Complying with the Cosmetics Regulations in the EU and US

Authors: Mary Kerley[1], Concy Aciro[2], Claire Mathis[3], Emily Bergmann[3], and Jim Mo[3]
[1]HH Compliance Ltd., Dublin, Ireland
[2]HH Compliance Ltd., Kent, United Kingdom
[3]H2 Compliance Inc., Washington, DC-Metropolitan Area, United States

Abstract

Cosmetics manufacturers selling into the European Union (EU) have already encountered regulatory requirements under Regulation (EC) No 1223/2009, and now will face new regulatory requirements in the US under the Modernization of Cosmetics Regulation Act (MoCRA). Certain elements of MoCRA are in line with current EU requirements, but will require manufacturers to consider new strategies for compliance measures in both the EU and US, including for product labelling and safety evaluation. This poster will review the similarities and differences between EC No. 1223/2009 and MoCRA requirements, as well as recommend strategies for collecting and managing information relevant to global compliance for cosmetic manufacturers.

Regulatory Background

EU Regulation – EC No. 1223/2009

Every cosmetic that is sold on the EU market must comply with Regulation (EC) No 1223/2009. This regulation entered into force in all the countries of the European Economic Area (EEA), Norway, Iceland, and Liechtenstein in 2013.

This is one of the most complicated cosmetic regulations in the world. The risks of non-compliance can result in substantial fines and/or product recall.

Under EC 1223/2009, a cosmetic is defined as:

> *'any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.'*

The EU law bans 1,328 chemicals from cosmetics that are known or suspected to cause cancer, genetic mutation, reproductive harm, or birth defects. The law also covers restrictions for substances such as colouring agents, preservatives, and UV filters.

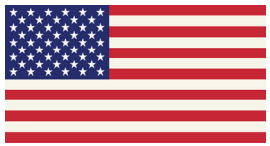
The following information must be compiled and/or actions taken for compliance measures:

- **Responsible person** – manufacturer (if in the EU), importer, distributor, or designated person.
- **Demonstrated product safety** – toxicological profiles of ingredients, compliance with prohibited and restricted substances, and a complete safety assessment, i.e., Cosmetic Product Safety Report (CPSR).
- **Correct labelling** – including:
  - Function of the cosmetic
  - List of ingredients in descending order (by concentration), using INCI names, and fragrance allergens above the level stated in the regulation
  - Precautions
  - Name and address of Responsible Person
  - Batch Number
  - Minimum date of durability or period after opening
- **Appropriate claims** – must not be misleading to consumers nor imply the cosmetic product has a characteristic or function which it does not have.
- **Product Information File (PIF)** – including but not limited to:
  - Composition
  - Manufacturing process
  - Stability
  - Efficacy
  - Packaging
- **Notification** – to the European Commission (EC) Cosmetics Products Notification Portal (CPNP).
- **Adverse effect reporting.**
- **Updating PIF** in compliance with regulatory evolution.

EU Member States

Each EU country has requirements around labelling and translations for cosmetic products. These vary by Member State.

US Regulations



Federal Food, Drug, and Cosmetic Act

In the US, cosmetics are currently regulated under the Federal Food, Drug and Cosmetic Act (FD&C Act).

The FD&C Act prohibits the marketing of **adulterated** or **misbranded** cosmetics in interstate commerce.

Under the FD&C Act, a cosmetic is defined as:

> *'articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body…for cleansing, beautifying, promoting attractiveness, or altering the appearance'.*

This US regulatory definition is more so defined by use. Under the FD&C Act, only 11 chemicals have been banned or restricted from cosmetics, and in addition, color additives must be approved.

Fair Packaging and Labeling Act (FPLA)

The Fair Packaging and Labeling Act (FPLA) is administered by the Federal Trade Commission (FTC) and FDA with regards to consumer commodities, and its aim is to prevent consumer deception.

The FPLA requires cosmetics to be labeled with the following:

- Identity of the commodity (by intended use, e.g., cosmetic)
- Name and place of business of the product's manufacturer, packer, or distributor
- Net quantity of contents, in terms of weights, measures, or numerical count (in both metric and inch/pound units) – in descending order (by concentration)

The Modernization of Cosmetics Regulation Act (MoCRA)

MoCRA (Modernization of Cosmetics Regulation Act) was signed in December 2022. It is the most significant expansion of the FDA's authority to regulate cosmetics since the FD&C Act was passed in 1938. It comes into effect on December 29, 2023, and labelling requirements will take effect at the end of 2024.

MoCRA provides the FDA with the following new authorities:

- Inspection of cosmetic records
- Mandatory cosmetic recalls
- Suspension of a facility's registration

There are also new obligations for cosmetic manufacturers/suppliers, including:

- **Adverse Event Reporting:** The Responsible Person (manufacturer, packer, or distributor of a cosmetic product whose name appears on the label or such cosmetic product) must submit serious adverse events along with a copy of the label to FDA within 15 days after a report is received. Each report should be kept for six years.
- **Facility Registration:** The manufacturing facility must register with the FDA. Foreign facilities must also identify a U.S. agent. This must be completed within a year after MoCRA's enactment for existing facilities and 60 days for new facilities.
- **Cosmetic Good Manufacturing Practices (CGMP):** consistent with national and international standards
- **Product Listing:** A responsible person must list each marketed cosmetic product with the FDA, including place of manufacture, product ingredients, and provide any updates annually. For existing product, it must be completed within a year after enactment and within 120 days of placing new product on the market.
- **Safety Substantiation:** The responsible person is required to ensure and maintain records supporting adequate safety substantiation for their products, using scientifically sound data. Such information must be provided within 30 days of request.
- **Labelling Requirements**: Will take effect at the end of 2024, and must include:
  - a domestic address, domestic phone number, or electronic contact information where a responsible person can receive adverse event reports.
  - fragrance allergens listing.

US States

The following states (as outlined in **Table 1**) have specific regulations in place impacting cosmetics.

Table 1. Overview of US State-Level Cosmetic Regulations

State	Regulation(s)	Requirements for Cosmetics
California	(1) Proposition 65 (2) Cosmetic Fragrance and Flavor Ingredient Right to Know Act (CFFIRKA)	The only state that requires companies to report harmful ingredients used in cosmetics, as outlined by the Proposition 65 and fragrance and flavor ingredients under the CFFIRKA.
Washington	Toxic-Free Cosmetics Act (HB 1047)	Bans PFAS, lead, phthalates and formaldehyde-releasing agents in cosmetics (phased in 2025) and requires further assessment of chemicals that may impact vulnerable populations
Colorado	Perfluoroalkyl and Polyfluoroalkyl Chemicals Consumer Protection Act (H.B.22-1345)	Prohibits sale or distribution of cosmetics containing PFAS (effective 2025)
New York	New York Cruelty Free Cosmetics Act (A. 5653-A/S. 4839)	Prohibits the manufacture or sale of most cosmetics tested on animals
Maryland	House Bill 643 (HB0643)	Prohibits harmful ingredients in cosmetic products
Minnesota	S.F.8.3.4	Prohibits PFAS in cosmetics
Maine	Title 10, Part 3, Chapter 233 §1500-M	Prohibits sale of cosmetics that have been newly tested on animals

Comparison of EU & US Cosmetic Regulations

Table 2. Comparison of scope and regulatory requirements and elements of EU and US cosmetics regulations

	EU		US (as updated under MoCRA)	
Scope				
Cosmetics Definition	-	Broad	-	Narrow
Type of Law	-	Protective, Precautionary, Transparent, Prescriptive	-	Interpretation-Dependent, Non-Prescriptive
Legal Responsibility	-	Responsible Person	-	Manufacturers, Suppliers, Distributors, Marketers
Enforcement	-	By EU Member State competent authority	-	By FDA
Requirements/Elements				
Notification	✓	Required	✗	Voluntary
Safety Assessment	✓	Required with specified elements under Article 10 (CPSR)	✓	Must substantiate product and ingredient safety prior to marketing, but no prescribed methodology
Good Manufacturing Practice (GMP)	✓	Required	✓	Required
Manufacturing Site Registration	✗	Not required	✓	Required
Animal Testing	✗	Banned	✓	Alternative methods encouraged
Preapproval of Ingredients	✗	Not required	✓	Color additives and coal tar hair dyes require preapproval and special labeling
Prohibited & Restricted Substances	✓	Listed in Annex II and III of regulation	✓	*Prohibited:* Bithionol, Chlorofluorocarbon propellants, Chloroform, Halogenated salicylanilides (di-, tri-, metabromsalan and tetrachlorosalicylanilide), Prohibited cattle materials, Methylene chloride, Vinyl chloride, Zirconium-containing complexes *Restricted:* Hexachlorophene, Mercury compounds, certain sunscreens and color additives
Labelling	✓	As outlined, including list of ingredients, precautionary statements, and function of the product	✓	As outlined, including ingredient list, color additives and fragrances, directions for safe use, and warning statements

Key Takeaways:

- The overarching goal of the regulations in both the EU and US are to ensure that cosmetics placed on the market are safe and that manufacturers and suppliers/distributors are responsible for the products that they are manufacturing and selling in these jurisdictions.
- US MoCRA has further aligned the US requirements with EU requirements around GMP, maintaining records for safety substantiation (although not yet requiring submission of such safety information), adverse event reporting, and more transparent labelling requirements.
- EU regulatory requirements, in particular the development of a PIF with safety substantiation, and notification to the European Commission, are more prescriptive and defined than those requirements for manufacturers and sellers in the US, where safety should be substantiated, but is not prescribed.

Strategies for EU & US Joint Compliance

- Currently, the more stringent requirements for the development of PIFs in the EU should be considered first when developing an overall cosmetics regulatory strategy. Data and information compiled for the PIF, provided formulations are the same or similar between the EU and US products, will be relevant for US market labels and product substantiation.
- It is further recommended that prohibited and restricted substances lists in both the EU and US are considered when formulating new or reformulating existing products. Supply chain management and further testing of sourced and manufactured substances is critical to achieving compliance when substances lists are enforced.
- Storing documentation in one place enables accessibility to EU Member State competent authorities and the US FDA as needed or requested. It also ensures that compliance information and data is easily sourced, compared, and in cases where product chemistries are similar, allows for the reuse of ingredient safety reports.

Contact Information: For further information about the contents of this poster, please contact **Mary Kerley** (m.kerley@h2compliance.com) and **Concy Aciro** (c.aciro@h2compliance.com) for assistance. References available upon request.