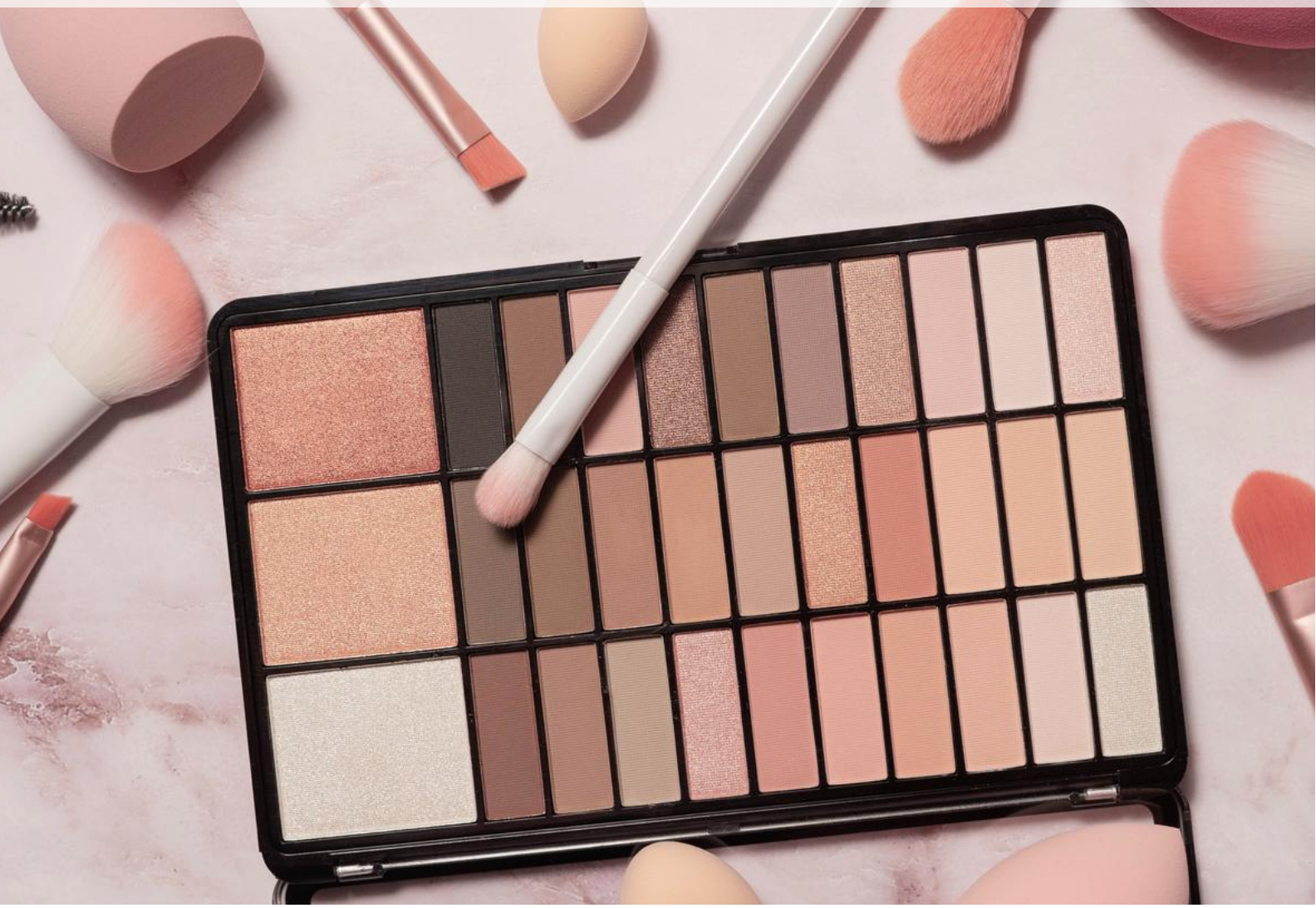
Modernization of Cosmetics Regulation Act of 2022

Chemical Regulation



Issue Summary

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) significantly expands FDA's rulemaking and enforcement authority over cosmetics and creates substantial new compliance obligations for manufacturers, packers, and distributors of cosmetics intended for sale in the United States.

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Impact on the Chemical Industry

MoCRA requires cosmetic manufacturers to:

- Register all facilities by December 29, 2023 and renew registrations every two years.
- Submit a “cosmetic product listing” for each cosmetic product and update annually, and
- Maintain records supporting substantiation of safety.

While specialty chemical companies may not manufacture the finished cosmetic product, they will need to assist downstream customers with information requests as required by MoCRA.

Definitions

Cosmetic Product	A preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.
Facility	Any establishment (including an importer) that manufactures or processes cosmetic products distributed in the United States.
Responsible Person	The manufacturer, packer, or distributor of a cosmetic product **whose name appears on the label of such cosmetic product.**
Serious Adverse Event (SAE)	An adverse effect that causes: • death • life-threatening experience • inpatient hospitalization • persistent or significant disability or incapacity • congenital anomaly or birth defect • infection • significant disfigurement • **or** requires medical intervention to prevent one of these outcomes.

Bill Summary

Serious Adverse Event Reporting Requirements:

The responsible person must submit a report of any SAE no later than 15 business days after the report is received.

- For one year after an SAE, the responsible person must submit any new medical information received in relation to the event no later than 15 business days after the report is received.
- Records of SAE reports must be kept for a period of six year (three years for small businesses) and made available to FDA during an inspection.
- If the FDA has reasonable grounds to believe that a fragrance or flavor ingredient caused or contributed to a SAE, FDA may request in writing a list of such ingredients from the responsible person, who must then submit it to FDA within 30 days.
- Information submitted is subject to certain protections for confidential business information and personally identifiable information.

Good Manufacturing Practice:

FDA will establish Good Manufacturing Practice (GMP) regulations no less than two years after enactment of the bill.

- GMP regulations will be developed in consultation with cosmetics manufacturers, including small businesses, consumer organizations, and other experts.

Facility Registration and Product Listing:

Facilities that currently manufacture or process a cosmetic product for distribution in the United States must register by December 29, 2023.

- Facilities that begin manufacturing or processing a cosmetic product for distribution in the United States must register within 60 days.
- Registration must be renewed biennially.
- Facilities that manufacture or process cosmetic products on behalf of a responsible person must only register a facility once, even if the facility is manufacturing or processing on behalf of more than one party.

The responsible person must submit a list of cosmetic products that are in market on December 29, 2022, no later than December 29, 2023.

- Products that are brought to market after December 29, 2022, must be registered within 120 days of marketing in interstate commerce.
- Product listings must be updated annually.

FDA may suspend the registration of a facility if it believes that a cosmetic product manufactured or processed at the facility has a reasonable risk of causing a serious adverse health consequence.

- The FDA must notify a facility in advance of suspending registration, provide an opportunity for corrective actions, and provide a hearing to determine actions required for reinstatement.

Substantiation Of Safety:

A responsible person for a cosmetic product must ensure and maintain records supporting, that there is adequate substantiation of the safety of the product.

- Substantiation may consist of tests or studies, research, analyses, or other scientific evidence.

Labeling:

- Cosmetic products labels must include a domestic address, domestic phone number, website, or electronic contact information, through which adverse events can be reported.
- Labels must identify any fragrance allergens.
    - GMP regulations will be developed in consultation with cosmetics manufacturers, including small businesses, consumer organizations, and other experts.
- Products that are intended only to be used by licensed professional must be clearly and prominently labelled as such.

Records:

If FDA has reasonable belief that a cosmetic product (or an ingredient in a cosmetic product) presents a risk of serious adverse health consequences, facilities must permit a designated officer to have access to and copy all records relating to the product.

- Recipes, formulas, financial data, pricing, or sales data are exempt.

Mandatory Recall Authority:

- If FDA has reasonable belief that a cosmetic product is adulterated, misbranded, or presents a risk of serious adverse health consequences, FDA will give the responsible person the opportunity to voluntarily cease distribution and recall the product.
- If the responsible person refuses to or does not voluntarily cease distribution or recall the product, FDA may order them to do so.
- In conducting a recall, FDA will publish a press release, alerts and notifications to consumers and retailers informing them of the recall.

Small Businesses:

Responsible persons, owners and operators of facilities, whose average gross annual sales of cosmetic products in the United States for the previous 3-year period is less than $1,000,000, (adjusted for inflation) are not subject to the Good Manufacturing Practice or Facility Registration and Product Listing requirements.

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