eurofins | Cosmetics & Personal Care

MoCRA Requirements

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. In this document you will find already enacted MoCRA law as well as upcoming MoCRA regulations and our capabilities for each requirment.

Eurofins Cosmetics & Personal Care can assist with MoCRA compliance in order to ensure cosmetics & personal care product safety. We can offer guidance on compliance as the final rules take effect.

KEY PROVISIONS	2024	2025
Adverse Events & Serious Adverse Event Reporting		
Good Manufacturing Practices		
Registration and Product Listing		
Safety Substantation		
Labeling of fragrance allergen		
Labeling - Contact Information		
Labeling - Professional Use		
Mandatory Recall Authority		
Record Access		
Testing Method for Asbestos in Talc-Containing Cosmetics		
Report on PFAS in Cosmetics		

Already Enacted MoCRA Law

(December 29th, 2023)

Labeling compliance (professional use)

Professional use labeling: cosmetic product introduced into interstate commerce and intended to be used only by a professional shall bear a label that-‘‘(A) contains a clear and prominent statement that the product shall be administered or used only by licensed professionals; and ‘‘(B) is in conformity with the requirements of the Secretary for cosmetics labeling under this Act and section 4(a) of the Fair Packaging and Labeling Act.

- Eurofins assists in developing new cosmetic product labels, signal words, hazard statements, and pictograms that should be indicated on the package. We carry out allergens testing on the cosmetic product(s) and raw material(s).

Adverse event reporting & Record keeping

A responsible person[1] is required to report serious adverse events associated with the use of cosmetic products in the United States to FDA.

The responsible person shall maintain records related to any adverse event associated with the use, in the United States, of a cosmetic product.

- Toxicological risk assessments are performed to evaluate the potential toxicity of the product in the case that a serious adverse event may occur. Eurofins assists with the expectedness assessment for the adverse event and reporting to FDA, as well as with standard operating procedures that will define the adverse event reporting and record keeping requirements.

Mandatory recall authority

If the Secretary determines that there is a reasonable probability that a cosmetic is adulterated under section 601 or misbranded under section 602 and the use of or exposure to such cosmetic will cause serious adverse health consequences or death, the Secretary shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article.

- Eurofins assists with recall management and standard operating procedures for mandatory recall requirements. In the case of product recalls, we can perform toxicological reviews and can provide physical safety evaluations.

Safety substantiation

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

- At Eurofins, the safety of a cosmetic product is evaluated under toxicological risk assessments which considers fragrance allergens, colorants, and other chemicals' potential adverse health effects. It covers all the relevant endpoints (local effects, acute/systemic toxicity, mutageniticity/ genotoxicity, reproductive toxicity, phototoxicity, etc.).

Records access

If certain conditions are met, FDA can access and copy certain records related to a cosmetic product, including safety records.

- Toxicological risk assessments are performed to ensure the safety of the cosmetic product. Eurofins assists with the requests from FDA.

Talc-containing cosmetics

Proposition of standardized asbestos testing methods for talc containing products.

- Eurofins carries out tests according to standardized talc testing methods once published.

Upcoming MoCRA Regulations

Labeling compliance: proposition of a list of fragrance allergen and fragrance allergens labeling (June 29th, 2024. Final rule 180 days after close of comment period) **contact information** (December 29th, 2024)

The responsible person shall identify on the label of a cosmetic product each fragrance allergen included in such cosmetic product and contact's informationto report potential adverse events

MoCRA facility registration & product listing (July 1st, 2024)

Registration of a facility: Section 607(a)(1) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility (with some exemptions).

Product Listing: Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person must submit a cosmetic product listing, or ensure such submission is made (with some exemptions).

- Eurofins assists with MoCRA Registration (incl. facility registration), product and ingredient listing and toxicological risk assessments, label reviews, and safety data sheets.

Good Manufacturing Practices (GMP) requirements (proposed rule December 29th, 2024. Final rule December 29th, 2025).

The Secretary shall by regulation establish GMP for facilities that are consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 601. Any such regulations shall be intended to protect the public health and ensure that cosmetic products are not adulterated. Such regulations may allow for the Secretary to inspect records necessary to demonstrate compliance with GMP.

- GMP certificates are reviewed alongside the product to ensure that traces or impurities will not harm the end user. Eurofins has audit services to ensure compliance to the new Cosmetic GMP requirements. We assist with GMP setup of the manufacturing site.

PFAS in cosmetics (December 29th, 2025)

The Secretary of Health and Human Services shall assess the use of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products and the scientific evidence regarding the safety of such use in cosmetic products, including any risks associated with such use. In conducting such assessment, the Secretary may, as appropriate, consult with the National Center for Toxicological Research.

- We understand the need to identify and monitor for emerging contaminants such as PFAS. Eurofins laboratories support standard and proprietary in-house methodology with all the necessary validation data to support the precision and accuracy of our methodology.

By leveraging our expertise, we can ensure your cosmetics & personal care products meet regulatory standards.

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Cosmetics & Personal Care

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