


# REGULATORY DIVERGENCE: EU, U.S., ASIA

The global cosmetic industry operates within a highly complex and fragmented regulatory landscape. As international trade expands, manufacturers and brands face the critical challenge of navigating divergent compliance frameworks across major global markets. A comparative analysis of the regulatory structures in the United States, the European Union, and Asia reveals profound differences in product classification, safety substantiation, and pre-market requirements.



Because the broader Asian market is heavily fragmented in itself, this article will focus specifically on the South Korean market, which represents a critical and highly influential part of the Asian cosmetic infrastructure. Understanding these structural divergences is essential for successful international market access and sustainable compliance.

## THE UNITED STATES: THE MOCRA PARADIGM SHIFT

The regulatory framework in the United States has recently undergone a massive transformation. The Modernization of Cosmetics Regulation Act (MoCRA) represents the largest cosmetic law reform in the U.S. since 1938. This legislation establishes a new regulatory standard, granting the Food and Drug Administration (FDA) significantly stronger powers – including, for the first time, mandatory recall authority and the right to access and copy manufacturing, complaint, and safety records under defined conditions. The core focus of MoCRA centers on safety, Good Manufacturing Practices (GMP), and transparency. Central to the new framework is the concept of the "responsible person" – the manufacturer, packer, or distributor whose name appears on the product label. This party bears the legal obligations for product listing, safety substantiation, and adverse event management, creating a U.S. counterpart to the accountability structures long established in other markets.

A fundamental operational change under MoCRA is the mandatory facility registration. Cosmetic manufacturing facilities must register with the FDA, update their information within defined deadlines, and renew this registration every two years. Additionally, products must be listed with the FDA, including ingredient and facility data, with annual updates. For foreign facilities exporting to the U.S., designating a U.S. Agent serves as a mandatory FDA contact point.

While the European Union requires a Product Information File (PIF), including a Cosmetic Product Safety Report (CPSR), MoCRA follows a different approach by requiring adequate safety substantiation rather than an equivalent product dossier. Instead, the responsible person must maintain records providing adequate substantiation of safety – documented scientific evidence demonstrating the product is safe under customary use – available to the FDA upon inspection. Serious adverse events must be reported to the FDA within 15 business days, with records retained for six years (three years for certain small businesses).

As a best practice, and in anticipation of FDA's pending GMP rule, complaints should be evaluated in a traceable manner and processes documented on an ongoing basis. While MoCRA provides exemptions for qualifying small businesses, these exemptions notably do not extend to safety substantiation or adverse event reporting

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Global cosmetic regulations vary significantly.

obligations – and do not apply to higher-risk product categories.

Furthermore, GMP is becoming a central foundation for sustainable compliance under MoCRA. Although the FDA's GMP rulemaking has been delayed beyond its statutory deadlines, the agency is already signaling its enforcement expectations through inspections and warning letters, and ISO 22716 is widely expected to serve as the reference framework for the eventual regulation. Early alignment is therefore a strategic advantage rather than a wait-and-see item: a robust GMP system requires rigorous documentation, validation, training, and audit readiness. Failure to adapt presents not only regulatory risks but real business risks, stemming from inadequate documentation, weak GMP systems, and missing adverse event processes.

Conversely, structured compliance and professionalized processes can yield significant competitive advantages, higher trust from retailers, and strengthen international market positions.

## THE EU: STRICT SAFETY AND DATA REQUIREMENTS

The European Union operates under a highly precautionary and structured framework, governed primarily by the Cosmetics Regulation (EC) No 1223/2009. A central pillar of the EU system is the legal requirement for an EU-based Responsible Person (RP) to ensure compliance. Ultimately, the legal burden of proof rests entirely on the RP to demonstrate that the product is safe. However, before a cosmetic product can be placed on the European market, a comprehensive Product Information File (PIF) containing a rigorous safety assessment must be compiled. Furthermore, the product must be notified in the Cosmetic Products Notification Portal (CPNP). Missing a PIF, safety report or CPNP notification can lead to immediate import stops.

A major regulatory divergence between the EU and other global markets is the strict legal demarcation between cosmetics and pharmaceuticals. In the EU, there is no legal definition for "cosmeceuticals"; products are exclusively classified as either cosmetics under Regulation 1223/2009 or as medicines under Directive 2001/83/EC. Cosmetic products are defined by their purpose to clean, perfume, change appearance, protect, keep in good condition, or correct body odors. Conversely, products that affect physiological functions or treat or prevent disease are classified as pharmaceuticals. Because of this strict separation, product claims are heavily scrutinized under EU Regulation 655/2013. Claims must be scientifically substantiated and may not be misleading. Medical promises, such as claiming a product "heals acne" or offers "cell rejuvenation," carry a severe risk of the product being reclassified as a medicine, thereby requiring drug approval – a significantly higher market barrier. To minimize risk, marketing language must be carefully adapted; for instance, instead of claiming a product "rejuvenates skin," compliant wording would state it "gives a younger appearance". Ingredient safety is another area of strict oversight in the EU. For reference, Annex II lists strictly prohibited substances, while Annex III dictates that certain restricted ingredients may only be used if they comply with strict concentration limits and warning label requirements. Furthermore, Annexes IV, V, and VI function as absolute "positive lists," meaning that only the colorants, preservatives, and UV filters explicitly listed within them are permitted for use. Nanomaterials require separate notification and specific labeling. Traditional or herbal active ingredients commonly used in other regions often face market blocks in the EU due to a lack of required toxicology data, adhering to the strict REACH principle of 'no data – no market'. Additionally, EU labeling must adhere to strict guidelines, including INCI declarations (which use standardized names and are not translated), product function, date of minimum durability or PAO, the RP's name and address, and the country of origin (if manufactured outside the EU). Language requirements for these non-INCI elements are set by each specific Member State.

## SOUTH KOREA: THE IMPORTANCE OF THE IMPORT ROUTE

South Korea, holding the position of the world's second-largest cosmetic exporter and major cosmetic launchpad in Asia, presents a completely different regulatory paradigm. The South Korean legal system for cosmetics is distinctly hierarchical, comprising the Cosmetic Act, Cosmetic Regulations, Cosmetic Rules, and specific Ministry of Food and Drug Safety (MFDS) Notifications. These MFDS notifications comprehensively cover test methods,

evaluation standards for functional cosmetics, cosmetic GMP, labeling, advertising, and safety management.

For reference, a profound point of divergence between South Korea and the EU is the legal recognition of "functional cosmetics". While the EU does not recognize a separate regulatory category for 'cosmeceuticals', cosmetic claims must comply with EU requirements and be adequately substantiated. In South Korea, the term 'cosmeceuticals' is commonly used in the market, while the regulatory framework provides a specific category of 'functional cosmetics'. Products falling within this category, including certain whitening, wrinkle improvement and UV protection products, are subject to MFDS evaluation or reporting procedures. This distinction is particularly important when Korean products are placed on the EU market. The import mechanism in South Korea also differs significantly from the EU model. In South Korea, market entry often relies on a specific distributor model where the importer and distributor assume the legal role of the "Cosmetics Responsible Seller". In this regulatory environment, the physical import of the goods and the title of the Responsible Person are intrinsically linked. This stands in direct contrast to the European Union, where the importation of goods and the legal role of the Responsible Person can be managed independently of one another. When European brands seek to enter South Korea, they must carefully navigate this, keeping in mind that local importers take on immense legal responsibility, and alternatives like setting up a branch office require significant investment. Therefore, proactive regulatory and strategic preparations must be made beforehand, allowing brands to carefully evaluate the different South Korea market-entry models available to ultimately import and distribute their products in South Korea. In practice, the most common models are branch models, exclusive distributors or importers and responsible sellers of record.

## STRATEGIC SOURCING AND MANUFACTURING

Sourcing ingredients and manufacturing across these divergent regions requires highly strategic partnerships. Trends originating in Korea, such as "Clean Biotech" utilizing bio-fermented ingredients like PDRN, exosomes, and postbiotics, are highly sought after globally. However, matching these innovative formulations with strict EU toxicological data requirements or U.S. MoCRA safety standards remains a significant hurdle.

A deep regulatory understanding of the target sales market is absolutely vital when utilizing a manufacturer from a third country. Overseas manufacturers naturally operate under their own domestic regulatory frameworks and may not be intimately familiar with the compliance nuances of the destination market. For instance, a formulation perfectly compliant for the South Korean market might contain ingredients restricted under the EU's Annex II-VI or lack the rigorous safety documentation required for a European Product Information File (PIF).

To mitigate these cross-border risks, implementing early classification and ingredient checks is crucial. Brands must not assume that a high-quality product is automatically a compliant one. Establishing a multi-eye principle for both quality control (QC) and regulatory compliance ensures that formulations, claims, and GMP processes are continuously vetted against the target market's specific laws. A successful global strategy must synthesize these operational and strict regulatory realities into a unified approach from the very beginning of product development.

## STATEMENT

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In our combined decades of experience bridging the gap between European, American, and Asian cosmetic markets, we have seen countless brands stumble not due to poor product quality, but because of regulatory blindness. The transition from one market to another is rarely a simple translation of labels. For example, a perfectly compliant "functional cosmetic" in Seoul can easily trigger a rapid product recall and legal action in Munich if the claims cross the strict line between European pharmaceuticals and cosmetics classification.

Conversely, European or U.S. manufacturers looking to penetrate the booming South Korean landscape often misunderstand the heavy legal and operational burden placed on local South Korean importers, who usually act as the ultimate Responsible Seller. As MoCRA reshapes the U.S. landscape into a highly regulated arena prioritizing GMP and strict facility registration, the era of flying under the radar is over. True international success now requires embedding regulatory strategy into the very DNA of product development from day one.



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