiting the knowing sale or distribution of cosmetic products that contain an enumerated list of banned substances, including several PFAS formulations. The chemicals banned under Maryland's new law are identical to those prohibited in cosmetic products sold in Europe under the EU's cosmetic products Regulation. Maryland's ban of such products is set to take effect in 2025, in conjunction with California's Toxic-Free Cosmetics Act;

Maine – on 15 July 2021, Maine enacted into law HP 1113 – L.D. 1503 – An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution. This banned the unnecessary use of PFASs in all products, including cosmetics. The law takes a phased approach to regulating the substances, instituting a ban on the sale of new products that intentionally contain them, starting 1 January 2030, unless a company can prove they are essential; and

Washington – On 31 March 202, Washington's governor signed into law HB 1694, which allows the state's Department of Ecology (DOE) to name "priority products" from any product category identified in the EPA's 2021 PFAS Chemical Action Plan and to prohibit or limit the use of PFAS in these products where it is feasible to do so. While the statute does not directly set chemical limits for cosmetics, because "personal care products" are identified in the EPA's plan, future regulation of PFASs in cosmetics may be anticipated as a result of the enactment of HB 1694. In addition to this recently enacted legislation, there are at least nine bills currently being considered by various states that would further regulate chemicals in cosmetic and/or personal care products sold within the respective jurisdictions. A brief summary of these bills is provided below:

- California AB 2771, banning the sale in California of cosmetics and other personal care products containing any chemicals within the PFAS family (measured by presence of total organic fluorine) (introduced in February 2022);
- Colorado HB 1345, prohibiting the sale of certain consumer goods, including food packaging, textile furnishing and cosmetics, that contain "intentionally added" PFAS (introduced on 28 March 2022);
- Connecticut SB 404, prohibiting the sale or distribution of consumer products that contain PFASs (currently before the Joint Committee on Public Health);
- Massachusetts HB 2350 prohibiting the sale or distribution of various consumer products, including personal care products, in which PFASs are present at a level greater than 1ppm (currently before the Joint Committee on Public Health);
- Minnesota HF 2906, prohibiting the sale or distribution of consumer products that contain PFASs (introduced in February 2022);
- New Jersey A 189 / S 1843, prohibiting the sale and distribution of nail salon products that contain dibutyl phthalates, toluene, or formaldehyde (currently before the Assembly Consumer Affairs Committee);
- New Jersey A 1720, prohibiting the sale of hand sanitisers and body cleaning products containing triclosan (currently before the Assembly Consumer Affairs Committee);
- New York A 143 / S 3331, creating a list of chemicals of concerns known to exist in personal care products, requiring manufacturers of such products to disclose any chemicals of concerns contained in their products and prohibiting the sale of personal care products containing chemicals of concern after three years (currently before the Environmental Conservation Committee);
- New York S 8291, prohibiting the sale of any cosmetic or personal care products that contain mercury (currently before the Environmental Conservation Committee);
- Rhode Island SB 2449, prohibiting the use of PFASs in a number of consumer and industrial products, including cosmetic products (currently before the Environment and Agriculture Committee and scheduled for further hearing and consideration);
- Vermont H 677 / S 267, prohibiting the sale or distribution of cosmetic products that contain one of 29 banned chemicals, including lead, formaldehyde and 1-4 dioxane (referred to the Committee on Human Services); and

 Washington state – SB 5703/HB 1853, prohibiting the sale or distribution of cosmetic products that contain PFASs, phthalates, formaldehyde and mercury (currently passed in the state senate only).

## Federal preemption of state laws

As more states promulgate legislation to regulate chemicals in cosmetic and personal care products, the regulated community may increasingly seek to argue that those state regulations are preempted by the FD&C Act and/or TSCA.

With respect to cosmetic products regulated by the FDA, the FD&C Act prohibits state or local governments from enacting "any requirement for labelling or packaging of cosmetics that is different from or in addition to, or that is otherwise not identical with" the federal rules. For example, courts have found that state labelling requirements for cosmetics products are preempted by the FD&C Act if they seek to impose consumer warnings or disclosures that are different from, or in addition to, labelling information required by the FDA (see for example Critcher v L'Oreal USA, Inc, No 19-2474 (2d Cir. 2020)).

Each state law regulating these emerging contaminants in cosmetics will need to be carefully evaluated to determine whether it runs afoul of the FD&C Act, in which case the state law may be preempted.

To the extent that the state law limits or bans the use of chemicals in personal care products not regulated by the FDA, a state law might be preempted by TSCA. This broadly prohibits state regulation of chemical substances in situations where EPA has already completed a risk evaluation for the chemical and determined that:

• the chemical does not present an unreasonable risk under any of the examined use conditions; or

- the chemical presents an unreasonable risk under certain use conditions, and the agency promulgates a rule restricting or prohibiting the use of the chemical under the identified condition.
- The EPA's ongoing TSCA risk evaluation may provide preemption arguments with respect to some state regulation of certain emerging contaminants such as 1,4-dioxane.

## No signs of a slowdown

State and federal efforts to regulate the presence of emerging contaminants in cosmetics and personal care products shows no sign of abating. At the same time, litigation relating to the alleged presence of these contaminants in cosmetics is on the rise. Companies would be well served to carefully evaluate their personal care and cosmetic product lines to assess if they contain any of these contaminants, even if these substances are not intentionally added as ingredients.

As acknowledged by the FDA on its website discussing PFASs "may be present in cosmetics unintentionally as a result of product impurities or due to the breakdown of PFAS ingredients that form other types of PFAS".

Similarly, the EPA has acknowledged that 1,4-dioxane may be found as a manufacturing byproduct in various personal care products including deodorants, shampoos and cosmetics. By engaging in this evaluation, companies will be better positioned to maintain compliance with what is becoming an increasing patchwork of state and federal regulation and defend potential product liability claims.

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