United States Government Accountability Office

Report to Congressional Requesters

December 2023

COSMETIC SAFETY

Better Planning Would Enhance FDA Efforts to Implement New Law

GAO-24-105542

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GAO Highlights

Highlights of GAO-24-105542, a report to congressional requesters

Why GAO Did This Study

Cosmetics accounted for approximately $43 billion in revenue in the United States in 2021, according to U.S. Census data, with tens of thousands of cosmetic products and formulations on the market. Consumer groups and some scientists have raised concerns that cosmetics may contain substances that harm human health. In December 2022, a new law—MoCRA—took effect, expanding FDA's authorities to oversee cosmetic safety.

GAO was asked to review FDA oversight of cosmetic safety. This report examines (1) research on the safety of selected substances in cosmetics and (2) FDA actions to implement its new authorities and the extent to which these actions addressed selected leading practices for agency reforms. This report also includes information on state laws and regulations that prohibit or restrict substances in cosmetics.

GAO reviewed scientific literature and FDA documents and interviewed FDA officials. GAO compared FDA actions to implement MoCRA with selected leading practices for agency reforms. GAO uses the term "reforms" to include organizational changes, such as those needed to implement new statutory authorities.

What GAO Recommends

GAO is making seven recommendations to strengthen FDA's efforts to implement its new cosmetic safety oversight responsibilities, including developing implementation and strategic workforce plans. FDA concurred with the recommendations.

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What GAO Found

Research has established that certain substances found in cosmetics are potentially harmful to human health. However, the effects can be difficult to confirm, in part because they may take years to develop. Most of these potentially harmful substances are added by manufacturers to serve a specific function. For example, parabens are chemicals added as preservatives to prevent the growth of microorganisms such as bacteria, but parabens have been linked in some studies to endocrine problems (i.e., hormone imbalances). Other substances may be present unintentionally as impurities, such as asbestos in talc, or as byproducts of manufacturing. Inhalation of asbestos is associated with mesothelioma, a type of cancer that develops on the lining of internal organs.

Examples of Potentially Harmful Substances in Cosmetics

Intentional Ingredient	Impurity
Parabens, preservatives used to prevent the growth of bacteria, are found in cosmetics such as foundation, and have been linked to endocrine problems.	**Asbestos contamination in talc** may be associated with cancer and has been found in makeup products that contain talc, such as blush.

Sources: GAO; Subbotina Anna/stock.adobe.com; Jacob Kearns/stock.adobe.com. | GAO-24-105542

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) significantly expands the regulatory authority of the Food and Drug Administration (FDA). MoCRA requires FDA to take several actions (e.g., issue standards for detecting asbestos in talc) by specific dates through December 2025. FDA has taken important steps to implement MoCRA, such as designating its Chief Scientist to lead FDA's implementation efforts. However, FDA has not fully addressed leading practices that help ensure the success of agency reforms—in this case, the organizational changes necessary to implement the law. For example:

- FDA has not developed an implementation plan for MoCRA. According to FDA's Chief Scientist, the agency is using MoCRA itself as its roadmap for implementation efforts. However, MoCRA generally does not detail interim steps or deadlines, as called for by project management guidance.
- FDA has not developed a strategic workforce plan, as called for by leading practices, to help ensure that the agency has the necessary personnel with the requisite skills and competencies to exercise its new authorities.

According to FDA's Chief Scientist, the agency had not developed such plans because FDA had been focused on meeting near-term MoCRA deadlines. By more fully addressing the leading practices, including planning, FDA can better ensure successful implementation of MoCRA and promote cosmetic safety.

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Abbreviations

DEIA	diversity, equity, inclusion, and accessibility
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
MoCRA	Modernization of Cosmetics Regulation Act of 2022
PFAS	per- and polyfluoroalkyl substances
PFOA	perfluorooctanoic acid
PFOS	perfluorooctane sulfonate

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Congressional Requesters

Cosmetics are widely marketed and used in the United States, but consumer groups and some scientists have raised concerns that substances in cosmetics may harm human health. Census data indicate that in 2021, cosmetics accounted for approximately $43 billion in revenue in the United States.[1] Tens of thousands of cosmetic products and formulations were on the market as of 2022, according to data from the U.S. Department of Health and Human Services' Food and Drug Administration (FDA). A 2023 survey found that the average American uses 11 to 13 cosmetics per day, resulting in exposure to as many as approximately 110 unique chemicals.[2]

FDA is responsible for ensuring the safety of domestic and imported cosmetics in interstate commerce. In December 2022, Congress passed legislation to significantly expand FDA's authorities to regulate cosmetics. Specifically, as part of the Consolidated Appropriations Act, 2023, Congress passed the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).[3] According to FDA, this new law will help ensure the safety of cosmetic products that many consumers use daily.[4] Changes under the law include a requirement for companies to report to FDA on serious

[1]The figures included sales, value of shipments, or revenue drawn from the U.S. Census Bureau's Annual Survey of Manufacturing. The data also included exports drawn from the U.S. Census Bureau's Annual Survey of Total Export Value.

[2]The survey was conducted in February 2023 by a private survey firm on behalf of an environmental health research nonprofit organization. The survey firm compiled information from more than 2,200 respondents on their use of personal care products. The survey asked about use of 66 product types in five categories as defined by the survey—body care, baby care, skin care, cosmetics, and hair care. The Federal Food Drug and Cosmetic Act (FFDCA) does not define personal care products but does define cosmetics. For the purposes of this report, we refer to these personal care products as cosmetics. The demographics of survey participants were weighted to match the demographic profile of the U.S. population. Environmental Working Group, *Survey finds use of personal care products up since 2004 – what that means for your health* (Washington, D.C.: July 26, 2023), accessed July 31, 2023, https://www.ewg.org/research/survey-finds-use-personal-care-products-2004-what-means-your-health.

[3]Pub. L. No. 117-328, div. FF, tit. III, subtit. E, 136 Stat. 4459, 5847.

[4]See Background on the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), accessed July 18, 2023, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022.

adverse events associated with the use of their products. The law also gives FDA authority to mandate that companies recall cosmetics if FDA determines there is a reasonable probability that the product is adulterated or misbranded and will cause serious adverse events.[5] In addition, manufacturers are now required to permit FDA access to certain records related to the safety of a given cosmetic ingredient or product if FDA has a reasonable belief that it is adulterated such that use or exposure presents a potential threat of serious adverse health consequences.[6]

[5]MoCRA defines serious adverse events as events that result in (A)(i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; (v) a congenital anomaly or birth defect; (vi) an infection; or (vii) significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance); or (B) require, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in (A)(i-vii). Pub. L. No. 117-328, div. FF, tit. III, subtit. E, § 3502; 136 Stat. 4459, 5847 (codified at 21 U.S.C. § 364(5)). MoCRA provides FDA with mandatory recall authority if FDA determines that there is a reasonable probability that a marketed cosmetic is adulterated or misbranded and the use of or exposure to the cosmetics will cause serious adverse health consequences or death. If the company associated with the cosmetic does not voluntarily cease distribution or recall the product, FDA may mandate that such a recall occur. Pub. L. No. 117-328, div. FF, tit. III, subtit. E, § 3502; 136 Stat. 4459, 5847 (codified at 21 U.S.C. § 364g).

[6]Pub. L. No. 117-328, div. FF, tit. III, subtit. E, § 3502; 136 Stat. 4459, 5847 (codified at 21 U.S.C. § 364f). These records are known as safety substantiation records. MoCRA requires that the manufacturer, packer, or distributor ensure, and maintain records supporting, that there is adequate substantiation of the safety of such cosmetic product. See Pub. L. No. 117-328, div. FF, tit. III, subtit. E, § 3502; 136 Stat. 4459, 5847 (codified at 21 U.S.C. §§ 364(4); 364d(a), (c)(1); 364f(a)). Safety substantiation records document a manufacturer's evidence for such attestations. See Pub. L. No. 117-328, div. FF, tit. III, subtit. E, § 3502; 136 Stat. 4459, 5847 (codified at 21 U.S.C. § 364d(c)(1)).

Adulterated or Misbranded Cosmetics

The Federal Food, Drug, and Cosmetic Act prohibits the distribution through interstate commerce of cosmetics that are adulterated or misbranded.

A cosmetic is considered adulterated if, among other things, it

- contains a poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling or under customary or usual usage;
- is prepared, packed, or held under insanitary conditions; or
- contains an unsafe color additive, unless it is a hair dye.

A cosmetic is considered misbranded if, among other things,

- its labeling is false or misleading;
- it fails to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Source: 21 U.S.C. §§ 331, 361, 362. | GAO-24-105542

According to FDA's website, MoCRA is the most significant expansion of FDA's authority to regulate cosmetics since the Federal Food, Drug, and Cosmetic Act (FFDCA) was passed in 1938.[7] Implementing significantly expanded authorities can necessitate organizational changes.[8] In February 2023, FDA proposed moving its cosmetics regulation functions out of its Center for Food Safety and Applied Nutrition and into the Office of the Chief Scientist as the agency implements MoCRA. According to FDA, this proposed move will better align the expertise of the agency's cosmetics subject-matter experts with the Chief Scientist, who is focused on research, science, and innovation.[9] We have previously reported that implementing agency reforms, such as significant organizational changes, can span several years and must be carefully and closely planned and

[7]https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022, accessed July 18, 2023.

[8]For example, when the Cybersecurity and Infrastructure Security Act of 2018 was passed, the authority of the Department of Homeland Security's National Protection and Programs Directorate was redesignated as the Cybersecurity and Infrastructure Security Agency and the agency's responsibilities were expanded. In response, the Department of Homeland Security carried out organizational changes to implement the law. See GAO, *Cybersecurity and Infrastructure Security Agency: Actions Needed to Ensure Organizational Changes Result in More Effective Cybersecurity for Our Nation*, GAO-21-236 (Washington, D.C.: Mar. 10, 2021).

[9]FDA is seeking to finalize its proposal in autumn 2023. This process includes the development of a reorganization package that contains the newly designed structure, an established budget, and a detailed mapping and crosswalk of staff from the current to the new organization. The package then undergoes a thorough review before advancing to Congress for a 30-day notification period, in which members may raise any concerns that FDA may need to address. Afterwards, FDA will issue a *Federal Register* Notice, provide notification to, and engage, as needed, in negotiations with unions representing affected staff, prior to initiation of the new proposal. FDA will continue to engage with stakeholders throughout this process, according to FDA's website.

managed.[10] We have identified leading practices to help ensure the success of such agency reforms.

You asked us to examine FDA's efforts in overseeing cosmetic safety. This report (1) describes research on the safety of selected substances in cosmetics and (2) examines what actions FDA has taken to implement its new authorities for cosmetic safety oversight and the extent to which these actions addressed selected leading practices for agency reforms. This report also provides information on state laws and regulations that prohibit or restrict substances in cosmetics.

To describe research on the safety of selected substances in cosmetics, we conducted a systematic search of databases, such as ProQuest and Harvard University's Think Tank search, to identify relevant literature published from 2017 to 2022. We supplemented the literature search with additional publications we identified through interviews with FDA officials and other stakeholders, as well as internet searches. We assessed the identified publications against screening criteria, such as whether the publication contained information on studies of the correlative or causative relationship between certain substances in cosmetics and associated adverse health effects. We analyzed those that met our criteria. We then categorized the substances in the cosmetic products that were studied and summarized their potential harmful effects. To further illustrate research on the potential health effects of certain substances in cosmetics, we summarize studies for three substances in appendix I.

To examine what actions FDA has taken to implement its new authorities for cosmetic safety oversight, we reviewed applicable laws, including FFDCA and MoCRA. We then reviewed agency documents for evidence of actions FDA had taken through August 2023 to implement MoCRA. We also interviewed FDA officials—including the senior official in charge of these efforts, FDA's Chief Scientist.

To examine the extent to which FDA's actions addressed selected leading practices for agency reforms, we compared the agency's actions

[10]GAO, *Government Reorganization: Key Questions to Assess Agency Reform Efforts*, GAO-18-427 (Washington, D.C.: June 13, 2018). We define "efficiency" as maintaining federal government services or outcomes using fewer resources (such as time and money) or improving or increasing the quality or quantity of services or outcomes while maintaining (or reducing) resources. See also GAO, *Streamlining Government: Key Practices from Select Efficiency Initiatives Should Be Shared Governmentwide,* GAO-11-908 (Washington, D.C.: Sept. 30, 2011).

since the law's enactment with selected leading practices compiled in our June 2018 report on government reorganization.[11] The leading practices are organized into categories, subcategories, and associated key questions. We selected those that we determined to be relevant to FDA's MoCRA implementation efforts.

To identify states that prohibit or restrict substances in cosmetics, we researched statutes and regulations in all 50 states and the District of Columbia. When relevant statutes and regulations were identified, we compared them against federal law and FDA regulations that prohibit or restrict substances in cosmetics. Through this comparison, we identified state prohibitions or restrictions that exceed federal standards or that are for substances not otherwise prohibited or restricted under federal law.[12] We summarize our results for all states and the District of Columbia in appendix II. We provide additional information for five specific states in appendix III. For more details on our objectives, scope, and methodologies, see appendix IV.

We conducted this performance audit from November 2021 to December 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

FDA's Authority to Regulate Cosmetics

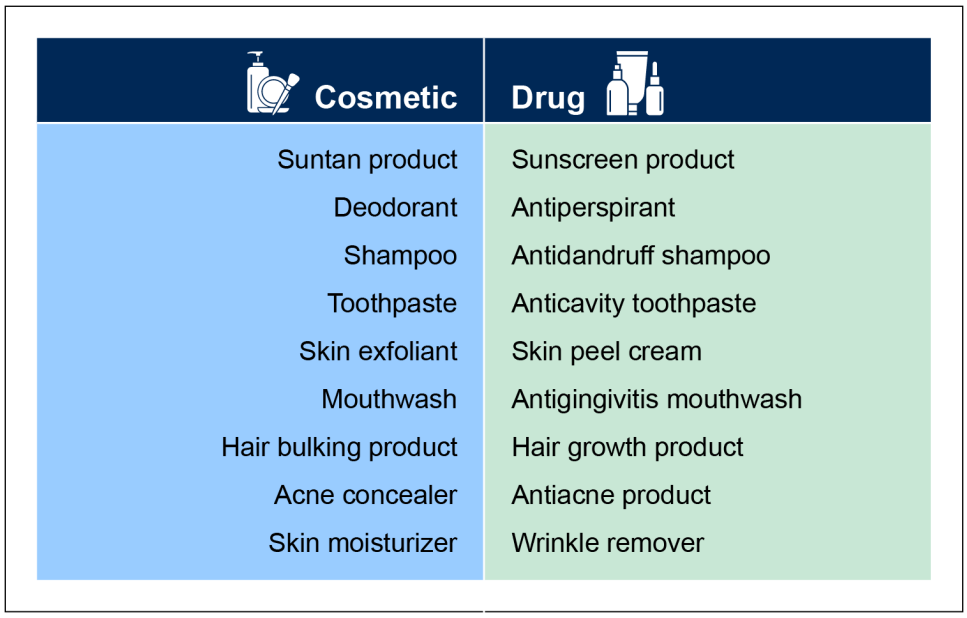
FDA's derives its authority to regulate cosmetics from the FFDCA, which defines cosmetics and their ingredients by their intended use as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body... for cleansing, beautifying,

[11]GAO-18-427. In developing the 2018 report to assist Congress, the Office of Management and Budget, and agencies in assessing agency reform plans, we reviewed our prior work on leading practices for organizational transformations; collaboration; government streamlining and efficiency; fragmentation, overlap, and duplication; and high-risk and other long-standing agency management challenges. The report includes 58 key questions to aid in assessing reform efforts.

[12]We did not assess the basis or rationale for the legal prohibitions or restrictions for cosmetic ingredients in individual states and the District of Columbia.

promoting attractiveness, or altering the appearance."[13] In contrast, if a product is intended for a therapeutic use, such as treating or preventing disease, or to affect the structure or function of the body, among other things, it is regulated as a drug, even if it also affects appearance.[14] Figure 1 provides examples of similar products regulated either as cosmetics or drugs, depending on their intended use.

Figure 1: Examples of Products Regulated as Cosmetics or Drugs



Source: GAO presentation of Congressional Research Service summary of Peter Barton Hutt, "Legal Distinction in USA between Cosmetic and Drug," in *Cosmeceuticals and Active Cosmetics: Drugs versus Cosmetics*, 2nd ed., Peter Eisner and Howard Maibach, eds. (2005): 630. | GAO-24-105542

Note: Some products meet the definitions of both cosmetics and drugs and must comply with the federal requirements for both. For example, an antidandruff shampoo is a cosmetic because it is a shampoo intended to cleanse hair, but it is also a drug because it contains an active ingredient to treat dandruff.

[13]21 U.S.C. § 321. The FFDCA explicitly exempted soap from the definition of cosmetics. 21 U.S.C. § 321(i)(2). However, FDA may regulate soap as a cosmetic under certain circumstances.

[14]21 U.S.C. § 321(g). See also 21 U.S.C. § 355.

Under the FFDCA, FDA is responsible for ensuring the safety and proper labeling of cosmetic products in interstate commerce.[15] In contrast to FDA's premarket approvals for certain drugs, biological products, medical devices, and products that emit radiation, FDA does not preapprove cosmetics prior to their entry into the market. FDA may, however, take action if a marketed cosmetic is adulterated or misbranded, as may be determined through inspections of cosmetics manufacturers and distributers and their cosmetic products, in accordance with the FFDCA.[16]

Cosmetics that are adulterated or misbranded within the meaning of the FFDCA may be subject to seizure. For example, FDA issued a warning letter in November 2022 to a national retail chain distributer after inspections at one of its distribution centers.[17] Earlier in the year, FDA investigators had observed insanitary conditions—including evidence of rodent activity and associated filth—that could cause contamination of cosmetics and other products stored at the center. Cosmetics stored in such conditions are considered adulterated. The warning letter notes that, after the inspections, the company had notified FDA of the company's decision to close the center and cease distribution of all FDA-regulated products from the site, including cosmetics. In addition to seizure, cosmetics from other countries that are not in compliance with the law may be blocked from entry into the United States through an import alert.[18]

[15]21 U.S.C. § 393(b)(2)(D). Existing facilities that manufacture or process cosmetic products distributed in the United States must register with FDA no later than December 29, 2023; new facilities that first manufacture or process cosmetic products distributed in the United States after that date must register with FDA within 60 days of engaging in such activity. 21 U.S.C. §§ 364(3)(A), 364c(a)(1). However, FDA does not have authority and is not required to review and approve cosmetic ingredients or products, other than color additives, 21 U.S.C. § 379e(a), before the products enter the market.

[16]The FFDCA prohibits the distribution of cosmetics that are adulterated or misbranded. 21 U.S.C. § 331(a). Section 601 of the FFDCA sets forth under what circumstances a cosmetic must be deemed adulterated, including that the cosmetic has been prepared, packed, or held under insanitary conditions, whereby it may have become contaminated with filth. 21 U.S.C. § 361. Section 602 of the FFDCA sets forth under what circumstances a cosmetic must be deemed misbranded, including if the cosmetic's labeling is false or misleading. 21 U.S.C. § 362.

[17]FDA issues warning letters to let companies know they have violated a law FDA enforces, such as the FFDCA, and to tell the companies what corrective action they need to take.

[18]An import alert informs FDA field staff and the public that the agency has enough evidence to detain suspect products, such as cosmetics, at U.S. ports of entry without physically examining them (known as detention without physical examination).

Prohibitions on Ingredients

Selling cosmetics that contain a substance that may harm a consumer in interstate commerce is prohibited by federal law.[19] FDA has also established regulations that prohibit or restrict the use of 11 specific ingredients in cosmetics: (1) bithionol; (2) chlorofluorocarbon propellants; (3) chloroform; (4) halogenated salicylanilides (i.e., di-, tri-, and meta-bromsalan, and tetrachlorosalicylanilide); (5) hexachlorophene; (6) mercury compounds, (7) methylene chloride; (8) certain cattle materials; (9) ingredients labeled as sunscreen, other than when qualified by a description of the cosmetic benefit of the ingredient; (10) vinyl chloride; and (11) zirconium-containing aerosols.[20]

Some states have also prohibited or restricted certain substances in cosmetics.[21] For more information on these state laws and regulations, see appendixes II and III.

Changes under MoCRA

MoCRA significantly expanded FDA's authorities for cosmetic safety and, in some cases, added new requirements for cosmetic manufacturers. However, MoCRA did not grant FDA the authority to review and approve cosmetics for safety prior to their entry into the market. Table 1 compares FDA's authorities and requirements under the FFDCA before and after MoCRA amended the FFDCA, as well as changes in requirements for cosmetic companies.

[19]The introduction in interstate commerce of a cosmetic that contains an ingredient that may render it injurious to users when used according to directions on its label or under conditions of customary or usual use is prohibited. 21 U.S.C. §§ 331(a), 361(a).

[20]21 C.F.R. pt. 700, subpt. B; also 21 C.F.R. § 250.250(e). Certain cattle materials are prohibited from cosmetics in order to protect against bovine spongiform encephalopathy, also known as Mad Cow Disease. Beef tallow (rendered fat) is an ingredient in some cosmetics, such as creams and lotions. Products that contain sunscreen for the purpose of protecting skin from sunburn, such as those that contain zirconium, are defined as drugs, not cosmetics. See 21 C.F.R. § 700.35(a).

[21]Under MoCRA, no state or political subdivision of a state may establish or continue in effect any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement applicable under MoCRA with respect to registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation. States may continue to prohibit or restrict individual substances from cosmetics. Pub. L. No. 117-328, div. FF, tit. III, subtit. E, § 3502 (codified at 21 U.S.C. § 364j(a), (b)).

Table 1: FDA Authorities and Requirements and Cosmetic Company Requirements under the FFDCA Before and After MoCRA

Subject	Prior to enactment of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA)	Following enactment of MoCRA[a]
Asbestos in talc	The Food and Drug Administration (FDA) **did not** have specific authority to regulate methods for detecting asbestos in cosmetic talc.	FDA **must** promulgate regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetics.
Fragrance and flavor	Cosmetics manufacturers **were not** required to provide FDA with fragrance and flavor ingredients.	FDA **may now** request, and cosmetics manufacturers are required to provide, a list of fragrance and flavor ingredients that are believed to have caused or contributed to a serious adverse health event.
Good manufacturing processes	Cosmetics manufacturers were not specifically directed to adhere to good manufacturing processes.[b]	FDA **must** establish good manufacturing processes in regulation for facilities that manufacture and process cosmetics.
Labeling	Cosmetics companies **were not** required to include the following on cosmetic product labels: • company contact information for reporting adverse events • list of fragrance allergens in the product	Cosmetics companies must include the following on cosmetic product labels: • company contact information for reporting adverse events • list of fragrance allergens in the product
Per- and polyfluoroalkyl substances (PFAS)	FDA **was no**t required to assess the safety of PFAS in cosmetics.	FDA **must** assess the use and evidence regarding the safety of PFAS in cosmetics.
Premarket review and approval	FDA **did not** have authority to review and approve cosmetics for safety prior to their entry into the market.	**No change** in FDA authority
Recalls	FDA **did not** have the authority to mandate recalls of cosmetics.	FDA **may now** mandate recalls of cosmetics under certain circumstances.
Records	Cosmetics manufacturers **were not** required to • maintain adverse event reports, • submit adverse event reports to FDA, or • permit FDA access to adverse event records during an inspection.	Cosmetics manufacturers must • maintain adverse event reports, • submit serious adverse event reports to FDA, and • permit FDA access to adverse event records during an inspection.
Registration	Cosmetics companies **were not** required to register with FDA their firms, cosmetic products, or the ingredients used in their products.	Persons who own or operate a facility engaged in manufacturing or processing cosmetic products **must** register with FDA their facilities and cosmetic products, including ingredients used in their products, and renew their registrations periodically.[c]
Safety substantiation	FDA **did not** have access to cosmetics manufacturers' safety substantiation records for their products.	Cosmetics manufacturers **must** maintain safety substantiation records for their products and provide FDA access to the documentation under certain circumstances.

Source: GAO analysis of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the FFDCA as amended by MoCRA. | GAO-24-105542

[a]MoCRA includes exemptions from some requirements for owners and operators of facilities whose average gross annual sales in the United States for the prior 3-year period were less than $1,000,000, adjusted for inflation, and meet certain other criteria.

[b]Good manufacturing practices entail guidance for quality assurance in the manufacturing process. Such practices are designed to better ensure that products are consistently manufactured to a quality

appropriate to their intended use. Good manufacturing practices are, therefore, related to both manufacturing and quality control procedures.

[c]MoCRA requires renewal of facility registrations biennially and cosmetic product listings annually.

MoCRA also authorized funding levels over the next several fiscal years that increase sharply, with authorized funding levels growing from $14.2 million in fiscal year 2023, to $26 million in fiscal year 2024, to $41.9 million in fiscal years 2025 through 2027.[22] However, the Consolidated Appropriations Act, 2023, did not appropriate any funding specifically for MoCRA implementation. FDA's allocations for the Office of Colors and Cosmetics in fiscal years 2012 through 2023 ranged from approximately $7 million to $8 million per year.[23] For fiscal year 2024, FDA requested additional funding through its congressional budget justification to hire new staff to implement MoCRA.[24] To fully implement all of MoCRA's provisions, FDA senior officials told us they anticipate requesting funding for additional staff in future fiscal years as well.

[22]MoCRA authorizes funding levels for the enactment of an appropriation in separate legislation. The ultimate amount appropriated may differ from the amount authorized.

[23]According to FDA officials, figures for allocations for the Office of Colors and Cosmetics in fiscal years 2012 through 2022 do not include funding arising from fees collected from cosmetics manufacturers for color certifications. Under the FFDCA, color additives, except coal-tar hair dyes, are subject to FDA approval and certification before they may be used in cosmetics. Fees for color certification are set by regulation.

[24]U.S. Department of Health and Human Services, Food and Drug Administration, *Justification of Estimates for Appropriations Committees, Fiscal Year 2024*.

Certain Substances Found in Cosmetics Are Potentially Harmful

Research has established that certain substances found in cosmetics are potentially harmful to human health, although the effects can be difficult to confirm, in part because of research limitations. Most of these substances, such as fragrances and preservatives, are ingredients added by manufacturers to serve a specific function in the product. However, some substances, such as asbestos, may be present unintentionally as impurities or as byproducts of the manufacturing process. (See fig. 2.) Appendix I presents additional information that further illustrates the potential health effects for selected cosmetic ingredients or contaminants.

Research Limitations

Studies conducted on the potentially harmful health effects of certain substances in cosmetics are subject to limitations. The methodologies and associated limitations vary across individual studies we reviewed. Four examples of limitations that apply to some of the studies we reviewed include

1. **small sample sizes.** Findings in some studies are based on small sample sizes that can make it difficult to detect a statistical association between exposure and health outcomes;
2. **limitations in exposure assessment.** Some studies we reviewed use a retrospective design that bases exposure assessment on self-reported histories of product use, which are subject to memory and recall limitations;
3. **variability in factors studied and patient populations.** The variety of products and differences in ingredient concentrations, patterns of use, and an individual's susceptibility to specific product formulations make it difficult to determine the health effects of specific substances in cosmetics; and
4. **studying health outcomes that may take years to develop.** Some health outcomes, such as certain types of cancer, may take several years after exposure to develop, making causal associations difficult to establish.

Source: GAO. | GAO-24-105542

Figure 2: Examples of Substances in Cosmetics Associated with Potentially Harmful Health Effects

Health effects of potentially harmful substances in cosmetics depend on multiple factors, including the exposure dose, cumulative exposure from other sources, nature of exposure, and the susceptibility of the individual.

Sources: GAO, Whitestorm/stock.adobe.com; Showcake/stock.adobe.com; Lumos SP/stock.adobe.com; Brulove/stock.adobe.com; Studio Light & Shade/stock.adobe.com. | GAO-24-105542

Certain Substances Are Ingredients in Cosmetics That May Harm Health

Correlative and Causative Relationships

In health effect studies, finding an association (also referred to as "correlation") between an exposure and a health outcome means that there is a statistical relationship between the exposure and outcome; however, it is not established whether the exposure caused the outcome. For example, a study may find that exposure to a substance in a cosmetic product is linked to a health condition but not demonstrate that the exposure caused the condition. Other factors unaccounted for in the study may be the cause of the health condition.

In contrast, a finding of a causal relationship between exposure to a substance in a cosmetic and a health outcome means that the exposure causes the outcome. Causal relationships are more difficult to establish than associations, in part because they require carefully controlled experimental study designs.

Source: GAO. | GAO-24-105542

Fragrances. Cosmetics may contain a wide range of fragrances, which are natural or synthetic compounds added to impart a characteristic and pleasant smell. However, certain fragrances may also cause allergic reactions. According to the International Fragrance Association, at least 3,000 fragrance ingredients have been identified in global use in consumer products such as cosmetics.[25]

Fragrances are generally found in high concentrations as ingredients in perfumes. In makeup and lotions, fragrances generally have lower concentrations and are used to increase product acceptance or to mask an unpleasant smell from other ingredients.

In our literature review, we identified and reviewed five studies that linked certain fragrances to allergic reactions on the skin.[26] For example, one study of allergens associated with suspected scalp contact dermatitis identified fragrances, including balsam of Peru, and fragrance mixes I and II, as the second most common allergens in skin patch tests, after metals such as nickel and cobalt.[27] According to the study, scalp itching and burning were reported as the most common symptoms of scalp contact dermatitis.

Preservatives. Preservatives, such as parabens and formaldehyde-releasing chemicals, are added to cosmetics to inhibit the growth of potentially harmful microorganisms such as molds, yeast, and bacteria. Parabens are widely used as preservatives and are effective at low

[25]*International Fragrance Association Transparency List*, accessed May 17, 2023, https://ifrafragrance.org/priorities/ingredients/ifra-transparency-list.

[26]Nouf M. Aleid et al., "Common Allergens Identified Based on Patch Test Results in Patients with Suspected Contact Dermatitis of the Scalp," *Skin Appendage Disorders*, no. 3 (2017): 7-14; V. Zaragoza-Ninet et al., "Allergic Contact Dermatitis Due to Cosmetics: A Clinical and Epidemiological Study in a Tertiary Hospital," *Actas Dermosifiliograficas*, vol. 107, no.4 (2016): 329-336; Joel G. DeKoven et al., "North American Contact Dermatitis Group Patch Test Results: 2013–2014," *Dermatitis*, vol. 28, no. 1 (2017): 33-46; Joel G. DeKoven et al., "North American Contact Dermatitis Group Patch Test Results: 2015–2016," *Dermatitis*, vol. 29, no.2 (2018): 297-309; and Joel G. DeKoven et al., "North American Contact Dermatitis Group Patch Test Results: 2017–2018," *Dermatitis*, vol. 32, no. 2 (2021): 111-123.

[27]Balsam of Peru is a fragrant resinous liquid that is used as a fragrance in various consumer products, including cosmetics. Fragrance mixtures I and II contain multiple types of chemical substances. Metals, including nickel and cobalt, were the most common allergens associated with suspected scalp contact dermatitis in skin patch tests, but these allergens were found in hair accessories, which are not classified as cosmetics. Aleid et al., "Common Allergens Identified Based on Patch Test Results."

concentrations. However, parabens have been linked to interference with the functioning of the endocrine system.

We identified and reviewed three studies that show the presence of parabens in personal care products that FDA defines as cosmetics.[28] For example, the presence of measurable concentrations of parabens in cosmetics was detected in a study of cosmetic products that included body wash, shampoo, hair conditioner, perfume, deodorant, and baby care products.[29] Parabens have also been detected in feminine hygiene products, some of which are categorized as cosmetics, including wipes, deodorant sprays, and powders.[30] According to the authors, cosmetics may be important sources of exposure to parabens.

Research has found an association between preservatives in cosmetics and allergic skin reactions. For example, one study found that quaternium-15, a formaldehyde-releasing preservative, elicited a positive reaction on skin patch test for some patients with scalp contact dermatitis; this preservative is commonly used in shampoos, conditioners, hair gels, and leave-on hair products.[31] Studies on the everyday use of such cosmetics are ongoing to determine their effects on the human body.

Plasticizers. Plasticizers are substances that are added to soften and increase flexibility and durability of cosmetics. For example, phthalates are added to cosmetics, such as certain feminine hygiene products and hair spray; they are also used to prevent undesired effects, such as

[28]For the purposes of this report, we refer to personal care products as cosmetics. Ying Guo and Kurunthachalam Kannan, "A Survey of Phthalates and Parabens in Personal Care Products from the United States and Its Implications for Human Exposure," *Environmental Science & Technology*, vol. 47 (2013): 14442-14449; Chong-Jing Gao and Kurunthachalam Kannan, "Phthalates, Bisphenols, Parabens, and Triclocarban in Feminine Hygiene Products from the United States and Their Implications for Human Exposure," *Environment International*, vol. 136 (2020): 1-10; and Jessica S. Helm et al., "Measurement of Endocrine Disrupting and Asthma-associated Chemicals in Hair Products used by Black Women," *Environmental Research*, vol. 165 (2018): 448-458.

[29]Guo and Kannan, "Survey of Phthalates and Parabens." This study did not differentiate between personal care products that are regulated as drugs or cosmetics. We report results only for those considered cosmetics: body wash, deodorant, face cleanser, perfume, shampoo and hair conditioner, and certain baby care products.

[30]Gao and Kannan, "Phthalates, Bisphenols, Parabens." This study did not differentiate between feminine hygiene products that are regulated as drugs or cosmetics. We report results only for those considered cosmetics: wipes, deodorant sprays, and powders.

[31]Aleid et al., "Common Allergens Identified Based on Patch Test Results."

chipping or cracking of nail polish.[32] However, exposure to phthalates has been associated with reproductive health risks.

We identified and reviewed three studies that detected the presence of measurable concentrations of phthalates in the examined cosmetics.[33] For example, one study found that more than 90 percent of feminine hygiene products analyzed—including two of three types of feminine hygiene products that are also cosmetics—contained measurable concentrations of phthalates.[34]

In our literature review, we identified and reviewed one study that found a possible association between exposure to phthalates, such as may occur through the use of cosmetics, and uterine health effects.[35] For example, the study found that women's exposure to certain phthalates, such as diethylhexyl phthalate, may contribute to increased fibroid burden, which has been associated with more severe symptoms and the need for more invasive surgical treatments.[36] The researchers noted that additional study is needed to understand the impact of phthalates on fibroid growth.

Solvents. In cosmetics, solvents are typically liquids that are added to dissolve solid ingredients, mix with liquids, and to add texture to cosmetic products. Volatile organic solvents, such as those found in nail polish removers, may cause respiratory problems, including irritation to the nose, throat, and lungs (see fig. 3).

[32]Phthalates are a group of chemicals generally used to make plastics more durable.

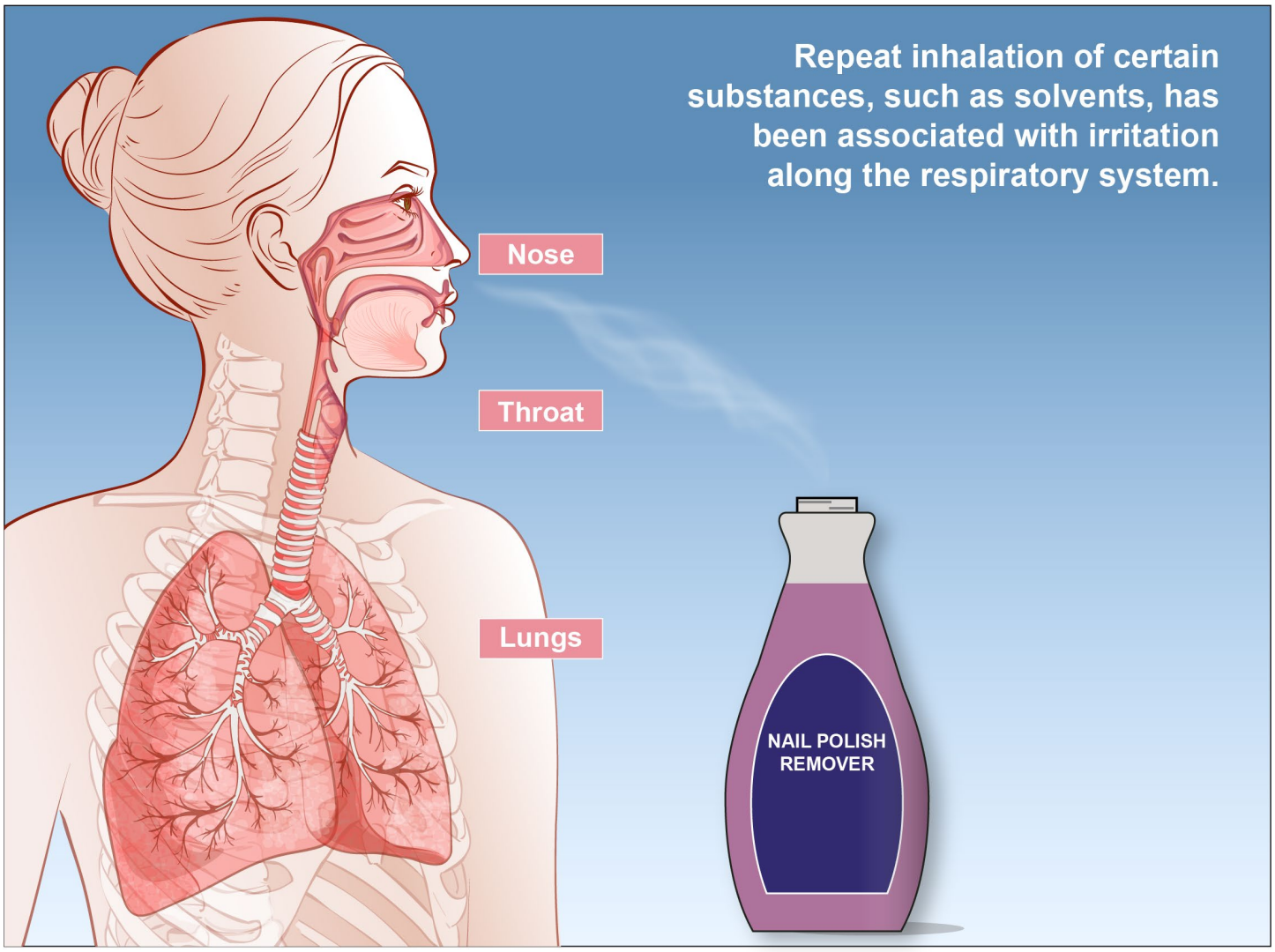
[33]Guo and Kannan, "Survey of Phthalates and Parabens," Gao and Kannan, "Phthalates, Bisphenols, Parabens," and Helm et al., "Endocrine Disrupting in Hair Products."

[34]Gao and Kannan, "Phthalates, Bisphenols, Parabens." This study included feminine hygiene products that are regulated either as medical devices or cosmetics. We report results only for those considered cosmetics: deodorant sprays, powders, and wipes. Phthalates were detected in powders and wipes but were below the limit of detection in deodorant sprays.

[35]Ami R. Zota et al., "Phthalates Exposure and Uterine Fibroid Burden Among Women Undergoing Surgical Treatment for Fibroids: A Preliminary Study," *Fertility and Sterility*, vol. 111 (2019): 112-121. The study did not identify the sources of phthalate exposure.

[36]Fibroids are noncancerous growths of the uterus that are usually benign but can cause a range of symptoms. This study looked at two measures of fibroid burden: diameter of the largest fibroid and uterine volume. Zota et al., "Phthalates Exposure and Uterine Fibroid Burden."

Figure 3: An Illustration of Solvent Inhalation along the Respiratory System



Sources: GAO; Mozart3737/stock.adobe.com. | GAO-24-105542

In our literature review, we identified and reviewed four studies establishing the presence of volatile organic solvents in nail cosmetics or linking exposure to these solvents to health problems.[37] For example, two studies found that nail polish may contain ingredients such as ethyl acetate and methyl methacrylate—two volatile organic solvents.[38] Additional volatile organic solvents, such as toluene, are also used in nail care products and were found in blood samples of nail technicians.[39] According to the authors, ethyl acetate and toluene have been associated with eye, skin, nose, and throat irritation. Another study, comprising 51 nail technician participants and 31 control participants, suggested that lung function and airway inflammation may be adversely affected by nail technicians' work environments.[40]

Manufacturing Byproducts and Impurities in Cosmetics May Also Harm Health

Substances may be present in cosmetics unintentionally—either as byproducts of the manufacturing process or due to raw material impurities—and some of these substances are linked to adverse health effects.

In our literature review, we identified and reviewed two studies that found byproducts or impurities in cosmetics.[41] For example, 1,4-dioxane is a

[37]Maria Lteif et et al., "Knowledge and Attitude Among Lebanese Women Toward Hazardous Chemicals Used in Nail Cosmetics," *Journal of Community Health*, vol. 45 (2020): 922-931; Diana M. Ceballos et al., "Biological and Environmental Exposure Monitoring of Volatile Organic Compounds among Nail Technicians in the Greater Boston Area," *Indoor Air*, vol. 29 (2019): 539-550; Sung-Ae Park, Sugyeong Gwak, and Sangjun Choi, "Assessment of Occupational Symptoms and Chemical Exposures for Nail Salon Technicians in Daegu City, Korea," *Journal of Preventative Medicine & Public Health*, vol. 47 (2014): 169-176; and Aaron Lamplugh et al., "Occupational Exposure to Volatile Organic Compounds and Health Risks in Colorado Nail Salons," *Environmental Pollution*, vol. 29 (2019): 518-526.

[38]Lamplugh et al., "Occupational Exposure;" and Ceballos et al., "Biological and Environmental Exposure."

[39]Ceballos et al., "Biological and Environmental Exposure." The authors note that most of the volatile organic solvents detected in nail salon air samples were below the level of detection in blood testing; the volatile organic solvents ethyl acetate and toluene were predominate in the air and blood samples. The authors also note the small sample size of this study.

[40]Susan R. Reutman et al., "A Pilot Respiratory Health Assessment of Nail Technicians: Symptoms, Lung Function, and Airway Inflammation," *American Journal of Industrial Medicine*, vol. 52 (2009): 868-875. The authors note the small sample size of this study.

[41]Nancy M. Hepp et al., "Survey of Cosmetics for Arsenic, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel Content," *Journal of Cosmetic Science*, vol. 65 (2014) 125-145; and Shazia Abraret et al., "Analysis of Lead, Cadmium, and Arsenic in Colored Cosmetics Marketed in Pakistan," *Journal of Public Health Policy*, vol. 43 (2022): 54-56.

byproduct that can form during the manufacturing process; it has been found in shampoos[42] and in sodium laureth sulfate, which is added to baby products.[43] According to the U.S. Agency for Toxic Substances and Disease Registry, exposure to significant concentrations of 1,4 dioxane can irritate the eyes, nose, and throat in humans.

A study in our literature review found that heavy metals, such as lead, cadmium, and arsenic, can be present in cosmetics, either as byproducts of the manufacturing process or as an environmental contaminant of raw ingredients.[44] The study found heavy metal impurities in some instances in compact powder, eye shadow, and lipstick. Two publications in our literature review noted that the accumulation of heavy metals in body organs over time may lead to bone, cardiovascular, kidney, or liver diseases.[45]

FDA conducted two surveys to detect heavy metals (arsenic, cadmium, chromium, cobalt, lead, mercury, and nickel) in cosmetics.[46] The surveys were completed in 2012 and 2013, respectively. According to FDA reports that summarize the findings, the surveys found that the amounts of heavy metals, if any, were very small in the cosmetics they tested. According to FDA, the agency does not have any information indicating that the very

[42]Byung-Mu Lee et al., "Perspectives on Trace Chemical Safety and Chemophobia: Risk Communication and Risk Management," *Journal of Toxicology and Environmental Health, Part A*, vol. 82, no.2 (2019): 113-127.

[43]Amrita Nepalia et al., "An Overview of the Harmful Additives and Contaminants Possibly Present in Baby Cosmetic Products," *International Journal of Chemical Sciences*, vol. 15 (2017): 2-8.

[44]Abrar et al., "Analysis of Lead, Cadmium, and Arsenic."

[45]Tamara Attard and Everaldo Attard, *Environmental Impact and Remediation of Heavy Metals: Heavy Metals in Cosmetics* (2022):1-22; and Abrar et al., "Analysis of Lead, Cadmium, and Arsenic."

[46]Hepp et al., "Survey of Cosmetics." FDA completed the first survey in 2012. The agency worked with a contractor to test 150 cosmetics, including eye shadows, blushes, lipsticks, lotions, mascaras, foundations, body powders, compact powders, shaving creams, and face paints. FDA completed the second survey in February 2013. For the second survey, FDA worked with a contractor to test 234 cosmetic products, of which 119 had been included in the first survey. Food and Drug Administration (FDA), *FDA Analyses of Seven Elements in Cosmetics – Second Survey (Elemental Content in Acid Extracts of Each Cosmetic Category),* accessed Aug.1, 2023, https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/fdas-testing-cosmetics-arsenic-cadmium-chromium-cobalt-lead-mercury-and-nickel-content#S2List.

small amounts of heavy metals that were found in the cosmetics would pose a health risk.

In addition, some studies suggest associations between asbestos contamination of talc and negative health effects. Specifically, one study we reviewed suggested that talc used in cosmetics —also known as talcum powder—may sometimes be contaminated with asbestos.[47] Talc is an ingredient in cosmetic products, including baby powder, blush, eyeshadow, and pressed powder. Asbestos, an impurity sometimes found in talc, is a naturally occurring silicate mineral and is a known carcinogen.

According to FDA, the agency monitors for potential safety problems in cosmetic products on the market, such as asbestos contamination in talc, and takes action when needed to protect public health. For example, in 2019, three private companies voluntarily recalled cosmetics products that tested positive for asbestos during FDA's ongoing testing of cosmetics for asbestos. The recalled cosmetic products included blush, bronzer, eyeshadows, and powder. FDA advised consumers not to use any of the products.

The talc industry has asserted that talc used in cosmetics has been asbestos free since 1976, when the industry created a voluntary specification for the asbestos content of cosmetic talc, which must be purer than talc used for industrial purposes. However, one study we reviewed suggested that the inhalation of talc contaminated with asbestos may be associated with mesothelioma, a type of cancer that develops on the thin layer of tissue that lines the lungs, chest wall, and many internal organs.[48] This case study in patients with a mesothelioma diagnosis

[47]Jacqueline Moline, Kesha Patel, and Arthur L. Frank, "Exposure to cosmetic talc and mesothelioma*," Journal of Occupational Medicine and Toxicology*," vol. 18, no.1 (2023):1-13.

[48]Moline, Patel, and Frank, "Exposure to Cosmetic Talc." The authors noted several limitations to this study, including potential biases inherent in studies of cases for which data were collected as part of litigation. Patients' exposure history was collected in sworn testimony from patients and patients' families as part of the litigation's medical-legal review.

found that in 122 of 166 cases, the only known exposure to asbestos was from cosmetic talc.[49]

FDA Has Taken Important Steps to Implement the New Cosmetics Law but Has Not Fully Addressed Leading Practices for Agency Reform

FDA has taken important steps, such as designating leadership and engaging its employees, to implement the new cosmetics law, but its actions do not fully address leading practices for agency reform. We use the term "reforms" to include organizational changes, such as those needed to implement the significant expansion of statutory authorities under MoCRA.[50] More specifically, FDA's actions have not fully addressed two categories of leading practices for agency reforms that we deemed relevant for the purposes of this review: (1) implementing the reforms and (2) strategically managing the federal workforce.

FDA Has Designated Leadership for MoCRA Efforts but Has Not Fully Addressed Leading Practices for Implementing the Reforms

Within the first year since enactment of MoCRA, FDA has taken important steps to implement its new authorities for cosmetic safety oversight, particularly with regard to leadership, but its actions have not fully addressed leading practices for implementing agency reforms.[51] Our prior work shows that addressing leading practices for implementing reforms improves the likelihood of successful reform.[52] Table 2 shows our assessment of the extent to which FDA's actions have addressed leading practices for implementing agency reforms and selected key questions that are associated with such leading practices.[53] These leading practices

[49]The case study also sought to identify other sources of exposure to asbestos, including worker exposure. Worker exposure to asbestos hazards is addressed in specific Department of Labor Occupational Safety and Health Administration standards for the construction industry, general industry, and shipyard employment sectors.

[50]We use the term "reforms" to broadly include any organizational changes—such as major transformations, mergers, consolidations, and other reorganizations—and efforts to streamline and improve the efficiency and effectiveness of government operations. See GAO-18-427.

[51]FDA is in the early stages of implementing the new law; the information we obtained to assess FDA's efforts to address our leading practices reflects the agency's first 8 months of implementation actions (January to August 2023).

[52]GAO-18-427.

[53]The leading practices include key questions that Congress, the Office of Management and Budget, and agencies should consider for the development and implementation of agency reforms. See GAO-18-427.

cover (1) leadership focus and attention and (2) managing and monitoring implementation of reforms.

Table 2: Extent to Which FDA Addressed Selected Leading Practices for Agency Reforms and Key Questions in Implementing MoCRA

Selected leading practice for agency reforms category	Selected leading practice for agency reforms subcategory and extent addressed overall	Selected key questions associated with the leading practice and extent addressed
Implementing the Reforms	Leadership Focus and Attention ●	Has the agency designated a leader or leaders to be responsible for the implementation of the proposed reforms? ●
		How will the agency hold the leader or leaders accountable for successful implementation of the reforms? ●
		Has the agency established a dedicated implementation team that has the capacity, including staffing, resources, and change management, to manage the reform process? ●
	Managing and Monitoring ◑	How has the agency ensured their continued delivery of services during reform implementation? ●
		Has the agency developed an implementation plan with key milestones and deliverables to track implementation progress? ○
		Has the agency ensured transparency over the progress of its reform efforts through reporting on key milestones? ◑
		Has the agency put processes in place to collect the needed data and evidence that will effectively measure the reforms' outcome-oriented goals? ○

● FDA took actions that generally addressed the leading practice or the individual key question.
◑ FDA took actions that partially addressed the leading practice or the individual key question.
○ FDA took few to no actions to address the leading practice or the individual key question.
FDA = Food and Drug Administration
MoCRA = Modernization of Cosmetics Regulation Act of 2022
Source: GAO analysis of FDA documents and interviews with FDA officials. | GAO-24-105542

FDA Designated a Leader and Established a Working Group of Senior Officials for MoCRA Implementation

FDA has a leader for MoCRA implementation, is holding that leader accountable, and has a team of senior officials to help manage the implementation efforts. These actions are consistent with our leading practice of leadership focus and attention.

Designated a leader: generally addressed. Our prior work has stated that agency reforms should be led by a high-performing leader or leaders within the agency. Consistent with our leading practice of designating a leader, FDA designated its Chief Scientist as its leader for MoCRA implementation.

Leader accountability: generally addressed. Our prior work has stated that fully implementing agency reforms can span several years and must be carefully and closely managed, including by holding leaders accountable for successful implementation over time. Consistent with our leading practice of leader accountability, FDA's Chief Scientist reports directly to the Office of the FDA Commissioner. According to FDA officials, the Chief Scientist routinely meets with the Commissioner to provide updates on the status of MoCRA implementation efforts.

Implementation team: generally addressed. Our prior work has stated that agency reforms should be implemented by a dedicated implementation team that has the capacity to manage the reform process. FDA's Chief Scientist chairs the MoCRA Implementation Working Group, which met on a weekly to biweekly basis from late January 2023 through mid-April 2023. According to FDA officials, the group continues to meet on an ad hoc basis, as needed. The working group comprises mostly senior officials from various FDA offices, such as the Office of the Chief Scientist, the Office of Cosmetics and Colors, and the Office of the Commissioner. According to FDA officials, the working group is leveraging the agency's existing resources to implement near-term MoCRA requirements. For example, FDA's Chief Scientist stated that the agency is drawing upon the subject-matter expertise of its current information technology staff to fulfill a near-term MoCRA requirement that FDA establish a mandatory system for cosmetic firm registration and product listing by December 2023. (Additional MoCRA requirements and deadlines are summarized later in this report.)

FDA Continues Its Oversight Activities but Has Not Taken Certain Other Actions to Manage and Monitor Its Implementation of MoCRA

FDA has continued its routine oversight activities for cosmetic safety but has not fully addressed our leading practice for managing and monitoring its implementation of MoCRA. This leading practice calls for continued delivery of services, development of an implementation plan, transparency on progress, and measurement of results.

Continued delivery of services: generally addressed. FDA has continued to oversee cosmetic safety through the delivery of existing services as it implements MoCRA. Senior FDA officials told us that existing staff continue to perform their regular duties, as well as the additional responsibilities they have been tasked with for MoCRA implementation. Existing services include reviewing potential compliance cases referred by the Center for Food Safety and Applied Nutrition's Office of Compliance to the Office of Cosmetics and Colors, based on, for example, reviews of cosmetic labels. In addition, the Office of Cosmetics and Colors also reviews any cosmetics-related adverse events reported to FDA, responds to emailed inquiries from industry on various cosmetics-related topics, and issues cosmetic export certificates.[54]

Implementation plan: generally not addressed. FDA has not developed a written implementation plan for carrying out MoCRA requirements that apply to the agency. According to FDA's Chief Scientist, FDA is using MoCRA itself as its roadmap for implementing the new law, given that the new law specifies various requirements and their deadlines for completion (see table 3). However, the new law generally does not detail the specific interim steps or interim deadlines that will need to be met to implement each MOCRA requirement, leaving those determinations to the agency's discretion. Establishing an implementation plan that details interim steps and interim deadlines would facilitate effective project management by allowing the agency to gauge its progress and identify if corrective action is needed.[55]

[54]According to FDA, firms exporting products from the United States are often asked by foreign governments or customers to supply a certificate as a required part of the process to import a product into their country. FDA issues such certificates, if requested.

[55]Setting interim milestones facilitates effective project management, according to guidance from the Project Management Institute, Inc. The Project Management Institute is a not-for-profit association that, among other things, provides standards for managing various aspects of projects, programs, and portfolios. The institute publishes the PMBOK® Guide, which calls for planning documents that articulate interim milestones, significant events, reviews, and decision points. See Project Management Institute, Inc., A *Guide to the Project Management Body of Knowledge (PMBOK® Guide),* Seventh Edition (2021). *PMBOK* is a trademark of the Project Management Institute, Inc.

Table 3: MoCRA Deadlines and Requirements

The President signed into law the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) through the Consolidated Appropriations Act, 2023, on December 29, 2022.

MoCRA deadline	MoCRA requirement
December 29, 2023	• Companies must register their existing cosmetic facilities and submit listings of their cosmetic products to the Food and Drug Administration (FDA).[a] • FDA must issue proposed regulations, to the public for comment, which establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. FDA must issue final regulations no later than 180 days after the public comment period closes. • Companies must ensure and maintain records supporting the adequate substantiation of the safety of their cosmetic products. • Companies must maintain records related to each report of an adverse event associated with a cosmetic product and provide FDA with access to such records during inspections. Companies must also submit reports of serious adverse events associated with the use of a cosmetic product to the FDA no later than 15 business days after the report is received by the company. • FDA's enforcement authority goes into effect to mandate cosmetic product recalls. • Cosmetic products intended to be used only by a professional must bear a label that contains a clear and prominent statement that the product shall be administered or used only by licensed professionals and must be in conformity with the cosmetic labeling requirements under MoCRA and the Fair Packaging and Labeling Act.
June 29, 2024	• FDA must issue a proposed rule, to the public for comment, on what substances it determines to be fragrance allergens. FDA must issue a final rule no later than 180 days after the public comment period closes.
December 29, 2024	• FDA must publish a proposed rule for good manufacturing practices for cosmetics facilities. • Companies must include their contact information on their cosmetic product labels, through which they can receive adverse event reports.
December 29, 2025	• FDA must publish a final rule for good manufacturing practices for cosmetics facilities. • FDA must publish a report summarizing the results of an assessment of the use of per- and polyfluoroalkyl substances in cosmetic products and the scientific evidence on the safety and risks associated with such use.

Source: GAO analysis of MoCRA. | GAO-24-105542

Note: MoCRA includes exemptions from some requirements for owners and operators of facilities whose average gross annual sales in the United States for the prior 3-year period were less than $1,000,000, adjusted for inflation, and meet certain other criteria.

[a]On November 8, 2023, FDA announced that it will delay enforcing the requirements related to cosmetic facility registration and cosmetic product listings until 6 months after the statutory deadline to provide companies additional time to comply with these requirements. FDA intends to begin enforcement on July 1, 2024.

According to FDA's Chief Scientist, FDA has not developed a written implementation plan for all MoCRA requirements because it has been prioritizing planning for the near-term requirements in the law. For example, FDA has been focused on establishing a mandatory cosmetic firm registration and product listing system by December 2023. FDA's prioritizing of near-term requirements is understandable and highlights FDA's focus on MoCRA's most immediate statutory deadlines; however, such a focus does not position the agency to address all of MoCRA's requirements and deadlines in later calendar years. By developing an implementation plan with interim steps, a timeline, key milestones, and deliverables, FDA would better ensure that MoCRA's requirements will be fulfilled in a timely manner.

Transparency through reporting: partially addressed. FDA has reported on its public website some actions it has taken to implement MoCRA. For example, in August 2023, FDA publicly announced its issuance of draft guidance that describes MoCRA's requirements for facility registration and product listing. FDA also publicly announced a June 2023 listening session designed to obtain input from cosmetics manufacturers on FDA's development of regulations for good manufacturing practices at cosmetics facilities, as required by MoCRA.[56]

However, FDA has not reported on its progress in meeting other MoCRA requirements, such as the requirement that FDA issue a proposed rule on fragrance allergens. According to FDA's Chief Scientist, FDA has not reported on its progress in meeting all MoCRA requirements because it has been prioritizing planning for the near-term requirements in the law. FDA's prioritization of near-term requirements is understandable and highlights FDA's focus on MoCRA's most immediate statutory deadlines. However, by more fully reporting on its actions, FDA would better ensure transparency for FDA management, Congress, and the public on the progress of its implementation efforts across all MoCRA requirements.

Measuring results: generally not addressed. FDA has not put in place processes for measuring the results of its efforts against the requirements identified in the new law. More specifically, FDA has not developed processes to collect the needed data and evidence to assess the effectiveness of its implementation efforts against the MoCRA requirements that apply to the agency. For example, according to FDA officials, the agency has not developed performance indicators that it

[56]Pub. L. No. 117-328, div. FF, tit. III, subtit. E, § 3502 (codified at 21 U.S.C. § 364b).

could use to assess company compliance with the registration and product listing system that FDA is required to develop under MoCRA. According to the Director of FDA's Office of Cosmetics and Colors, FDA has not developed such processes because it is too early to do so, given that FDA is in the initial stages of implementing MoCRA's provisions. FDA's prioritizing of the initial stages of implementing MoCRA's provisions is understandable. However, such processes should be established from the beginning of an agency reform effort to facilitate ongoing assessment of whether the effort is meeting the agency's reform goals—in this case, MoCRA's requirements.[57] By developing processes for collecting the necessary data and determining how it will use it to measure results, FDA would better ensure that it is implementing MoCRA effectively.

FDA Has Taken Steps to Engage Its Employees in Implementing MoCRA but Has Not Fully Addressed Leading Practices for Strategic Management of Its Workforce

FDA has taken steps to engage its employees in implementing MoCRA—for example, by establishing working groups—but its actions have not fully addressed leading practices for strategically managing its workforce in implementing the new law. Such practices are designed to enhance employee engagement and provide for long-term workforce planning. Table 4 shows our assessment of the extent to which FDA has addressed leading practices for strategically managing the federal workforce and selected key questions that are associated with such leading practices. These leading practices cover (1) employee engagement and (2) strategic workforce planning.

[57]Performance measurement is the ongoing monitoring and reporting of program accomplishments, particularly progress toward achieving preestablished goals. See GAO, *Program Evaluation: Key Terms and Concepts*, GAO-21-404SP (Washington, D.C.: Mar. 22, 2021).

Table 4: Extent to Which FDA Addressed Selected Leading Practices for Agency Reforms and Key Questions for Strategically Managing the Federal Workforce in Implementing MoCRA

Selected leading practice for agency reforms category	Selected leading practice for agency reforms subcategory and extent addressed overall	Selected key question associated with the leading practice and extent addressed
Strategically Managing the Federal Workforce	Employee Engagement ◑	How does the agency plan to sustain and strengthen employee engagement during and after the reforms? ●
		How specifically is the agency planning to manage diversity and ensure an inclusive work environment in its reforms? ○
	Strategic Workforce Planning ◑	To what extent has the agency conducted strategic workforce planning to determine whether it will have the needed resources and capacity, including the skills and competencies, in place for the proposed reforms or reorganization? ◑
		How has the agency assessed the effects of the proposed agency reforms on the current and future workforce and what does that assessment show? ◑
		To what extent does the agency track the number and cost of contractors supporting its agency mission and the functions those contractors are performing? ●
		What succession planning has the agency developed and implemented for leadership and other key positions in areas critical to reforms and mission accomplishment? ●
		To what extent have the reforms included important practices for effective recruitment and hiring, such as customized strategies to recruit highly specialized and hard-to-fill positions? ◑

● FDA took actions that generally addressed the leading practice or the individual key question.

◑ FDA took actions that partially addressed the leading practice or the individual key question.

○ FDA took few to no actions to address the leading practice or the individual key question.

FDA = Food and Drug Administration

MoCRA = Modernization of Cosmetics Regulation Act of 2022

Source: GAO analysis of FDA documents and interviews with FDA officials. | GAO-24-105542

FDA Has Engaged with Its Employees in Implementing MoCRA but Has Not Developed a Specific Plan to Strengthen Diversity in Hiring

FDA has established working groups to engage with its employees in implementing MoCRA; however, FDA has not developed a specific plan to strengthen diversity, equity, inclusion, and accessibility (DEIA) in its implementation of the law.[58] Overall, FDA has partially addressed our leading practice of employee engagement.

Employee engagement: generally addressed. FDA has engaged with its employees through the MoCRA Implementation Working Group and its associated subworking groups.[59] These groups comprise employees from various offices at FDA, thus engaging employees within and beyond the Office of Cosmetics and Colors in MoCRA implementation.[60] FDA has also engaged with its employees on MoCRA implementation through various meetings and communications. Included were meetings with FDA's Chief Scientist, the senior executive lead for FDA's MoCRA implementation, and town halls for agency staff held by the Office of the Commissioner.[61] Communications included agency-wide informational emails from the Office of the Commissioner. Our prior work has found that increased levels of employee engagement can lead to better

[58]Since issuance of GAO-18-427, GAO has expanded its focus on diversity and inclusion to also include equity and accessibility. See GAO, *Federal Workforce: Strengthening Diversity, Equity, Inclusion, and Accessibility,* GAO-23-106254 (Washington, D.C.: Jan. 24, 2023). This report defines diversity as "the practice of including the many communities, identities, races, ethnicities, backgrounds, abilities, cultures, and beliefs of the American people, including underserved communities." Equity is defined as "the consistent, systematic, fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment." Inclusion is defined as "the recognition, appreciation, and use of the talents and skills of employees of all backgrounds." Accessibility is defined as "the provision of accommodations and modifications to ensure equal access to employment and participation in activities for people with disabilities, and the reduction or elimination of physical and attitudinal barriers to equitable opportunities."

[59]According to FDA officials, FDA established four subworking groups that cover the following MoCRA provisions: (1) good manufacturing practices for the cosmetics industry, (2) mandatory cosmetic firm registration and product listing system, (3) cosmetic fragrance allergen labeling, and (4) standardized testing methods for detecting asbestos in talc-containing cosmetics. Pub. L. No. 117-328, div. FF, tit. III, subtit. E, §§ 3502 (codified at 21 U.S.C. §§ 364b, 364c, 364e(b)); 3505.

[60]Additional FDA offices represented in the membership of the subworking groups include the Center for Drug Evaluation and Research, the Office of the Chief Counsel, the Office of the Chief Scientist, the Office of Compliance, the Office of Economics and Analysis, the Office of Food Additive Safety, the Office of Operations, the Office of Regulations and Policy, and the Office of Regulatory Affairs.

[61]According to FDA officials, these meetings covered multiple topics, including MoCRA implementation.

organizational performance and can sustain or increase levels of employee morale.[62]

Diversity, equity, inclusion, and accessibility: generally not addressed. Senior FDA officials acknowledged that the agency does not have a specific plan to strengthen DEIA in its implementation of MoCRA.[63] The officials told us they intend to incorporate DEIA through the recruitment and hiring of diverse personnel to implement MoCRA. However, FDA has not specifically planned for how it will incorporate DEIA into its recruitment and hiring. For example, FDA has not developed targeted outreach strategies to ensure that a diverse applicant pool is aware of potential new employment opportunities related to MoCRA implementation. According to senior FDA officials, they have not developed a specific plan for incorporating DEIA into MoCRA-related hiring because they do not yet know whether they will receive funding to hire new personnel. By developing such a plan as FDA moves forward with future MoCRA hiring efforts, FDA would better ensure it recruits diverse and qualified job applicants and fosters a wider and more diverse talent pool to address MoCRA hiring needs.

FDA Has Begun Taking Steps for Strategic Workforce Planning but Has Not Developed a Plan to Fully Address the Leading Practice

FDA has taken steps to begin strategic workforce planning for implementing MoCRA's requirements. However, FDA has not conducted the full range of strategic workforce planning needed to ensure that it has the right number of personnel with the requisite skills and competencies to implement all of MoCRA's provisions. Thus, FDA has partially addressed our leading practice for strategic workforce planning. Strategic workforce planning is an essential activity that an agency needs to align its human capital program with its current and emerging mission and programmatic goals and to develop long-term strategies for acquiring, developing, and retaining staff to achieve those goals.[64]

[62]GAO-18-427. Employee engagement is generally defined as the sense of purpose and commitment employees feel toward their employer and its mission.

[63]FDA has a *Diversity and Inclusion Strategic Plan, 2018-2021,* which includes a goal to build and maintain a diverse workforce through targeted outreach, recruitment, and hiring. According to FDA officials, FDA's *Diversity and Inclusion Strategic Plan, 2018-2021,* has not been updated and is still in effect. In addition, Executive Order 14035 directed federal agencies to promote DEIA in their workforces. See Exec. Order. No. 14035, *Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce*, 86 Fed. Reg. 34,593 (June 30, 2021).

[64]GAO, *Human Capital: Key Principles for Effective Strategic Workforce Planning,* GAO-04-39 (Washington D.C.: Dec. 11, 2003).

Strategic workforce planning: partially addressed. According to FDA officials, FDA has tasked existing personnel and contractors with implementing MoCRA in the short term.[65] For fiscal year 2024, FDA requested $5 million through its congressional budget justification to hire 12 additional full-time staff to implement MoCRA.[66] According to FDA officials, the 12 additional staff include six employees for the Office of the Chief Scientist and six employees for the Office of Cosmetics and Colors. To fully implement all of MoCRA's provisions, FDA senior officials told us they anticipate needing additional staff beyond the 12 new hires requested. However, as of August 2023, FDA had not developed a strategic workforce plan that identifies the full number and type of personnel, with the requisite skills and competencies, needed to implement MoCRA over the long term.[67]

Assessing effects on workforce: partially addressed. Senior FDA officials told us that having existing staff perform their regular duties, as well as the additional responsibilities they have been tasked with for MoCRA implementation, is not sustainable in the long term. Such additional responsibilities include participating in the four subworking groups for MoCRA implementation. Officials said that the additional workload has not yet undermined morale but poses a risk of doing so. Accordingly, as previously noted, FDA has requested funding for 12 new staff to implement MoCRA. Senior FDA officials said that they also plan to request additional funding to hire more personnel to implement MoCRA in future years.

[65]As of August 2023, FDA officials reported that the agency had assigned two detailees—a senior regulatory counsel and a senior program manager—and three contractors, in addition to its existing staff, to implement MoCRA in the short term.

[66]U.S. Department of Health and Human Services, Food and Drug Administration, *Justification of Estimates for Appropriations Committees, Fiscal Year 2024*.

[67]As of August 2023, FDA also did not yet have an agency-wide strategic workforce plan in place. In January 2022, GAO recommended that FDA develop and implement an agency-wide strategic workforce plan to document agency-wide human capital goals and strategies. See GAO, *FDA Workforce: Agency-Wide Workforce Planning Needed to Ensure Medical Product Staff Meet Current and Future Needs*, GAO-22-104791 (Washington, D.C.: Jan. 14, 2022). In December 2022, the Food and Drug Omnibus Reform Act of 2022 was enacted through the Consolidated Appropriations Act, 2023; this law requires FDA to develop an agency-wide strategic workforce plan by September 30, 2023. Pub. L. No. 117–328, div. FF, title III, subtit. F, Ch. 3, § 3623, 136 Stat. 4459, 5878 (codified at 21 U.S.C. § 379d–3b).

However, as of August 2023, FDA had not developed a written assessment of the effects of implementing all of MoCRA's requirements on the agency's current and future workforce. For example, such an assessment would enable FDA to identify and develop strategies to address gaps in personnel and capacity, including the skills and competencies needed to implement MoCRA. FDA's assessment to date has been informal and focused on meeting near-term requirements. A written assessment is a prerequisite for developing a strategic workforce plan for MoCRA implementation; it would also help support future requests for funding.[68]

Tracking contractors: generally addressed. As of August 2023, FDA had employed three contractors for MoCRA implementation and had tracked the cost of these contractors. Two individual contractors, both epidemiologists, were hired on one-year contracts totaling approximately $447,000. In addition, according to agency officials, FDA issued a task order to an existing FDA information technology service provider for 4,800 hours of services related to MoCRA implementation, at a cost of approximately $857,000.

Succession planning: generally addressed. FDA's MoCRA Implementation Working Group includes both FDA's Chief Scientist and the Deputy Director of the Office of the Chief Scientist, as well as both the Director and Deputy Director of the Office of Cosmetics and Colors. Including the deputies in the working group provides for leadership succession in MoCRA implementation if either the Chief Scientist or the Director of the Office of Cosmetics and Colors were to leave the agency to take a new position, retire, or leave for other reasons.

Recruitment and hiring: partially addressed. To implement MoCRA, FDA may need additional personnel with expertise in subjects including toxicology, cosmetic chemistry, epidemiology, microbiology, and medicine, according to senior FDA officials. The funding that FDA requested to hire 12 staff members in fiscal year 2024 includes funding to hire additional experts to implement MoCRA provisions, such as the required assessment of the use of per- and polyfluoroalkyl substances (PFAS) in cosmetics. Additionally, FDA officials told us they intend to use FDA's expanded authorities, as appropriate, to help recruit and hire cosmetics experts if the agency receives funding to hire new personnel to

[68]For more details on the strategic workforce planning process, see GAO-04-39.

implement MoCRA.[69] According to FDA officials, these hiring authorities enhance FDA's ability to pay potential hires more than otherwise allowed by the federal pay system and allows FDA to target and recruit staff with specialized skills and knowledge that demand higher salaries. However, FDA has not developed customized strategies to recruit and hire personnel needed for MoCRA implementation. For example, FDA has not identified specific sources for recruiting new personnel, such as through professional and industry associations for cosmetics, nor has it developed position descriptions for the personnel needed.

According to FDA's Chief Scientist, the reason FDA has not fully addressed the leading practice of strategic workforce planning is because the agency has been prioritizing planning for the near-term requirements in MoCRA. FDA's prioritizing the near-term requirements in the new law is understandable. However, to successfully implement all of MoCRA's provisions by December 2025, FDA will need the right number of personnel with the requisite skills and competencies—some of which may be specialized and scientific or technical. FDA would be better positioned to implement all of MoCRA's requirements within the statutory deadlines by developing (1) an assessment of the effects of MoCRA on the current and future workforce; (2) a multiyear strategic workforce plan; and (3) effective recruitment and hiring practices for MoCRA implementation, such as customized strategies to recruit highly specialized and hard-to-fill positions. Such strategic workforce planning could also help inform any future FDA budget requests for additional personnel to implement MoCRA.

Conclusions

Cosmetics are used by millions of people every day. Consumer groups and some scientists have raised concerns that substances in cosmetics may harm human health. Research has established that certain substances found in cosmetics are potentially harmful. In December 2022, Congress enacted MoCRA, which significantly expanded FDA's authorities to regulate the safety of cosmetics and established new requirements for the agency. The new law set deadlines for implementation of these authorities and requirements in calendar years 2023 through 2025.

[69]The Food and Drug Omnibus Reform Act expanded FDA's authority to appoint and set the annual rate of pay for candidates to scientific, technical, or professional positions, such that this authority now applies to the regulation of cosmetics and food, in addition to medical products. Pub. L. No. 117–328, div. FF, title III, subtit. F, Ch. 3, § 3624, 136 Stat. 4459, 5879 (amending 21 U.S.C. § 379d–3a).

To the agency's credit, FDA has taken a number of important steps to implement some of MoCRA's requirements since its enactment. However, to better ensure full and successful implementation of MoCRA, FDA will need to manage and monitor the progress of its MoCRA-related efforts against planned interim steps and interim deadlines contained in an implementation plan. FDA leadership and Congress could better track such progress if the agency ensured reform effort transparency by reporting on the status of implementation for all of MoCRA's key milestones and deliverables. FDA leadership could better manage and monitor MoCRA implementation efforts if the agency established data and evidence collection processes to facilitate ongoing assessment of the effectiveness of these efforts.

FDA would also better ensure successful implementation of MoCRA by strengthening employee engagement and strategic workforce planning efforts. Leadership could more strategically plan for FDA's workforce needs if the agency assessed the law's effects on the agency's current and future workforce against the agency's expanded authorities. Such an assessment could help inform development of a strategic workforce plan that identifies the needed personnel and capacity, including skills and competencies, to implement all of MoCRA's requirements. By more fully addressing our leading practices for agency reforms, FDA would better ensure its promotion of public health through its efforts to oversee cosmetic safety.

Recommendations for Executive Action

We are making the following seven recommendations to FDA:

The FDA Commissioner should ensure that the Office of the Chief Scientist develops an implementation plan for MoCRA—including a timeline with interim steps and interim deadlines—for completing all MoCRA requirements within the statutorily prescribed deadlines. (Recommendation 1)

The FDA Commissioner should ensure that the Office of the Chief Scientist reports on key milestones for all MoCRA requirements. Processes for such reporting could be incorporated into an implementation plan for MoCRA. (Recommendation 2)

The FDA Commissioner should ensure that the Office of the Chief Scientist develops processes to collect needed data and evidence to measure the agency's MoCRA implementation efforts against requirements identified in the new law. Such processes for data and

evidence collection could be incorporated into FDA's implementation plan for MoCRA. (Recommendation 3)

The FDA Commissioner should ensure that the Office of the Chief Scientist assesses the effects of implementing all MoCRA provisions on the current and future workforce. (Recommendation 4)

The FDA Commissioner should ensure that the Office of the Chief Scientist develops a multiyear strategic workforce plan that identifies the needed personnel and capacity, including skills and competencies, to implement all MoCRA requirements. (Recommendation 5)

The FDA Commissioner should ensure that the Office of the Chief Scientist develops a plan to strengthen DEIA when recruiting and hiring additional staff to implement MoCRA. Such a plan could be incorporated into a multiyear strategic workforce plan for MoCRA implementation. (Recommendation 6)

The FDA Commissioner should ensure that the Office of the Chief Scientist adopts effective recruitment and hiring practices for MoCRA implementation, such as customized strategies to recruit highly specialized and hard-to-fill positions. Such practices could be incorporated into a multiyear strategic workforce plan for MoCRA implementation. (Recommendation 7)

Agency Comments

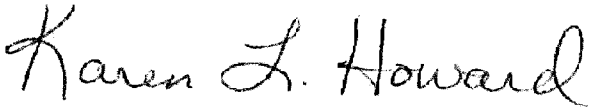
We provided a draft of this report to FDA for review and comment. In written comments reproduced in appendix V the Department of Health and Human Services stated that FDA generally agreed with our findings and concurred with our recommendations.

In some cases, the department identified steps that FDA is planning to take in response to our recommendations. For example, the department noted that FDA's MoCRA implementation working groups are planning timelines with interim steps and interim deadlines for implementation efforts. In addition, the department noted that FDA has developed an internal database to aid in tracking MoCRA implementation deliverables. The department stated that future progress in implementing MoCRA and addressing our recommendations is contingent upon funding. The department also provided technical comments from FDA, which we incorporated, as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the FDA Commissioner, and other interested parties. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

If you or your staff have any questions, please contact Steve Morris at (202) 512-3841 or morriss@gao.gov or Karen Howard at (202) 512-6888 or howardk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made significant contributions to this report are listed in appendix VI.

Steve Morris
Director, Natural Resources and Environment



Karen L. Howard, PhD
Director, Science, Technology Assessment, and Analytics

List of Requesters

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Andy Harris
Chairman
The Honorable Sanford D. Bishop, Jr.
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
Committee on Appropriations
House of Representatives

The Honorable Betty McCollum
House of Representatives

The Honorable Grace Meng
House of Representatives

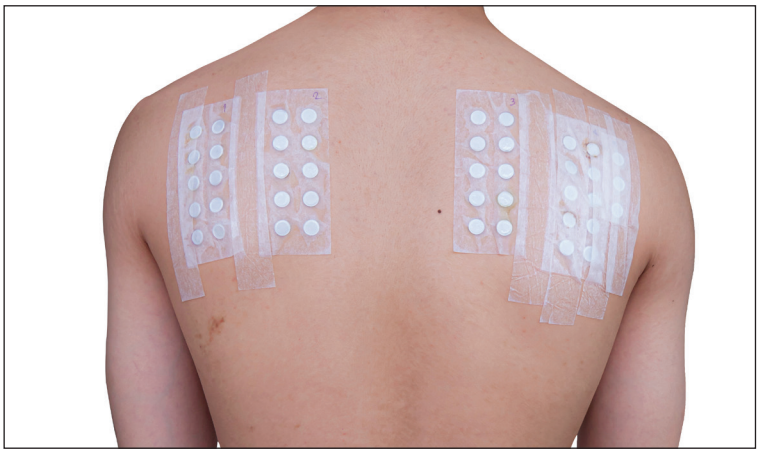
Appendix I: Examples of Ingredients or Contaminants in Cosmetics and Scientific Findings on Their Health Effects

Enclosure I: EXAMPLES OF INGREDIENTS OR CONTAMINANTS IN COSMETICS AND SCIENTIFIC FINDINGS ON THEIR HEALTH EFFECTS

Ingredients That Are Allergens

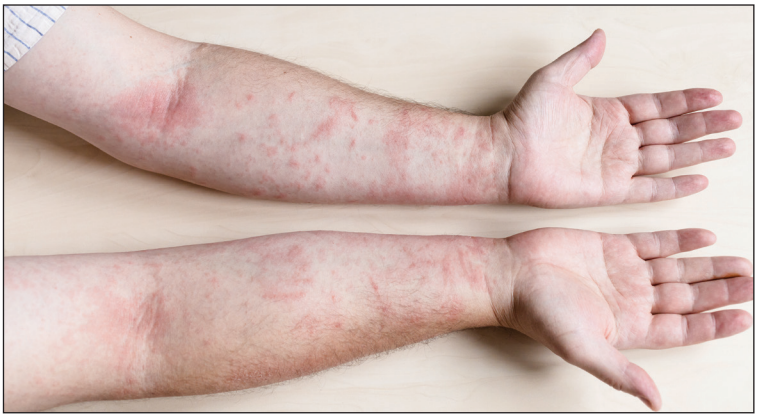
Allergens are ingredients that are usually harmless but can trigger an immune response that results in an allergic reaction in some people. Several chemicals that serve a variety of functions in cosmetics are also allergens. These chemicals include fragrances and preservatives such as formaldehyde releasers (e.g., quaternium-15 and dimethylol dimethyl hydantoin).[1] These ingredients are found in cosmetics such as shampoos, facial cleansers, moisturizers, and hair gel.

The diagnosis of cosmetic allergy is established by reviewing the patient's clinical history and physical examination findings, followed by skin patch testing. Skin patch testing is a multiday process for identifying potential allergens, which are applied to a series of patches on the back.



Source: superrider/stock.adobe.com. | GAO-24-105542

A positive patch test indicates that a certain ingredient may elicit a specific type of allergic reaction known as allergic contact dermatitis (see figs.). Allergic contact dermatitis is a form of eczema that can affect skin on different parts of the body. It is characterized by rashes, blisters, and flaky, dry skin that can itch or burn.



Source: vvoe/stock.adobe.com. | GAO-24-105542

Studies on allergens in cosmetics have shown how allergic contact dermatitis can affect the body.

For example:

- A study of allergens associated with suspected scalp contact dermatitis identified fragrances, including balsam of Peru and fragrance mixes I and II, as the second most common allergens associated in skin patch tests, after metals including nickel and cobalt.[2]

  Patients in the study most commonly reported scalp itching or burning symptoms. Frequent causes of contact dermatitis of the scalp in the patients in the study included shampoos, conditioners, hair gels or oils, as well as leave-on hair products.

- In another study, the top 15 chemicals that most frequently tested positive as allergens in patch tests in patients with dermatitis included cosmetic ingredients. These ingredients included fragrances—specifically fragrances in fragrance mix I and fragrance mix II, balsam of Peru, and hydroperoxides of linalool—as well as preservatives: methylisothiazolinone (MI), methylchloroisothiazolinone/methylisothiazolinone 0.02 percent (MCI/MI), benzisothiazolinone (BIT), and formaldehyde 2 percent.[3]

[1]Formaldehyde-releasing ingredients are preservatives that release small amounts of formaldehyde over time.

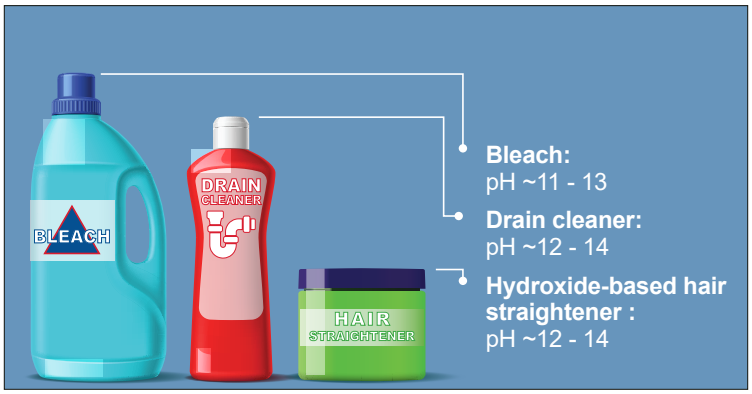
[2]Metals, including nickel and cobalt, were the most common allergens associated with suspected scalp contact dermatitis in skin patch tests, but these allergens were also found in hair accessories, which are not classified as cosmetics. Nouf M. Aleid et al., "Common Allergens Identified Based on Patch Test Results in Patients with Suspected Contact Dermatitis of the Scalp," *Skin Appendage Disorders*, no. 3 (2017): 7-14. The study population included 226 patients, referred for patch testing from a hair clinic. Most of the study population were female (90.7 percent) and had preexisting conditions (82.7 percent). Patients with preexisting conditions may show different results than a general population with contact dermatitis. No allergen could be detected in 45 of the 226 patients.

[3]Joel G. DeKoven et al., "North American Contact Dermatitis Group Patch Test Results: 2017–2018," *Dermatitis*, vol. 32, no. 2 (2021): 111-123. The study population mainly represents patients referred for dermatitis care to 14 dermatologists participating in the study; therefore, findings do not reflect the general population or general dermatology patients.

Ingredients in Hydroxide-Based Hair Straighteners

Source: Kehinde/stock.adobe.com. | GAO-24-105542

Hydroxide-based straighteners, also known as hair relaxers, are cosmetic products used to straighten highly curly hair (see fig. above).[4] Common cosmetic ingredients in these straightener products include guanidine hydroxide (CH_6N_3O) and metal hydroxides such as sodium hydroxide (NaOH), lithium hydroxide (LiOH), and potassium hydroxide (KOH). These ingredients usually have a highly alkaline pH (pH 12–14) and are very irritating to the scalp (see fig. below comparing the pH of common household products and hydroxide-based hair straighteners).[5]



Sources: GAO; VectorBum/stock.adobe.com; Filimon/stock.adobe.com. | GAO-24-105542

Hydroxide-based hair straighteners may also contain ingredients such as fragrances and phthalates—a type of plasticizer, added to soften and add flexibility to cosmetics. As discussed previously, fragrances can be allergens and phthalates have been associated with effects on uterine health (see textbox for an example of a study on this topic).

Some studies have looked at the relationship between hair straighteners, including but not limited to hydroxide-based hair straighteners, and adverse health outcomes. For example, the Sister Study, a large U.S.-based cohort study, found a higher uterine cancer rate for women who self-reported either ever or frequently using hair straightener in the 12 months prior to baseline (at enrollment in the study), relative to those who did not.[6] The association was stronger when comparing frequent use (>4 times in the past 12 months) with no use.

The study found there was no difference in the risk of uterine cancer from hair straightener use between racial and ethnic groups. However, the authors note adverse health effects associated with straighteners could be more consequential for Black women because of their greater frequency of hair product use and younger age of initiating use, resulting in higher concentrations of endocrine-disrupting chemicals in their bodies.

Phthalates, which are common ingredients in cosmetics and other personal care products, have been associated with effects on uterine health. For example, a study we reviewed on phthalate exposure and uterine fibroids in 57 women found that exposure to certain phthalates, such as diethylhexyl phthalate (DEHP), may be associated with fibroid outcomes. The study did not attempt to identify environmental sources of exposure instead looking for biomarkers for exposure. Specifically, the study looked at the associations between phthalate biomarkers in urine and two measures of uterine fibroid burden: diameter of the largest fibroid and uterine volume. The study found that higher urinary concentrations of several phthalate biomarkers were significantly associated with greater uterine volume when controlling for other factors.[7]

[4]Hydroxide-based relaxers are cosmetic products that are not subject to premarket approval by the Food and Drug Administration. Hydroxide-based relaxers are generally creams, which makes application and spreading easier.

[5]The pH indicates how acidic or basic a substance or solution is, measured on a scale of 0 to 14. On this scale, a pH value of 7 is neutral, which means it is neither acidic nor basic. Having the right pH in the blood and other body fluids is important for the body to function properly.

[6]Che-Jung Chang et al., "Use of Straighteners and Other Hair Products and Incident Uterine Cancer," *Journal of the National Cancer Institute*, vol. 114, no.12 (2022): 1636-1645.

[7]Ami R. Zota et al., "Phthalates Exposure and Uterine Fibroid Burden Among Women Undergoing Surgical Treatment for Fibroids: A Preliminary Study," *Fertility and Sterility*, vol. 111 (2019): 112-121. Fibroids are noncancerous growths of the uterus that often appear during childbearing years. They are usually benign but can cause a range of symptoms. The authors note important limitations to this preliminary study, including that all the women in the study were seeking surgical interventions for their fibroids. These results may not be generalizable in women with asymptomatic fibroids or those not seeking medical intervention, and potential measurement error related to the various sources used to characterize the dimensions of individual fibroids and the uterus across the patient populations. The study did not identify the sources of phthalate exposure.

Asbestos Contamination in Talc

Source: Minakryn Ruslan/stock.adobe.com. | GAO-24-105542

Talc is a naturally occurring mineral mined from the earth (see fig.). It has the chemical name hydrous magnesium silicate and the chemical formula $Mg_3Si_4O_{10}(OH)_2$. Talc is an ingredient in cosmetic products such as baby powder (also known as talcum powder), blush, eyeshadow, and pressed powder. Talc may be used to absorb moisture, prevent caking, make facial makeup opaque, or improve the feel of a cosmetic product. Asbestos, an impurity sometimes found in talc, is a naturally occurring silicate mineral and is a known carcinogen.

According to the Food and Drug Administration (FDA), the agency monitors for potential safety problems, such as asbestos contamination in talc in cosmetic products on the market, and takes action when needed to protect the public.[8] The Cosmetic Ingredient Review's Expert Panel for Cosmetic Ingredient Safety, through evaluations, has determined cosmetic talc to be safe (see timeline below). However, some nongovernment studies have found associations between exposure to asbestos in talc and mesothelioma. Mesothelioma is a type of cancer that occurs in the thin layer of tissue that covers the body's internal organs.

The use and safety of talc as a cosmetic ingredient has been evaluated numerous times. The presence of asbestos in talc was identified as early as 1898.[9]

Some studies suggest that mesothelioma may be associated with the use of talcum powder contaminated with asbestos. For example, one study reviewed data on the years of total cosmetic talcum powder usage or other potential asbestos exposures in patients with a mesothelioma diagnosis.[10] The case study found that in 122 of 166 cases, the only known exposure to asbestos was from cosmetic talc. For 44 cases, potential or documented alternate exposures in addition to the cosmetic talc were identified. The authors note that the use of cosmetic talc is often overlooked in studies as a source of asbestos exposure and that for individuals with mixed exposures to asbestos, all exposures should be considered.

Timeline of Key Federal and Industry Trade Association Cosmetic Talc Safety Evaluations

1994	The Food and Drug Administration (FDA) and the International Society of Regulatory Toxicology and Pharmacology held an open workshop to review all the available data on talc safety. They concluded that no health hazards had been demonstrated in connection with the normal use of cosmetic talc.
2004	The National Toxicology Program (NTP) in the U.S. considered listing talc in its report on carcinogens after a NTP review in 2000 found considerable confusion over the physical properties (e.g., mineral characteristics) and consequences of exposure to talc.[a] In October 2005, however, NTP stated that the existing scientific data were insufficient to identify talc as a cancer-causing agent, and NTP withdrew talc from its review process.
2009-2010	FDA conducted an exploratory survey of the cosmetic-grade raw material talc that was marketed at that time. FDA analyzed different talc samples, including four cosmetic-grade talc samples and 34 cosmetic products containing talc. The survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc.
2013	The Cosmetic Ingredient Review's Expert Panel for Cosmetic Ingredient Safety released its report on the safety assessment of talc used in cosmetics.[b] The report concluded that talc is safe in the current usage practices and concentrations.
2020-2022	FDA released results in 2020 for 2019 testing of talc products for asbestos contamination, in 2021 for 2021 testing, and in 2022 for the 2022 testing. In 2022, FDA tested 50 samples and did not detect any asbestos.[c]

Source: GAO. | 105542

[a]The National Toxicology Program is a cooperative effort among Department of Health and Human Services agencies to conduct tests on chemicals to determine whether they have a toxic or cancer-causing effect. The program is the responsibility of the department's National Institute of Environmental Health Sciences.

[b]The Cosmetic Ingredient Review (CIR) was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council), with the support of the U.S. Food and Drug Administration and the Consumer Federation of America. Although funded by the Personal Care Products Council, CIR, the Expert Panel for Cosmetic Ingredient Safety, and the review process are independent from the Personal Care Products Council and the cosmetics industry.

[c]AMA Analytical Services, Inc., was awarded a contract to test talc-containing cosmetics for the presence of asbestos.

[8]For more information on FDA's monitoring of asbestos contamination in talc, see FDA, "Talc," (Washington, D.C.: Dec.7, 2022), accessed Nov.27, 2023, https://www.fda.gov/cosmetics/cosmetic-ingredients/talc.

[9]Edward Salisbury Dana, *A Textbook of Mineralogy With an Extended Treatise on Crystallography and Physical Mineralogy,* (New York, NY: John Wiley & Sons, Inc., 1998).

[10]Jacqueline Moline, Kesha Patel, and Arthur L. Frank, "Exposure to cosmetic talc and mesothelioma," *Journal of Occupational Medicine and Toxicology*," vol. 18, no.1 (2023): 1-13 The authors noted several limitations to this study, including potential biases inherent in studies of cases for which data were collected as part of litigation. Information on patient exposure was collected in sworn testimony from patients and patients' families as part of the litigation's medical-legal review.

Appendix II: Twenty States Prohibit or Restrict Certain Substances in Cosmetics in Addition to Federal Limits

The Modernization of Cosmetics Regulation Act (MoCRA), enacted in December 2022, preempts state or local governments from establishing or continuing any requirement for cosmetics that is different from, or in addition to, any requirement applicable under the law with respect to registration and product listing, good manufacturing practices, records, recalls, adverse event reporting, or safety substantiation.[1] However, states are not preempted from prohibiting or restricting the amount of individual substances in cosmetics.

The FFDCA prohibits the distribution through interstate commerce of cosmetics that are adulterated or misbranded.[2] The Food and Drug Administration (FDA) specifically prohibits or restricts the use of 11 substances in cosmetics.[3] In many instances FDA cites potential health effects of using the substances. For example, FDA regulations state that mercury compounds, which FDA restricts to certain levels, may cause

[1]Pub. L. No 117-328, tit. III, subtit. E, § 3502, 136 Stat. 4459, 5847 (codified at 21 U.S.C. § 364j). As defined in the Federal Food, Drug, and Cosmetic Act (FFDCA), a cosmetic is a product, except soap, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and articles intended for use as a component of any such articles. 21 U.S.C. § 321(i). Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants.

[2]A cosmetic is considered adulterated if, among other things, it contains of a poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling or under customary or usual usage; consists in whole or in part of a filthy, putrid, or decomposed substance; is prepared, packed, or held under insanitary conditions, whereby it may have become contaminated with filth, or may have become injurious to health; or is not a hair dye and contains an unsafe color additive. 21 U.S.C. § 361. A cosmetic is considered misbranded if, among other things, its labeling is false or misleading; it fails to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; any word, statement, or other information required by law to appear on the label or labeling is not prominently placed and in such terms as to render it conspicuous and understood by an ordinary individual under customary conditions of purchase and use; its container is so made, formed, or filled as to be misleading; or it is a color additive, unless its packaging and labeling are in conformity with packaging and labeling requirements applicable to color additives. 21 U.S.C. §362.

[3]The restricted or prohibited substances are (1) bithionol (21 C.F.R. § 700.11); (2) chlorofluorocarbon propellants (21 C.F.R. § 700.23); (3) chloroform (21 C.F.R. § 700.18; (4) halogenated salicylanilides (21 C.F.R. § 700.15; (5) hexachlorophene (21 C.F.R. § 250.250); (6) mercury compounds (21 C.F.R. § 700.13); (7) methylene chloride (21 C.F.R. § 700.19); (8) certain cattle materials (21 C.F.R. § 700.27); (9) ingredients labeled as sunscreen, other than when qualified by a description of the cosmetic benefit of the ingredient (21 C.F.R. § 700.35); (10) vinyl chloride (21 C.F.R. § 700.14); and (11) zirconium-containing aerosols (21 C.F.R. § 700.16).

allergic reactions or skin irritation and accumulate in the body with chronic use.[4] FDA prohibits vinyl chloride in aerosol products, stating that this ingredient has been linked to cancer, among other health problems.[5]

We identified 20 states that have enacted legislation that prohibit or restrict more substances in cosmetics than are prohibited or restricted under federal law and FDA regulations.[6] These states are California, Colorado, Florida, Hawaii, Illinois, Iowa, Maryland, Minnesota, Montana, Mississippi, Nevada, New Mexico, New Jersey, New York, Ohio, Oregon, Vermont, Virginia, Washington, and Wisconsin. In some of these states, legislation describes concerns regarding potential human health effects of such substances.[7]

Some Substances in Cosmetics Are Prohibited or Restricted by Multiple States

Some substances in cosmetics are prohibited or restricted by more than one state. Such substances include 1,4-dioxane, cadmium, color additives, formaldehyde, mercury, parabens, per- and polyfluoroalkyl substances (PFAS), phthalates, methyl (wood) alcohol, and methyl methacrylate, among others. The limits states place on these substances in cosmetics exceed federal law and regulations.

[4]21 C.F.R. § 700.13(b). The use of mercury in cosmetics is prohibited, with the exception of allowing a *de minimus* (less than 0.0001 parts per million) unavoidable amount due to processing and use of less than 0.0065 parts per million as a preservative in eye area cosmetics when no alternatives exist.

[5]21 C.F.R. § 700.14.

[6]Our research methodology may not have captured all state statutes and regulations relevant to substances in cosmetics. Therefore, there may be additional substances that are restricted or prohibited in cosmetics in these states.

[7]For example, the California legislature noted that exposure to perfluoroalkyl and polyfluoroalkyl substances, a class of chemicals known as "PFAS," may lead to serious and harmful health effects. PFAS chemicals have been linked by scientific, peer-reviewed research to severe health problems, including breast and other cancers, hormone disruption, kidney and liver damage, thyroid disease, developmental harm, and immune system disruption, including interference with vaccines. See Cal. Health & Safety Code § 108981(c). In another example, the Colorado General Assembly found that a growing body of scientific research has found that exposure to PFAS chemicals may lead to serious and harmful health effects. Citing this reason and others, Colorado legislation states that the General Assembly determines it necessary for the health and safety of the state's residents to create a regulatory scheme that phases out the sale or distribution of certain products in the state, including cosmetics that contain intentionally added PFAS chemicals. See Colo. Rev. Stat. Ann. § 25-15-602(1)(b), (2).

1,4-dioxane

In New York, the sale or offering for sale any cosmetic product containing 1,4-dioxane, other than trace amounts below 10 parts per million, is prohibited.[8] State law provides that no later than May 1, 2025, and every 2 years thereafter, the Departments of Environmental Conservation and Health shall review such trace concentration thresholds and determine whether such concentrations shall be lowered to better protect human health and the environment.[9]

Oregon, Vermont, and Washington also list 1,4-dioxane among the intentionally added substances in children's products that these states consider as potentially interfering with a child's growth and development.[10] See appendix III for a detailed list of these substances.

Cadmium

Oregon's Toxic-Free Kids Act requires that manufacturers of children's products, including children's cosmetics, offered for sale in the state that contain at or above a minimum level of listed high-priority chemicals, including cadmium, report to the Oregon Health Authority every 2 years, if the manufacturer has worldwide gross sales of $5 million or more.[11] On or before a manufacturer reports for the third time, the manufacturer is required to remove or make a substitution for the chemical or seek a waiver.[12]

In Washington, no manufacturer, wholesaler, or retailer may manufacture, knowingly sell, offer for sale, distribute for sale, or distribute for use a children's cosmetic, among other things, containing cadmium at more than 40 parts per million.[13]

Color Additives

In Virginia, any added poisonous or deleterious substance, or any color additive, shall, with respect to any particular use or intended use, be deemed unsafe with respect to any cosmetic, unless there is a regulation allowing limited use of a quantity of such substance, and the use or

[8]N.Y. Envtl. Conserv. Law § 37-0117(3).

[9]N.Y. Envtl. Conserv. Law § 37-0117(5).

[10]Vt Stat. Ann. tit. 18, § 1773(a)(42); Or. Admin. R. 333-016-2020(45); Wash. Admin. Code § 173-334-130(2).

[11]Or. Rev. Stat. Ann. §§ 431A.253(3)(a)(iv); 431A.255; 431A.258(1)(a); 431A.263; 431A.268. Manufacturers may be granted exemptions for limited purposes. Or. Rev. Stat. Ann. § 431A.258(5)(a).

[12]Or. Rev. Stat. Ann. §§ 431A.260(1)(b), 431A.258, 431A.263, 431A.265.

[13]Wash. Rev. Code Ann. § 70A.430.020(1)(b).

intended use of such substance conforms to the terms prescribed by regulation.[14]

In Hawaii and Montana, the Director of Health and the Department of Health and Human Services, respectively, may adopt regulations prescribing tolerances for any added poisonous or deleterious substances for color additives, prescribing the conditions under which a color additive may be safely used, and providing exemptions where the color additive is to be used solely for investigational or experimental purposes.[15] Similarly, in New Mexico, the Board of Pharmacy may adopt regulations prescribing the conditions under which a color additive may be safely used and exemptions where the color additive is to be used solely for investigational or experimental purposes.[16]

Formaldehyde

In California, starting January 1, 2025, the manufacturing, sale, delivery, holding, or offering for sale of a cosmetic product containing any one of a number of intentionally added ingredients, including formaldehyde and paraformaldehyde, is prohibited, unless the product contains a technically unavoidable trace quantity of the ingredient stemming from impurities of natural or synthetic ingredients.[17] In addition, the California Safe Cosmetics Act of 2005 requires that cosmetics manufacturers provide the California Division of Environmental and Occupational Disease Control within the State Department of Health Services a list of its cosmetic products that are sold in California and that contain any ingredient that is a chemical identified as causing cancer or reproductive toxicity.[18]

In Maryland, starting January 1, 2025, a person may not knowingly manufacture, sell, deliver, hold, or offer for sale a cosmetic product that contains any one of a number of listed intentionally added ingredients, including formaldehyde and paraformaldehyde, unless the product is

[14]Va Code Ann. § 54.1-3460. As of April 21, 2023, we did not identify any existing Virginia regulations allowing limited use of a quantity of a substance.

[15]Haw. Rev. Stat. §328-13(b). Mont. Code Ann. § 50-31-108(1). As of April 21, 2023, we did not identify any existing Hawaii or Montana regulations to this effect.

[16]N.M. Stat. Ann. § 26-1-9(C). As of April 21, 2023, we did not identify any existing New Mexico regulations to this effect.

[17]Cal. Health & Safety Code § 108980.

[18]Cal. Health & Safety Code § 111792(a).

manufactured through a process compliant with the law and contains a technically unavoidable trace quantity.[19]

In Minnesota, a manufacturer, retailer, or wholesaler may not sell or offer for sale a children's product that intentionally contains formaldehyde, including formaldehyde contained in a solution. The prohibition also applies to a children's product that contains intentionally added chemical ingredients that chemically degrade under normal conditions of temperature and pressure to release free formaldehyde at levels exceeding a minimum level of 0.05 percent.[20]

Oregon, Vermont, and Washington also list formaldehyde among other intentionally added chemicals on the states' lists of chemicals of high concern to children's health. [21] In Vermont, for example, manufacturers of children's cosmetics are required to notify the Vermont Department of Health of a chemical of high concern to children if the chemical is intentionally added to a children's product at a level above the lowest concentration that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions (practical quantification limit) or is present in a children's cosmetic as a contaminant at a concentration of 100 parts per million or greater.[22] The Vermont Commissioner of Health is to review the list of chemicals designated as chemicals of high concern to children every 2 years to determine if additional chemicals should be added and may consider designations made by other states, the federal government, other countries, or other governmental agencies.[23]

Lead

In Washington, state law prohibits a manufacturer, wholesaler, or retailer from manufacturing, knowingly selling, offering for sale, distributing for

[19]Md. Code Ann., Health-Gen. § 21-259.2.

[20]Minn. Stat. Ann. § 325F.177(a), (b).

[21]Vt. Stat. Ann. tit. 18, § 1773(a)(1); Or. Admin. R. § 333-016-2020(1); Wash. Admin. Code § 173-334-130.

[22]Vt. Stat. Ann. tit. 18, §§ 1772(5), (7)(A)(i), (15); 1773(a)(1); 1775(a).

[23]Vt. Stat. Ann. Tit. 18, § 1773(b). Vermont's Commissioner of Health may designate additional chemicals of high concern to children by rule. Vt. Stat. Ann. tit. 18, §§ 1773, 1776.

sale, or distributing for use any children's cosmetics containing lead at more than 0.009 percent by weight (90 parts per million).[24]

Mercury

In California, starting January 1, 2025, the manufacturing, sale, delivery, holding, or offering for sale of a cosmetic product containing any one of a number of intentionally added ingredients, including mercury, is prohibited, unless the product contains a technically unavoidable trace quantity of the substance stemming from impurities of natural or synthetic ingredients.[25]

In Illinois, the distribution or sale of any cosmetics, toiletries, or fragrances containing mercury is prohibited,[26] and anyone manufacturing cosmetics, toiletries, or fragrances containing mercury must disclose the level of mercury in the product.[27]

In Maryland, starting January 1, 2025, a person may not knowingly manufacture, sell, deliver, hold, or offer for sale a cosmetic product that contains intentionally added mercury unless it is manufactured through a process compliant with the law and contains a technically unavoidable trace quantity.[28]

In Minnesota, a person may not sell, offer for sale, or distribute any cosmetic containing intentionally added mercury.[29]

In Wisconsin, a person may not sell or distribute a cosmetic, toiletry, or fragrance product containing mercury unless the Department of Natural Resources grants an exemption if it finds that the mercury-added product is reasonable and appropriate for a specific use.[30] Prior to approving an exemption, the Department of Natural Resources may consult with

[24]Wash. Rev. Code Ann. § 70A.430.020(1)(a).

[25]Cal. Health & Safety Code § 108980.

[26]Ill. Comp. Stat. Ann. Ch. 410 § 46/22.

[27]Ill. Comp. Stat. Ann. Ch. 410 § 46/23.

[28]Md. Code Ann., Health-Gen. § 21-259.2.

[29]Minn. Stat. Ann. § 116.92 (Subd. 8i.).

[30]Wis. Stat. Ann. § 299.49(3)(b), (f)(5).

neighboring states to promote consistency in the regulation of mercury-added products.[31]

Parabens

In California and Maryland, starting January 1, 2025, the manufacturing, sale, delivery, holding, or offering for sale of cosmetic products containing intentionally added isobutylparaben and isopropylparaben is prohibited, unless the product contains a technically unavoidable trace quantity of the substance stemming from impurities of natural or synthetic ingredients.[32]

In Washington, a manufacturer of a children's cosmetic containing parabens and other chemicals that the state considers to be high priority in protecting children's health is required to notify the Washington Department of Ecology annually.[33] The Washington Children's Safe Products Act defines a "high priority chemical" as a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as known to do one or more of the following: (a) harm the normal development of a fetus or child or cause other developmental toxicity; (b) cause cancer, genetic damage, or reproductive harm; (c) disrupt the endocrine system; (d) damage the nervous system, immune system, or organs or cause other systemic toxicity; (e) be persistent, bioaccumulative, and toxic; or (f) be very persistent and very bioaccumulative.[34]

PFAS

In California and Maryland, starting January 1, 2025, the manufacturing, sale, delivery, holding, or offering for sale of cosmetic products containing certain intentionally added per- and polyfluoroalkyl substances (PFAS) including perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), is prohibited, unless it contains a technically unavoidable trace quantity of the substance stemming from impurities of natural or synthetic ingredients.[35] Similarly, starting January 1, 2025, in Colorado, the sale,

[31]Wis. Stat. Ann. § 299.49(3)(c).

[32]Cal. Health & Safety Code § 108980 and Md. Code Ann., Health-Gen. § 21-259.2.

[33]Wash. Rev. Code Ann. § 70A.430.060; Wash. Admin. Code § 173-334-130.

[34]Wash. Rev. Code Ann. § 70A.430.010(9). "Bioaccumulative" refers to chemicals accumulating in the tissues of a human or animal's body over time.

[35]Cal. Health & Safety Code § 108980; Md. Code Ann., Health-Gen. § 21-259.2.

offering for sale, distribution for sale, or distribution for use of cosmetic products containing PFAS is prohibited.[36]

Phthalates

In California, starting January 1, 2025, the manufacturing, sale, delivery, holding, or offering for sale of cosmetic products containing intentionally added dibutyl phthalate or diethylhexyl phthalate is prohibited, unless the product contains a technically unavoidable trace quantity of the substance stemming from impurities of natural or synthetic ingredients.

In Maryland, starting January 1, 2025, a person may not knowingly manufacture, sell, deliver, hold, or offer for sale a cosmetic product that contains intentionally added dibutyl phthalate or diethylhexyl phthalate unless the product is manufactured through a process compliant with the law and contains a technically unavoidable trace quantity.

In Washington, no manufacturer, wholesaler, or retailer may manufacture, knowingly sell, offer for sale, distribute for sale, or distribute for use children's cosmetics containing phthalates, individually or in combination, at more than 1,000 parts per million.[37]

Methyl (Wood) Alcohol

In Iowa, no person may possess or dispose of a product intended for cosmetic purposes containing methyl (wood) alcohol, crude or refined, or completely denatured alcohol.[38]

In New Jersey, no person may sell or offer or expose for sale, or possess with intent to distribute or sell, any cosmetic product containing methyl or wood alcohol.[39] In addition, no person may sell or offer or expose for sale, or possess with intent to distribute or sell, or use upon or apply to the body of another, any hair tonic, bay rum or similar preparation, intended for external use, which contains methyl or wood alcohol.[40]

[36]Colo. Rev. Stat. Ann. § 25-15-604(3)(a).

[37]Wash. Rev. Code Ann. § 70A.430.020(1)(c).

[38]Iowa Code Ann. § 205.4.

[39]N.J. Stat. Ann. § 24:5-13.

[40]N.J. Stat. Ann. § 24:5-13.

Methyl Methacrylate

Florida prohibits the use or possession of a cosmetic product containing a liquid nail monomer containing any trace of methyl methacrylate (MMA) in the practice of cosmetology.[41]

Mississippi prohibits the use of any product containing MMA in manicuring or pedicuring procedures; and requires that all products be correctly labeled, and manufacturer's data sheets for any nail product be readily available for review by any agent of the Board of Cosmetology.[42]

Ohio prohibits anyone at a salon or school of cosmetology from using or having a liquid nail monomer containing any trace of MMA.[43]

Flame-Retardant Organohalogenated Chemicals

In Nevada, no manufacturer or wholesaler may knowingly manufacture, sell, offer for sale, distribute for sale or distribute for use a children's product that contains any flame-retardant organohalogenated chemical in any product component in amounts greater than 1,000 parts per million.[44] In addition, no retailer may sell or offer for sale or use a children's product that contains any flame-retardant organohalogenated chemical in any product component in amounts greater than 1,000 parts per million.[45]

Washington has also prohibited manufacturers, wholesalers, or retailers from manufacturing, knowingly selling, offering for sale, distributing for sale, or distributing for use any children's cosmetics containing any of the following flame retardants in amounts greater than 1,000 parts per million: tris 1,3-dichloro-2-propyl phosphate (TDCPP); tris 2-chloroethyl phosphate (TCEP); decabromodiphenyl ether; hexabromocyclododecane (HBCD); or additive tetrabromobisphenol-A (TBBPA).[46]

[41]Fla. Stat. Ann. § 477.0265(1)(g). MMA is used in artificial nail enhancement products.

[42]Miss. Code. Ann. § 73-7-7(3); 30 Miss. Admin. Code Pt. 2101, R. 7.15(H).

[43]Ohio Rev. Code Ann. § 4713.14(M)(3).

[44]Nev. Rev. Stat. Ann. § 597.7139(2). Furthermore, a manufacturer shall not replace a flame-retardant organohalogenated chemical with a chemical that has been identified by a state or federal agency on the basis of credible scientific evidence as being known or suspected to have a high degree of probability to (1) harm the normal development of a fetus or child or cause other developmental toxicity; (2) cause cancer, genetic damage, or reproductive harm; (3) disrupt the endocrine system; or (4) damage the nervous system, immune system or organs, or cause other systemic toxicity. Nev. Rev. Stat. Ann. § 597.714.

[45]Nev. Rev. Stat. Ann. § 597.7139(2).

[46]Wash. Rev. Code Ann. § 70A.430.030.

Appendix III: Prohibited or Restricted Substances in Cosmetics in Five Selected States

We identified 20 states that have enacted legislation prohibiting or restricting more substances in cosmetics than the Food and Drug Administration (FDA) (see app. II). The table below contains information on the five states—California, Maryland, Oregon, Vermont, and Washington—that currently or will prohibit or restrict the greatest number of substances.

Table 5: Prohibited or Restricted Substances in Cosmetics in California, Maryland, Oregon, Vermont, and Washington

State	Prohibited or restricted substance in cosmetics

California	Starting January 1, 2025, the manufacturing, sale, delivery, holding, or offering for sale of a cosmetic product containing any of the following intentionally added ingredients is prohibited, unless the product contains a technically unavoidable trace quantity of the ingredient stemming from impurities of natural or synthetic ingredients.[a] The California list of prohibited ingredients includes
	• dibutyl phthalate (CAS no. 84-74-2);
	• diethylhexyl phthalate (CAS no. 117-81-7);
	• formaldehyde (CAS no. 50-00-0);
	• isobutylparaben (CAS no. 4247-02-3);
	• isopropylparaben (CAS no. 4191-73-5);
	• m-phenylenediamine and its salts (CAS no. 108-45-2);
	• mercury (CAS no. 7439-97-6);
	• methylene glycol (CAS no. 463-57-0);
	• o-phenylenediamine and its salts (CAS no. 95-54-5);
	• paraformaldehyde (CAS no. 30525-89-4);
	• the following per- and polyfluoroalkyl substances (PFAS) and their salts:
	  • ammonium nonadecafluorodecanoate (CAS no. 3108-42-7);
	  • ammonium pentadecafluorooctanoate (CAS no. 3825-26-1);
	  • ammonium perfluorononanoate (CAS no. 4149-60-4);
	  • ammonium perfluorooctane sulfonate; ammonium heptadecafluorooctanesulfonate (CAS 29081-56-9);
	  • diethanolamine perfluorooctane sulfonate (CAS 70225-14-8);
	  • lithium perfluorooctane sulfonate; lithium heptadecafluorooctanesulfonate (CAS 29457-72-5);
	  • nonadecafluorodecanoic acid (CAS no. 355-76-2);
	  • perfluorononanoic acid (PFNA)(CAS no. 375-95-1);
	  • perfluorooctane sulfonate (PFOS); heptadecafluorooctane-1-sulfonic acid (CAS no. 1763-23-1);
	  • perfluorooctanoic acid (PFOA)(CAS no. 335-67-1);
	  • potassium perfluorooctanesulfonate; potassium heptadecafluorooctane-1-sulfonate (CAS no. 2795-39-3);
	  • sodium heptadecafluorononanoate (CAS no. 21049-39-8);
	  • sodium nonadecafluorodecanoate (CAS no. 3830-45-3); or
	• quaternium-15 (CAS no. 51229-78-8).
	
	In addition, starting January 1, 2027, the manufacturing, sale, delivery, holding, or offering for sale of a cosmetic product containing any of the following intentionally added ingredients is prohibited, unless the product contains a technically unavoidable trace quantity of the ingredient stemming from impurities of natural or synthetic ingredients.[b] The California list of prohibited ingredients includes
	• 2–Chloracetamide (CAS no. 79–07–2).
	• 3(or5)-((4–(benzylmethylamino)phenyl)azo)–1,2 -(or1,4)-dimethyl–1H–1,2,4–triazolium and its salts (CAS nos. 89959–98–8 and 12221–69–1).
	• Acetaldehyde (CAS no. 75–07–0).
	• Allyl isothiocyanate (CAS no. 57–06–7).

State	Prohibited or restricted substance in cosmetics

California	• Anthraquinone (CAS no. 84–65–1).
	• Basic blue 3 (CAS no. 33203–82–6).
	• Basic blue 7 (CAS no. 2390–60–5).
	• Basic blue 9 (CAS no. 61–73–4).
	• Basic green 1 (CAS no. 633–03–4).
	• Basic violet 4 (CAS no. 2390–59–2).
	• The following boron substances:
	  ○ Perboric acids:
	  ▪ Sodium salt (CAS no. 11138–47–9).
	  ▪ Sodium salt, monohydrate (CAS no. 12040–72–1).
	  ▪ Sodium perborate monohydrate (CAS no. 10332–33–9).
	  ○ Boric acid (CAS nos. 10043–35–3 and 11113–50–1).
	  ○ Borates, tetraborates, octaborates, and boric acid salts and esters, including all of the following:
	  ▪ Disodium octaborate anhydrous (CAS no. 12008–41–2).
	  ▪ Disodium octaborate tetrahydrate (CAS no. 12280–03–4).
	  ▪ 2–Aminoethanol, monoester with boric acid (CAS no. 10377–81–8).
	  ▪ 2–Hydroxypropyl ammonium dihydrogen orthoborate (CAS no. 68003–13–4).
	  ▪ Potassium borate, boric acid potassium salt (CAS no. 12712–38–8).
	  ▪ Trioctyldodecyl borate.
	  ▪ Zinc borate (CAS no. 1332–07–6).
	  ▪ Sodium borate, disodium tetraborate anhydrous; boric acid, sodium salt (CAS no. 1330–43–4).
	  ▪ Tetraboron disodium heptaoxide, hydrate (CAS no. 12267–73–1).
	  ▪ Orthoboric acid, sodium salt (CAS no. 13840–56–7).
	  ▪ Disodium tetraborate decahydrate; borax decahydrate (CAS no. 1303–96–4).
	  ▪ Disodium tetraborate pentahydrate; borax pentahydrate (CAS no. 12179–04–3).
	• C.I. disperse blue 1 (CAS no. 2475–45–8).
	• C.I. disperse blue 3 (CAS no. 2475–46–9).
	• Cyclohexylamine (CAS no. 108–91–8).
	• Cyclotetrasiloxane (CAS no. 556–67–2).
	• Lily aldehyde (CAS no. 80–54–6).
	• Malachite green (CAS no. 569–64–2).
	• Oil from the seeds of Laurus nobilis L. (CAS no. 84603–73–6).
	• Phytonadione (CAS no. 84–80–0).
	• Pyrogallol (CAS no. 87–66–1).
	• Sodium perborate (CAS no. 15120–21–5).
	• Styrene (CAS no. 100–42–5).
	• Trichloroacetic acid (CAS no. 76–03–9).
	• Tricresyl phosphate (CAS no. 1330–78–5).
	• Trisodium nitrilotriacetate (CAS no. 5064–31–3).
	• Vinyl acetate (CAS no. 108–05–4).

State	Prohibited or restricted substance in cosmetics

Maryland	Starting January 1, 2025, a person may not knowingly manufacture, sell, deliver, hold, or offer for sale a cosmetic product that contains any one of a number of listed intentionally added ingredients unless the product is manufactured through a process compliant with the law and contains a technically unavoidable trace quantity.[c] The Maryland list of prohibited ingredients includes
	• dibutyl phthalate (CAS no. 84-74-2);
	• diethylhexyl phthalate (CAS no. 117-81-7);
	• formaldehyde (CAS no. 50-00-0);
	• isobutylparaben (CAS no. 4247-02-3);
	• isopropylparaben (CAS no. 4191-73-5);
	• m-phenylenediamine and its salts (CAS no. 108-45-2);
	• mercury (CAS no. 7439-97-6);
	• methylene glycol (CAS no. 463-57-0);
	• o-phenylenediamine and its salts (CAS no. 95-54-5);
	• paraformaldehyde (CAS no. 30525-89-4);
	• the following per- and polyfluoroalkyl substances (PFAS) and their salts:
	  • ammonium nonadecafluorodecanoate (CAS no. 3108-42-7);
	  • ammonium pentadecafluorooctanoate (CAS no. 3825-26-1);
	  • ammonium perfluorononanoate (CAS no. 4149-60-4);
	  • ammonium perfluorooctane sulfonate or ammonium heptadecafluorooctanesulfonate (CAS no. 29081-56-9);
	  • diethanolamine perfluorooctane sulfonate (CAS no. 70225-14-8);
	  • lithium perfluorooctane sulfonate or lithium heptadecafluorooctanesulfonate (CAS no. 29457-72-5);
	  • nonadecafluorodecanoic acid (CAS no. 335-76-2);
	  • perfluorooctane sulfonate (PFOS) or heptadecafluorooctane-1-sulfonic acid (CAS no. 1763-23-1);
	  • perfluorooctanoic acid (PFOA) (CAS no. 335-67-1);
	  • perfluorononanoic acid (PFNA) (CAS no. 375-95-1);
	  • potassium perfluorooctane sulfonate or potassium heptadecafluorooctane-1-sulfonate (CAS no. 2795-39-3);
	  • sodium heptadecafluorononanoate (CAS no. 21049-39-8);
	  • sodium nonadecafluorodecanoate (CAS no. 3830-45-3); or
	• quaternium-15 (CAS no. 51229-78-8).

State	Prohibited or restricted substance in cosmetics
Oregon	Oregon's Toxic-Free Kids Act requires that manufacturers of children's products, including children's cosmetics, offered for sale in the state that contain at or above a minimum level of listed high-priority chemicals, report to the Oregon Health Authority every 2years, if the manufacturer has worldwide gross sales of $5 million or more.[c] The Oregon list of high-priority chemicals of concern for children's health includes • 1,1,2,2-tetrachloroethane (CAS no. 79-34-5); • 1,4-dioxane (CAS no. 123-91-1); • 2-aminotoluene (CAS no. 95-53-4); • 2-ethyl-hexyl-4-methoxycinnamate (CAS no. 5466-77-3); • 2-ethylhexanoic acid (CAS no. 149-57-5); • 2-ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB) (CAS no. 183658-27-7); • 2-methoxyethanol (CAS no. 109-86-4); • 2,4-diaminotoluene (CAS no. 95-80-7); • 3,3′-dimethylbenzidine and dyes metabolized to 3,3′-dimethylbenzidine (CAS no. 119-93-7); • 4-chloroaniline (CAS no. 106-47-8); • 4-hydroxybenzoic acid (CAS no. 99-96-7); • 4-nonylphenol (CAS no. 104-40-5); 4-np and its isomer mixtures including CAS no. 84852-15-3 and CAS no. 25154-52-3; • 4-octylphenol (CAS no. 1806-26-4); • 4-tert-octylphenol (CAS no. 140-66-9); • acetaldehyde (CAS no. 75-07-0); • acrylonitrile (CAS no. 107-13-1); • aniline (CAS no. 62-53-3); • antimony and antimony compounds (CAS no. 7440-36-0); • arsenic and arsenic compounds (CAS no. 7440-38-2), including arsenic trioxide (CAS no. 1327-53-3) and dimethyl arsenic (CAS no. 75-60-5); • benzene (CAS no. 71-43-2); • benzophenone-2 (Bp-2) (CAS no. 131-55-5); • butyl benzyl phthalate (BBP) (CAS no. 85-68-7); • bisphenol A (BPA) (CAS no. 80-05-7); • bisphenol F (BPF) (620-92-8) ; • bisphenol S (BPS) (CAS no. 80-09-1); • butyl paraben (CAS no. 94-26-8); • butylated hydroxyanisole (BHA) (CAS no. 25013-16-5); • cadmium and cadmium compounds (CAS no. 7440-43-9); • carbon disulfide (CAS no. 75-15-0); • chlorinated paraffins ((CAS no. 108171-26-2) • c.i. solvent yellow 14; (CAS no. 842-07-9); • cobalt and cobalt compounds (CAS no. 7440-48-4); • decabromodiphenyl ether (BDE-209) (CAS no. 1163-19-5); • dicyclohexyl phthalate (DCHP) (CAS no, 84-61-7); • diethyl phthalate (DEP) (CAS no. 84-66-2); • diisobutyl phthalate (DIBP) (CAS no. 84-69-5); • di-2-ethylhexyl phthalate (DEHP) (CAS no. 117-81-7);

State	Prohibited or restricted substance in cosmetics
Oregon	• di-n-butyl phthalate (DBP) (CAS no. 84-74-2); • di-n-hexyl phthalate (DnHP) (CAS no. 84-75-3); • di-n-octyl phthalate (DnOP) (CAS no. 117-84-0); • diisodecyl phthalate (DIDP) (CAS no. 26761-40-0); • diisononyl phthalate (unbranched) (DINP) (CAS no. 28553-12-0); • estragole (CAS no. 140-67-0); • ethylbenzene (CAS no. 100-41-4); • ethylhexyl diphenyl phosphate (EHDPP) (CAS no.1241-94-7); • ethyl paraben (CAS no. 120-47-8); • ethylene glycol (CAS no. 107-21-1); • ethylene glycol monoethyl ether (CAS no. 110-80-5); • formaldehyde (CAS no. 50-00-0); • hexabromocyclododecane (CAS no. 25637-99-4); • hexachlorobenzene (CAS no. 118-74-1); • hexachlorobutadiene (HCDB) (CAS no. 87-68-3); • mercury and mercury compounds (CAS no. 7439-97-6); • methyl ethyl ketone (CAS no. 78-93-3); • methyl paraben (CAS no. 99-76-3); • methylene chloride (CAS no. 75-09-2); • n-methylpyrrolidone (CAS no. 872-50-4); • n-nitrosodimethylamine (CAS no. 62-75-9); • n-nitrosodiphenylamine (CAS no. 86-30-6); • pentachlorobenzene (CAS no. 608-93-5); • perfluorooctane sulfonic acid and its salts (PFOS) (CAS no. 1763-23-1); • phenol (CAS no. 108-95-2); • propyl paraben (CAS no. 94-13-3); • short-chain chlorinated paraffins (SCCP) (CAS no. 85535-84-8); • styrene (CAS no. 100-42-5); • tetrabromobisphenol A (TBBPA) (CAS no. 79-94-7); • tetrachloroethene (CAS no. 127-18-4); • toluene (CAS no. 108-88-3); • triphenyl phosphate (TPP) (CAS no. 115-86-6); • tris(1-chloro-2-propyl) phosphate (TCPP) (CAS no. 13674-84-5); • tris(1,3-dichloro-2-propyl) phosphate (TDCPP) (CAS no. 13674-87-8); • tris(2-chloroethyl) phosphate (TCEP) (CAS no. 115-96-8); or • vinyl chloride (CAS no. 75-01-4).

State	Prohibited or restricted substance in cosmetics
Vermont	A manufacturer of a children's product, including a children's cosmetic is required to notify the Vermont Department of Health of a chemical of high concern to children if the chemical is intentionally added to a children's product at a level above the lowest concentration that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions (practical quantification limit); or is present in a children's cosmetic as a contaminant at a concentration of 100 parts per million or greater. Vermont has designated the following intentionally added chemicals as chemicals of high concern to children:[f] • 1,4-dioxane (CAS no. 123-91-1); • 1,1,2,2-tetrachloroethane (CAS no. 79-34-5); • 2-aminotoluene (CAS no. 95-53-4); • 2,4-diaminotoluene (CAS no. 95-80-7); • 2-ethyl-hexyl-4-methoxycinnamate (CAS no. 5466-77-3); • 2-ethylhexanoic acid (CAS no. 149-57-5); • 2-methoxyethanol (CAS no. 109-86-4); • 2,2',3,3',4,4',5,5',6,6'-decabromodiphenyl ether; BDE-209 (CAS no. 1163-19-5); • 3,3'-dimethylbenzidine and dyes metabolized to 3,3'-dimethylbenzidine (CAS no. 119-93-7); • 4-nonylphenol (CAS no. 104-40-5); 4-NP and its isomer mixtures including CAS no. 84852-15-3 and CAS no. 25154-52-3); • 4-tert-octylphenol (CAS no. 140-66-9); 4(1,1,3,3-tetramethylbutyl) phenol; • acetaldehyde (CAS no. 75-07-0); • acrylonitrile (CAS no. 107-13-1); • aniline (CAS no. 62-53-3); • antimony and antimony compounds (CAS no. 7440-36-0); • arsenic (CAS no. 7440-38-2) and arsenic compounds, including arsenic trioxide (CAS no. 1327-53-3) and dimethyl arsenic (CAS no. 75-60-5); • benzene (CAS no. 71-43-2); • benzene, pentachloro (CAS no. 608-93-5); • benzophenone-2 (Bp-2) (CAS no. 131-55-5); 2,2',4,4'-tetrahydroxybenzophenone; • bisphenol A (CAS no. 80-05-7); • butyl benzyl phthalate (CAS no. 85-68-7); • butyl paraben (CAS no. 94-26-8); • butylated hydroxyanisole (BHA) (CAS no 25013-16-5); • cadmium and cadmium compounds (CAS no. 7440-43-9); • carbon disulfide (CAS no. 75-15-0); • c.i. solvent yellow 14 (CAS no. 842-07-9); • cobalt and cobalt compounds (CAS no. 7440-48-4); • di-2-ethylhexyl phthalate (CAS no. 117-81-7); • di-n-hexyl phthalate (CAS no. 84-75-3); • di-n-octyl phthalate (DnOP) (CAS no. 117-84-0); • dibutyl phthalate (CAS no. 84-74-2);

State	Prohibited or restricted substance in cosmetics
Vermont	• diethyl phthalate (CAS no. 84-66-2); • diisodecyl phthalate (DIDP) (CAS no. 26761-40-0); • diisononyl phthalate (DINP) (CAS no. 28553-12-0); • estragole (CAS no. 140-67-0); • ethylbenzene (CAS no. 100-41-4); • ethylene glycol (CAS no. 107-21-1); • ethylene glycol monoethyl ether (CAS no. 110-80-5); • ethyl paraben (CAS no. 120-47-8); • formaldehyde (CAS no. 50-00-0); • hexabromocyclododecane (CAS no. 25637-99-4); • hexachlorobenzene (CAS no. 118-74-1); • hexachlorobutadiene (CAS no. 87-68-3); • methylene chloride (CAS no. 75-09-2); • methyl ethyl ketone (CAS no. 78-93-3); • methyl paraben (CAS no. 99-76-3); • mercury (CAS no. 7439-97-6) and mercury compounds, including methyl mercury (CAS no. 22967-92-6); • molybdenum and molybdenum compounds (CAS no. 7439-98-7); • n-methylpyrrolidone (CAS no. 872-50-4); • n-nitrosodimethylamine (CAS no. 62-75-9); • n-nitrosodiphenylamine (CAS no. 86-30-6); • octamethylcyclotetrasiloxane (CAS no. 556-67-2); • p-hydroxybenzoic acid (CAS no. 99-96-7); • para-chloroaniline (CAS no. 106-47-8); • perchloroethylene (CAS no. 127-18-4); • perfluoroheptanoic acid (PFHpA) (CAS no. 375-85-9); • perfluorohexane sulfonic acid (PFHxS) (CAS no. 355-46-4); • perfluorononanoic acid (PFNA) (CAS no. 375-95-1); • perfluorooctanyl sulphonic acid (PFOS) (CAS no. 1763-23-1) and its salts; • phenol (CAS no. 108-95-2); • phenol, 4-ocytl- (CAS no. 1806-26-4); • phthalic anhydride (CAS no. 85-44-9); • propyl paraben (CAS no. 94-13-3); • styrene (CAS no. 100-42-5); • tetrabromobisphenol A (CAS no. 79-94-7); • toluene (CAS no. 108-88-3); • tris(1,3-dichloro-2-propyl)phosphate (CAS no. 13674-87-8); • tris(2-chloroethyl) phosphate (CAS no. 115-96-8); or • vinyl chloride (CAS no. 75-01-4).

State	Prohibited or restricted substance in cosmetics
Washington	A manufacturer of a children's product, including a children's cosmetic containing any chemical that the state considers to be high priority in protecting children's health is required to notify the Washington Department of Ecology annually.[f] Washington has designated the following as chemicals of high concern to children:[g] • 1,4-dioxane (CAS no.123-91-1); • 1,1,2,2-tetrachloroethane (CAS no. 79-34-5); • 2-aminotoluene (CAS no. 95-53-4); • 2,4-diaminotoluene (CAS no. 95-80-7); • 2-ethyl-hexyl-4-methoxycinnamate (CAS no. 5466-77-3); • 2-ethylhexyl-2,3,4,5-tetra-bromobenzoate (TBB) (CAS no. 183658-27-7); • 2-ethylhexanoic acid (CAS no. 149-57-5); • 2-methoxyethanol (CAS no. 109-86-4); • 3,3′-dimethylbenzidine and dyes metabolized to 3,3′-dimethylbenzidine (CAS no. 119-93-7); • 4-chloroaniline (CAS no. 106-47-8); • 4-hydroxybenzoic acid (CAS no. 99-96-7); • 4-nonyl phenol branched (CAS no. 84852-15-3); • 4-nonylphenol (CAS no.104-40-5); • 4-octylphenol (CAS no. 1806-26-4); • 4-octylphenol (CAS no. 140-66-9); • acetaldehyde (CAS no. 75-07-0); • acrylonitrile (CAS no. 107-13-1); • aniline (CAS no. 62-53-3); • antimony & antimony compounds (CAS no. 7440-36-0); • arsenic & arsenic compounds (CAS no. 7440-38-2) including arsenic trioxide (1327-53-3) and dimethyl arsenic acid (75-60-5); • benzene (CAS no. 71-43-2); • benzophenone-2 (Bp-2) (CAS no. 131-55-5); • bis(chloromethyl)propane-1,3-diyl tetrakis-(2-chloroethyl) bis(phosphate)(V6) (CAS no. 38051-10-4); • bis(2-ethylhexyl) tetrabromophthalate (TBPH) (CAS no. 26040-51-7); • bisphenol A (BPA) (CAS no. 80-05-7); • bisphenol F (BPF) (CAS no. 620-92-8); • bisphenol S (BPS) (CAS no. 80-09-1); • butyl benzyl phthalate (BBP) (CAS no. 85-68-7); • butyl paraben (CAS no. 94-26-8); • butylated hydroxyanisole (BHA) (CAS no. 25013-16-5); • cadmium & cadmium compounds (CAS no. 7440-43-9); • carbon disulfide (CAS no. 75-15-0); • chlorinated paraffins (CAS no. 108171-26-2); • c.i. solvent yellow 14 (CAS no. 842-07-9); • decabromodiphenyl ethane (DBDPE) (CAS no. 84852-53-9); • decabromodiphenyl ether (BDE-209) (CAS no. 1163-19-5); • di-(2-ethylhexyl) phthalate (DEHP) (CAS no. 117-81-7); • di-(2-methoxyethyl) phthalate (DMEP) (CAS no. 117-82-8);

State	Prohibited or restricted substance in cosmetics
Washington	• di-n-butyl phthalate (DBP) (CAS no. 84-74-2); • di-n-hexyl phthalate (DnHP) (CAS no. 84-75-3); • di-n-octyl phthalate (DnOP) (CAS no. 117-84-0); • dicyclohexyl phthalate (DCHP) (CAS no. 84-61-7); • diethyl phthalate (DEP) (CAS no. 84-66-2); • diisobutyl phthalate (DIBP) (CAS no. 84-69-5); • dipentyl phthalate (DPP) (CAS no. 131-18-0); • diisodecyl phthalate (DIDP) (CAS no. 26761-40-0); • diisononyl phthalate (unbranched) (DINP) (CAS no. 28553-12-0); • estragole (CAS no. 140-67-0); • ethylbenzene (CAS no. 100-41-4); • ethylhexyl diphenyl phosphate (EHDPP) (CAS no. 1241-94-7); • ethylene glycol (CAS no. 107-21-1); • ethylene glycol monoethyl ether (CAS no.110-80-5); • ethyl paraben (CAS no. 120-47-8); • formaldehyde (CAS no. 50-00-0); • hexachlorobenzene (CAS no. 118-74-1); • hexachlorobutadiene (CAS no. 87-68-3); • hexabromocyclododecane (HBCD) (CAS no. 25637-99-4); • isopropylated triphenyl phosphate (IPTPP) (CAS no. 68937-41-7); • methylene chloride (CAS no. 75-09-2); • methyl ethyl ketone (CAS no. 78-93-3); • methyl paraben (CAS no. 99-76-3); • mercury & mercury compounds including methyl mercury (22967-92-6) (CAS no. 7439-97-6); • n-methylpyrrolidone (CAS no. 872-50-4); • n-nitrosodiphenylamine (CAS no. 86-30-6); • n-nitrosodimethylamine (CAS no. 62-75-9); • nonyl phenol (CAS no. 25154-52-3); • perfluorooctanoic acid (PFOA) and related substances (CAS no. 335-67-1); • pentachlorobenzene (CAS no. 608-93-5); • perfluorooctane sulfonic acid (PFOS) and its salts (CAS no. 1763-23-1); • phenol (CAS no. 108-95-2); • propyl paraben (CAS no. 94-13-3); • short-chain chlorinated paraffins (SCCP) (CAS no. 85535-84-8); • styrene (CAS no. 100-42-5); • tetrabromobisphenol A (TBBPA) (CAS no. 79-94-7); • toluene (CAS no. 108-88-3); • triphenyl phosphate (TPP) (CAS no. 115-86-6); • tris(2-chloroethyl) phosphate (TCEP) (CAS no. 115-96-8); • tris(2,3-dibromopropyl) phosphate (TDBPP) (CAS no. 126-72-7);

State	Prohibited or restricted substance in cosmetics
Washington	• tri-n-butyl phosphate (TNBP) (CAS no. 126-73-8); • tetrachloroethene (CAS no. 127-18-4); • tricresyl phosphate (TCP) (CAS no. 1330-78-5); • tris(1,3-dichloro-2-propyl)phosphate (TDCPP) (CAS no. 13674-87-8); • tris(1-chloro-2-propyl) phosphate (TCPP) (CAS no. 13674-84-5); or • vinyl chloride (CAS no. 75-01-4).

Source: GAO analysis of statutes and regulations in California, Maryland, Oregon, Vermont, and Washington. | GAO-24-105542.

[a]Cal. Health & Safety Code § 108980.

[b]Cal. Health & Safety Code § 108980.

[c]Md. Code Ann., Health-Gen. § 21-259.2.

[d]Or. Rev. Stat. Ann. §§ 431A.253(3)(a)(iv); 431A.255; 431A.258(1)(a); 431A.263; 431A.268. Manufacturers may be granted exemptions for limited purposes. Or. Rev. Stat. Ann. § 431A.258(5)(a). On or before a manufacturer reports for the third time, the manufacturer is required to remove or make a substitution for the chemical or seek a waiver. Or. Rev. Stat. Ann. §§ 431A.260(1)(b), 431A.263, 431A.265.

[e]Or. Admin. R. 333-016-2020.

[f]Vt. Stat. Ann. tit. 18, §§ 1772(5), (7)(A)(i), (15); 1773(a)(1); 1775(a). The Vermont Commissioner of Health is to review the list of chemicals designated as chemicals of high concern to children every 2 years to determine if additional chemicals should be added and may consider designations made by other states, the federal government, other countries, or other governmental agencies. Vt. Stat. Ann. Tit. 18, § 1773(b). Vt. Stat. Ann. tit. 18, §§ 1172(7)(A)(ii), 1773, 1776. Vermont's Commissioner of Health may designate additional chemicals of high concern to children by rule.

[g]Wash. Rev. Code Ann. § 70A.430.060; Wash. Admin. Code § 173-334-130.

[h]The Washington Children's Safe Products Act defines a "high priority chemical" as a chemical identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative by the department on the basis of credible scientific evidence as known to do one or more of the following: (a) harm the normal development of a fetus or child or cause other developmental toxicity; (b) cause cancer, genetic damage, or reproductive harm; (c) disrupt the endocrine system; (d) damage the nervous system, immune system, or organs or cause other systemic toxicity; (e) be persistent, bioaccumulative, and toxic; or (f) be very persistent and very bioaccumulative. Wash. Rev. Code Ann. § 70A.430.010(9). "Bioaccumulative" refers to chemicals accumulating in the tissues of a human or animal's body over time.

Appendix IV: Objectives, Scope, and Methodology

This report (1) describes research on the safety of selected substances in cosmetics and (2) examines what actions the Food and Drug Administration (FDA) has taken to implement its new authorities for cosmetic safety oversight and the extent to which these actions address selected leading practices for agency reforms. This report also includes information on state cosmetics laws and regulations.

To describe research on the safety of selected substances in cosmetics, we conducted a literature search and review. In developing our literature search and review methods, we also interviewed agency officials, industry association representatives, academics, and representatives of nongovernmental organizations about research on cosmetic ingredient safety. Specifically, we took the following steps:

1. **Conducted a literature search.** We conducted a systematic literature search covering a 6-year period (2017-2022). A research librarian conducted searches of databases including ProQuest, Scopus, EBSCO, and Harvard's Think Tank search to identify scholarly literature; books; conference reports; and trade, association, and nonprofit publications—from both domestic and international perspectives—published from 2017 to 2022. We searched the literature using a list of selected keywords related to cosmetics ingredients and contaminants that we developed in consultation with external stakeholders. We used the following keywords, among others, to identify relevant documents: cosmetic, personal care product, hair impact, skin irritation, cosmetic fragrance, heavy metal, preservatives, and safety. The literature search identified 118 documents for potential inclusion in our review. We supplemented this search with studies we identified from our background (nonsystematic) literature search, interviews, and document reviews, including a review of FDA, Campaign for Safe Cosmetics, and other websites, resulting in 49 more documents for potential inclusion in our review. In addition, during an interview with FDA officials, we became aware of published documents funded by FDA that were not identified in our database search because the documents did not contain our selected keywords or were outside the 6-year period we searched. Through this FDA information, we added 11 documents to our search, resulting in total of 178 documents for potential inclusion. (See table 6.)

Table 6: Literature Review Sources

Document sources	Number of documents
Systematic Literature search	118
Nonsystematic internet literature searches, interviews, and document reviews	49
Food and Drug Administration	11
Total	**178**

Source: GAO. | GAO-24-105542

2. **Selected documents for relevance.** To select documents that were relevant to our research objective, two specialists independently assessed each of the 178 documents using the following screening inclusion criteria: (1) documents that discuss the safety of substances in cosmetics and associated categories (e.g., parabens, fragrances, heavy metals); (2) documents that include information on studies, such as epidemiological or other scientific research on harmful effects from the use of certain substances in cosmetics; and (3) documentation of studies including, but not limited to, correlative relationships for substances in cosmetics and associated adverse health effects and, if any, causative relationships for substances in cosmetics and associated adverse health effects. We identified 129 documents that met these criteria.
3. **Systematically extracted and reviewed information from the documents.** Using a structured data entry form, two specialists extracted and reviewed information from the 129 documents. The data entry form included pertinent details for each document, such as title, author(s), publication year, methodology, cosmetic ingredients discussed, and findings or statements on safety of cosmetic ingredients. The form also cited relevant information from studies such as epidemiological or other scientific research on harmful effects from the use of certain substances in cosmetics. Each specialist also reviewed each article to assess if it showed correlative or causative relationships between substances in cosmetics and adverse health events. The specialists discussed and reconciled the differences in their respective assessments.
4. **Reviewed and summarized literature findings.** A specialist analyzed the information extracted from the 129 documents to identify themes in two categories: (1) the presence and potential health effects of intentional ingredients in cosmetics such as fragrances,

preservatives, plasticizers, solvents; and (2) the presence and potential health effects of impurities and manufacturing byproducts in cosmetics such as 1,4-dioxane, heavy metal impurities, and asbestos contamination in talc. As part of this review, the specialist categorized the substances in cosmetics products in order to identify themes and summarize the potential harmful effects from certain substances in cosmetics. We included in our findings the studies and literature we identified that illustrate these themes.

To further illustrate what research has shown about the safety of substances in cosmetics, we selected examples of ingredients or contaminants in cosmetics and scientific findings on their health effects from our literature search and review. To identify and assess the appropriateness of the studies' underlying scientific findings, to further illustrate the research on health effects, we then took the following steps:

1. **Selected cosmetic ingredients or contaminants to use as examples.** To select cosmetic ingredients or contaminants for inclusion in an appendix on health effects, the example ingredients or contaminants had to meet one of the following criteria: (1) have at least five sources identified from the literature review discussing the health risks linked to selected cosmetic ingredients or contaminants as a safety concern; or (2) have at least three studies from the literature review identifying correlative relationships and, if there was sufficient evidence of a correlation, one primary source of evidence indicating a causative relationship. The specialist identified a total of 28 documents, 20 of which were for cosmetic ingredients or contaminants that met the first criterion and another eight of which were for cosmetic ingredients or contaminants that met the second criterion. During the literature review (described above), two specialists reviewed each of the 20 documents meeting the first criterion.
2. **Collected data on documents identifying correlative and causative relationships.** Two specialists reviewed the 20 documents regarding cosmetic ingredients or contaminants that met the first criterion following the same process as described for the broader literature review (see methodology for literature review above). For the eight studies regarding cosmetic ingredients or contaminants meeting the second criterion, a third specialist extracted information on each study, such as the years covered by the studies' research, methods described in the article, author(s), and author affiliations; the third specialist then assessed the studies' strengths and limitations. The three specialists discussed and reconciled the differences in their

assessments. Through this review of the eight studies, we identified seven studies of sufficient quality to include that cite examples of health effects for the selected cosmetic ingredients or contaminants.

3. **Identifying themes.** A specialist summarized the documents based on correlative and/or causative relationships and identified the following themes: (1) ingredients that are allergens, (2) ingredients in hydroxide-based hair straighteners, and (3) asbestos contamination in talc. These themes are presented as illustrative examples in appendix I.

To examine what actions FDA has taken to implement its new authorities for cosmetic safety oversight, we reviewed applicable laws for cosmetic safety oversight, including the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). We then reviewed agency documents for evidence of actions FDA had taken as of August 2023 to implement MoCRA and interviewed FDA officials—including the senior official in charge of these efforts, FDA's Chief Scientist. For example, FDA officials provided us with copies of agendas and resulting minutes from meetings of FDA's MoCRA implementation working group in 2023.

To examine the extent to which FDA's actions address selected leading practices for agency reforms, we compared the agency's actions since the law's enactment on December 29, 2022, through August 2023, with selected leading practices compiled in our June 2018 report on government reorganization.[1] We determined that it was appropriate to assess FDA's actions against these leading practices because, according to our prior work, agency reforms include any organizational change, such as major transformations, mergers, consolidations, and other reorganizations, as well as efforts to streamline and improve the efficiency and effectiveness of government operations. The report includes key questions to aid in assessing agency reform efforts. The key questions are organized into four broad categories and 12 subcategories.

[1]GAO, *Government Reorganization: Key Questions to Assess Agency Reform Efforts*, GAO-18-427 (Washington, D.C.: June 13, 2018). The report includes 58 key questions to aid in assessing reform efforts. In developing this report to assist Congress, the Office of Management and Budget, and agencies in assessing agency reform plans, we reviewed our prior work on leading practices for organizational transformations; collaboration; government streamlining and efficiency; fragmentation, overlap, and duplication; and high risk and other long-standing agency management challenges to develop the key questions. In developing GAO-18-427, we contacted subject matter specialists to review the major categories of leading practices that were covered by our questions to ensure that there were no major gaps and that they were presented in the appropriate context.

Two GAO analysts assessed the key questions and associated leading practice subcategories and categories and came to an agreement regarding the relevance to our audit objective for each key question, subcategory, and category. We grouped these criteria into the resulting selected leading practice categories, subcategories, and associated key questions.

We determined that two of four leading practice categories were relevant to FDA's implementation of MoCRA: Implementing the Reforms and Strategically Managing the Federal Workforce. We determined that the categories of Goals and Outcomes and Process for Developing the Reforms were not applicable to our assessment because Congress enacted MoCRA, thereby establishing the goals and outcomes and the process for developing the reform effort.

Within the leading practice category of *Implementing the Reforms,* we determined that both subcategories, *Leadership Focus and Attention* and *Managing and Monitoring* were relevant to implementation of MoCRA; therefore, we included those subcategories in our review.[2] Within the leading practice category of *Strategically Managing the Federal Workforce*, we determined that two of four subcategories were relevant to implementation of MoCRA: *Employee Engagement* and *Strategic Workforce Planning*; therefore, we included those subcategories in our review.[3] We determined the subcategories of *Workforce Reduction Strategies* and *Employee Performance Management* were not relevant to implementation of MoCRA and excluded those subcategories from our review.

We applied the selected leading practices that we determined to be relevant by comparing them with FDA's MoCRA implementation efforts as of August 2023. The two GAO analysts independently compared FDA's MoCRA implementation actions, identified through agency documents and interviews with FDA officials, against the selected leading practice

[2]We modified one key question within the Managing and Monitoring subcategory. Specifically, we excluded the reference to "web-based" in the following key question: "Has the agency ensured transparency over the progress of its reform efforts through web-based reporting on key milestones?" We excluded the reference because reporting on FDA's implementation of MoCRA may occur through other mechanisms.

[3]We modified a key question in the Employee Engagement subcategory. Specifically, we excluded the reference to "workforce reductions" in the following key question: "How specifically is the agency planning to manage diversity and ensure an inclusive work environment in its reforms, or as it considers workforce reductions?" We excluded the reference because FDA's implementation of MoCRA does not entail workforce reductions.

subcategories and key questions using a three-point scale (i.e., generally, partially, or not addressed).[4] The two analysts subsequently reached agreement on all assessments. To report our assessment at the subcategory level, we averaged the assessments for each key question within each subcategory, using the same three-point scale.

To identify states that have enacted statutes and regulations that prohibit or restrict more substances in cosmetics than are prohibited or restricted under federal law and FDA regulations, we engaged in a two-part legal research and analysis methodology and summarized our results in appendixes II and III.

1. **Legal research.** To identify state statutes referencing substances in cosmetics that are prohibited or restricted at the state level, a senior analyst used a legal resource database to research statutes in all 50 states and the District of Columbia.

2. **Legal analysis.** To identify states that prohibit or restrict more substances in cosmetics than the 11 substances that are prohibited or restricted under federal law and FDA regulations, this analyst reviewed the statutes and regulations prohibiting or restricting substances in cosmetics in each state against relevant federal law and regulations.[5] When a state statute was identified as prohibiting or restricting more substances in cosmetics than federal law, the senior analyst conducted research in the legal resource database to identify and analyze any relevant regulations implementing the corresponding statutes. Results from each of the 50 states and the District of Columbia identified by this analyst were reviewed by a second analyst prior to attorney review.

We conducted this performance audit from November 2021 to December 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe

[4]The three-point scale is (1) generally addressed–FDA took actions that generally addressed the leading practice or the individual key question; (2) partially addressed–FDA took actions that partially addressed the leading practice or the individual key question; and (3) generally not addressed–FDA took few or no actions to address the leading practice or the individual key question.

[5]We did not assess the basis or rationale for the legal prohibitions or restrictions for cosmetic ingredients in individual states and the District of Columbia.

that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix V: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

November 14, 2023

Karen L. Howard
Director, Science, Technology Assessment,
and Analytics
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Steve Morris
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Howard and Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"COSMETIC SAFETY: Better Planning Would Enhance FDA Efforts to Implement New Law" (GAO-24-105542).**

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — COSMETIC SAFETY: BETTER PLANNING WOULD ENHANCE FDA EFFORTS TO IMPLEMENT NEW LAW (GAO-24-105542)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report. Most American consumers use multiple cosmetic products every day. Examples of some of these products include makeup, nail polishes, shaving cream and other grooming products, perfumes, face and body cleansers, haircare products including shampoos and conditioners, moisturizers, and other skincare products. The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is the most significant expansion of FDA's authority to regulate cosmetics since the Federal Food, Drug, and Cosmetic (FD&C) Act was passed in 1938. This new law will help ensure the safety of cosmetic products. GAO evaluated early stage of activities (January to August, 2023) following the passage of MoCRA on December 29, 2022. FDA has made significant strides in implementing MoCRA using existing resources, particularly for registration and listing of cosmetic product facilities and products, as well as convening a public meeting on good manufacturing practices to support rulemaking. However, timely progress in implementing MoCRA and addressing GAO's recommendations hinges upon a significant increase in funding.

Recommendation 1
The FDA Commissioner should ensure that the Office of the Chief Scientist develops an implementation plan for MoCRA—including a timeline with interim steps and interim deadlines—for completing all MoCRA requirements within the statutorily prescribed deadlines.

HHS Response
FDA concurs with the recommendation. The Office of the Chief Scientist has already begun development of an implementation plan for MoCRA, and FDA believes it is important to emphasize significant efforts are ongoing to implement MoCRA. FDA has formed working groups for each major MoCRA requirement and project managers are planning timelines with interim steps and interim deadlines for task execution. Further, FDA has developed an internal database to aid in tracking deliverables.

Recommendation 2
The FDA Commissioner should ensure that the Office of the Chief Scientist reports on key milestones for all MoCRA requirements. Processes for such reporting could be incorporated into an implementation plan for MoCRA.

HHS Response
FDA concurs with the recommendation. The Office of the Chief Scientist is committed to further strengthening processes to publicly report on key milestones for all MoCRA requirements. We will continue to update the information related to MoCRA on our webpage and communicate this information with stakeholders.

Recommendation 3
The FDA Commissioner should ensure that the Office of the Chief Scientist develops processes to collect needed data and evidence to measure the agency's MoCRA implementation efforts

against requirements identified in the new law. Such processes for data and evidence collection could be incorporated into FDA's implementation plan for MoCRA.

HHS Response
FDA concurs with the recommendation. The Office of the Chief Scientist will develop processes to collect needed data and evidence to measure the agency's MoCRA implementation efforts against requirements identified in the new law. FDA has already developed a database to aid in this effort, as described in FDA's response to Recommendation 1.

Recommendation 4
The FDA Commissioner should ensure that the Office of the Chief Scientist assesses the effects of implementing all MoCRA provisions on the current and future workforce.

HHS Response
FDA concurs with the recommendation. The Office of the Chief Scientist will develop an assessment. We note that timely progress in implementing MoCRA and addressing GAO's recommendations hinges upon a significant increase in funding. Accordingly, the FY 2024 President's Budget request included $5 Million for Modernization of Cosmetics Implementation.

Recommendation 5
The FDA Commissioner should ensure that the Office of the Chief Scientist develops a multi-year strategic workforce plan that identifies the needed personnel and capacity, including skills and competencies, to implement all MoCRA requirements.

HHS Response
FDA concurs with the recommendation. The Office of the Chief Scientist will develop a multi-year strategic workforce plan to implement MoCRA requirements. We note that timely progress in implementing MoCRA and addressing GAO's recommendations hinges upon a significant increase in funding. Accordingly, the FY 2024 President's Budget request included $5 Million for Modernization of Cosmetics Implementation.

Recommendation 6
The FDA Commissioner should ensure that the Office of the Chief Scientist develops a plan to strengthen DEIA when recruiting and hiring additional staff to implement MoCRA. Such a plan could be incorporated into a multi-year strategic workforce plan for MoCRA implementation.

HHS Response
FDA concurs with the recommendation. The Office of the Chief Scientist will develop a plan to strengthen DEIA when recruiting and hiring additional staff to implement MoCRA. We intend to be consistent with FDA's Diversity, Equity, Inclusion, and Accessibility 2022-2025 Strategic Plan (https://www.fda.gov/media/170844/download); that plan represents FDA leadership's continuing commitment to build and maintain a diverse workforce and to cultivate and support an inclusive culture.

Recommendation 7
The FDA Commissioner should ensure that the Office of the Chief Scientist adopts effective recruitment and hiring practices for MoCRA implementation, such as customized strategies to recruit highly specialized and hard-to-fill positions. Such practices could be incorporated into a multi-year strategic workforce plan for MoCRA implementation.

HHS Response
FDA concurs with the recommendation. The Office of the Chief Scientist will adopt effective recruitment and hiring practices for MoCRA implementation.

Appendix VI: GAO Contacts and Staff Acknowledgments

GAO Contacts

Steve Morris at (202) 512-3841 or morriss@gao.gov, and

Karen L. Howard at (202) 512-6888 or howardk@gao.gov.

Staff Acknowledgments

In addition to the contacts named above, the following staff members made key contributions to this report: Anne K. Johnson (Assistant Director), David Lysy (Analyst in Charge), Farah Angersola, Adrian Apodaca, Kevin Bray, Clifton Douglas Jr., Emily Gupta, Nacole King, Serena Lo, Mike Meleady, Cynthia Norris, Amber Sinclair, and Sarah Veale.

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