

Challenges and Strategies in Global Cosmetics Supervision

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ABSTRACT

This review thoroughly examines the challenges of cosmetic regulation in various countries and assesses the effectiveness of current harmonization strategies. It further investigates the role of cross-sector collaboration and emerging technologies in creating evidence-based policy recommendations for regulators, industry, and other stakeholders to strengthen the governance and cosmetic oversight. Regulatory discrepancies create market entry barriers, increase compliance costs, and impede global trade. Technological innovations, such as digital platforms, databases, artificial intelligence for safety assessments, and blockchain for traceability offer promising ways to enhance compliance and consumer safety. Ensuring product safety while encouraging innovation and market access requires an adaptive and globally coordinated cosmetic regulatory framework. Advancing regulatory efficiency and consumer protection further depends on strengthening international coordination, leveraging new evaluation technologies, and fostering collaboration among industry, academia, and governmental bodies. As a result, this review delivers practical insights that enable policymakers and industry stakeholders to build a sustainable and globally unified cosmetics regulatory system.

Keywords: cosmetic regulation, regulatory challenges, harmonization strategies, regulatory variations, new approach methodology (NAM)

INTRODUCTION

The cosmetics industry has experienced incredible growth and innovation in recent decades, resulting in a vast array of new products and a significant increase in sales. In 2020, the global cosmetics market was valued at approximately \$341.1 billion. It's expected to reach \$560.50 billion by 2030, growing at a compound annual growth rate (CAGR) of 5.1% from 2021 to 2030 (Ferreira et al., 2022). Cosmetics are no longer limited to enhancing appearance but have become integral to health, wellness, and modern lifestyles. Alves et al., (2024) described scientific advancements in nanotechnology in cosmetics, including nanoparticles, niosomes, and liposomes, and most of the formulations analysed in this review utilize antioxidant activities to combat premature aging, which is primarily driven by free radical damage. While not vital for physical health, cosmetic and beauty products have a great role in boosting mental well-being and confidence, a factor that accounts for their extensive application (Nayak et al., 2021). The global cosmetics industry is undergoing a significant transformation, driven

by five key trends: clean beauty, artificial intelligence and big data, men's cosmetics, multifunctional products, and a strong focus on sustainability and consumer loyalty (Ustymenko, 2023). These trends reflect a growing consumer preference for cosmetic formulations that align with the future and promise to be safer, more effective, and personalized, ushering in a new era in beauty science. Nonetheless, the rapid growth of the pharmaceutical industry presents new challenges, including regulatory oversight, product safety, and distribution, particularly in the context of market globalization and emerging innovative technologies. Regulating cosmetics involves navigating a multifaceted landscape, including rigorous safety assessments, precise ingredient labelling requirements, and compliance with both regional and international standards. Achieving global compliance necessitates harmonizing regulations across diverse markets while carefully considering cultural nuances and consumer expectations (Beg, 2020). However, cosmetic regulatory frameworks differ widely across

markets and countries, exhibiting a considerable lack of harmonization. This disparity presents a major obstacle for the global cosmetics industry in achieving a truly global product offering (Ferreira et al., 2022). The growing complexity of cosmetics, driven by rapid technological advances and the use of innovative materials, such as nanomaterials and bioengineered ingredients, underscores the need for updated regulatory approaches.

Countries have established diverse regulatory frameworks to safeguard the safety and efficacy of cosmetics. For instance, the European Union (EU) mandates non-animal testing methods for product safety evaluations, addressing both ethical and sustainability concerns (Pistollato et al., 2021). China has strengthened its oversight of the cosmetics industry through the Cosmetic Supervision and Administration Regulation (CSAR), which encompasses ingredient classification and the regulation of efficacy claims (Su et al., 2020). Dahiya et al., (2022) discussed the differences in nano-cosmetics regulations among countries; a paramount objective of any regulatory framework for nano-cosmetics to ensure the highest level of consumer safety. Nevertheless, the absence of universally accepted definitions and standardized testing protocols for cosmetics poses a significant barrier to achieving cohesive global regulation.

Despite several efforts toward unified regulatory guidelines, true global alignment has yet to be realized. Drawing from the EU's regulatory standards, the ASEAN Harmonized Cosmetic Regulatory Scheme aims to uphold the safety and quality of cosmetic products across ASEAN member states. However, its enforcement faces obstacles, including variations in national regulations and the need for separate notifications per country (REACH24H, 2025). The lack of mutual recognition agreements further complicates the regulatory landscape, increasing the administrative burden for manufacturers and potentially hindering market access. Kittisak (2023) provided a comprehensive analysis of small and medium-sized cosmetic enterprises (SMEs) challenges in inventory management and proposed actionable strategies that leverage technology and data analytics to enhance operational efficiency and competitiveness in the cosmetics industry.

Skin Consult BV, (2025) identifies major challenges in global cosmetics manufacturing, including compliance with diverse regulatory standards, simultaneous product quality checks,

affordable access to quality ingredients, supply chain issues, brand-specific formulation needs, timely delivery, protection of proprietary formulas and secrets, cost-price competitiveness, and the adoption of sustainable and eco-friendly practices. Similarly, Veeva Systems (2019) identifies four critical hurdles for cosmetic companies: expedited product launches, substantiated product claims, global regulatory adherence, and talent acquisition and retention. Hale Cosmeceuticals Inc., (2024) emphasizes the multifaceted challenges of global cosmetic manufacturing, encompassing market understanding, supply chain vulnerabilities, raw material costs, consumer demands, technological advancements, sustainability concerns, cultural nuances, and rigorous quality assurance. As consumer demands for transparency and ethical practices grow, addressing these challenges requires the integration of sustainability, technological innovation, and regulatory harmonization into business strategies. (Faster Capital (2025) further underscores the complexity of navigating international regulatory frameworks, highlighting stark differences such as the EU's stringent safety protocols under REACH compared to the U.S. FDA's more flexible, voluntary approach. These differences also extend to policies on animal testing, ingredient restrictions, and labelling requirements. The lack of a unified global framework creates significant business challenges, requiring companies to balance compliance costs with market access and consumer trust.

This review offers a comprehensive analysis of the challenges faced in cosmetic supervision across various national contexts while evaluating the effectiveness of strategies implemented to address them. By exploring the potential for intersectoral collaboration and leveraging technological advancements, this work provides evidence-based policy recommendations to assist regulatory agencies, industry stakeholders, and other relevant entities in strengthening cosmetic regulatory oversight. A narrative literature review approach was applied using references selected based on their relevance to global cosmetic regulation from 2019 to 2025, sourced from major scientific databases, official regulatory documents, and published articles. This aims to serve as a valuable reference for developing more adaptive and sustainable regulatory frameworks for cosmetics, in line with the dynamic demands of the global market and the rapid advancement of technologies.

CHALLENGES IN GLOBAL COSMETICS MANUFACTURING AND SUPERVISION

Regulatory Variations

Morel et al. (2023) discussed the regulatory aspects of cosmetics in the EU and 17 other countries, including ASEAN nations. Variations in regulatory frameworks create significant challenges for global trade and marketing, making it difficult to sell the same product universally. Disparities in cosmetic classification and ingredient regulations add complexities to trade, while the EU's prohibition on animal testing imposes further constraints. Ferreira et al. (2022) provided a detailed review of the cosmetic regulatory standards in the EU, USA, Canada, Japan, China, and Brazil, highlighting key differences and similarities. This study examined definitions, classifications, pre-market requirements, ingredient management, labelling, advertising regulations, and animal testing bans. Moreover, it also evaluated regulatory differences affecting product safety and accessibility across these regions.

The Indonesian Food and Drug Authority (BPOM) oversees cosmetics to guarantee product safety and quality by enforcing strict regulations on manufacturing, importation, and labelling, as well as ensuring the accuracy of advertising claims. All 11 (eleven) BPOM cosmetic regulations (in Indonesian), e.g., Supervision of Cosmetics Production and Distribution (BPOM No. 12/2023), Technical Requirements for Cosmetic Ingredients (BPOM No. 17/2022), Labelling, Promotion, and Advertising (BPOM No. 18/2024), Import Supervision (BPOM No. 28/2023), etc., are available for free download at this URL (Biro Hukum dan Organisasi, 2025). While Indonesia's cosmetics regulations align with the ASEAN Cosmetic Directive, which retain distinct elements, such as optional Halal certification (LPPOM MUI, 2023).

Pistollato et al. (2021) summarized the EU Directive 2010/63/EU (2010), Regulation (EC) No 1272/2008, Regulation (EC) No 1907/2006, Regulation (EC) No 440/2008, and Regulation (EC) No 1223/2009 on Cosmetics. The EU has progressively advanced the use of non-animal testing methods; however, animal testing remains necessary for assessing certain systemic effects. The integration of modern in vitro and silico methods is crucial, particularly for endpoints with validated alternatives, such as skin corrosion and irritation. Furthermore, collaboration is essential to advance and align regulatory practices with scientific progress. The latest EU guidelines on

cosmetics are outlined in Commission Regulation (EU) 2024/996 (The European Commission, 2024), which amends Regulation (EC) No 1223/2009. Regulatory changes now encompass stricter ingredient controls, revised safety assessment protocols, updated labelling mandates, and strengthened oversight through market surveillance and adverse effect reporting. See the Regulation for details.

The FDA (US Food and Drug Administration, 2022b) provides a comprehensive resource on cosmetics on its official website, entitled Cosmetics Guidance & Regulation. This section includes information on laws and regulations enforced by the FDA and guidance for the industry. It contains links to relevant laws, regulations, and guidance documents, making it a valuable resource for understanding FDA regulations on cosmetics. The FDA has also published numerous guidelines related to cosmetics, including 'Cosmetics & U.S. Law', 'Cosmetic Products & Ingredients,' 'Colour Additives Permitted for Use in Cosmetics,' 'International Harmonization; Policy on Standards,' and notices published in the Federal Register (e.g., Volume 60), etc. (US Food and Drug Administration, 2024a). As the most significant regulatory update since the FD&C Act of 1938, the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) enhances the FDA's role in overseeing cosmetic safety. The law is intended to ensure better protection for consumers who use these products regularly (US Food and Drug Administration, 2025). A summary of the FDA regulations for the cosmetic industry has been described at the URL of Precision Stability Storage (Precision Stability Storage, 2024).

Several key differences between cosmetic regulations by the FDA and the EU have been described and discussed by the URL of CosmeticScientist.com (Cuross, 2024), SkinConsult BV (Van der Burg, 2023) and Biorius (Biorius, 2022). The primary regulatory distinctions between the FDA and the EU pertain to pre-market approval, ingredient restrictions, safety assessments, the designation of responsible parties, and animal testing. Dela Cosmetics (2024) analysed the regulatory distinctions in cosmetics manufacturing between the EU and Asia, offering guidance to help brands navigate these intricate frameworks. The main differences are (1) the regulatory framework governing cosmetics, (2) safety and efficacy testing, (3) ingredient regulations, (4) product labelling and claims, as well as (5) the market entry and approval process.

Table I. Comparison of the Cosmetics Regulations in the EU, USA, China, and ASEAN

Regulatory Body	Key Characteristics	Challenges	Reference
European Union (EU)	Safety assessments, Bans on Animal Testing, Interface with REACH, Promotion of Alternative Methods, Guidance and Compliance	Compliance with Animal Testing Ban, Integration of Alternative Methods, Complexity of Regulatory Framework, Knowledge Gaps, Stakeholder Engagement.	(Pistollato et al., 2021)
United States (FDA)	Voluntary Registration, Post-market Surveillance, Manufacturer Responsibility, No Pre-market Approval Requirements	Limit of Regulatory Updates, Lack of Pre-Market Approval, Consumer Safety Risks, Variability in Ingredient Regulation, Global Harmonization Issues.	(Ferreira et al., 2022)
China (CSAR)	Comprehensive Structure, Focus on Safety and Quality, Regulatory Evolution, Emphasis on Scientific Evaluation, Future Prospects	Implementation Complexity, Transition from CHSR, Increased Responsibilities for Enterprises, Need for Innovation and Technical Adaptation, Regulatory Compliance Costs, Public Awareness and Education.	(Su et al., 2020)
ASEAN (ACD)	Inspired by EU Regulations aims for harmonization within ASEAN	Variations in National Implementation, Lack of Mutual Recognition	(REACH24H, 2025), (HSA (Health Science Authority) Government of Singapore, 2024)
Indonesia (BPOM)	Indonesia's cosmetics regulations emphasize safety, quality assurance, clear labelling, responsible advertising, mandatory notification, and optional Halal certification if claimed.	Lack of mutual recognition despite ASEAN harmonization, administrative burden, and varying interpretations of ASEAN guidelines across member states.	(Biro Hukum dan Organisasi, 2025)

The outlines the key regulatory standards for cosmetics in the EU, USA, China, ASEAN, and Indonesia (BPOM), summarizing the key characteristics of each regulator and the challenges that must be addressed in achieving global cosmetics regulatory harmonization (Table I). For region- or country-specific regulations, see the official website of the respective regulatory authorities (EU, FDA, CSAR, ACD, BPOM), where documents are typically available for free download.

The variation in global cosmetic regulations, as discussed above, has several implications for the industry, consumers, and regulatory bodies (Ferreira et al., 2022), (Morel et al., 2023); (a) Market Access, regulatory differences affect market entry and competition. Companies must adapt their products to meet the specific regulations of each market, which can be costly and time-consuming; (b) Product Safety, variations in regulations impact consumer safety. The differences in the regulations can lead to variations in product standards,

potentially affecting consumer safety; (c) Labelling & Advertising, different rules can lead to consumer confusion; (d) R&D, compliance with various standards influences product development. Companies may need to conduct additional testing and modify formulations to meet the requirements of global markets; (e) Economic Viability, multi-market compliance costs affect business; and (f) Consumer Access, regulations determine product availability in markets. Consumers in some regions may access a wider range of products, while others may be limited to a smaller selection.

As outlined above, the variety in global cosmetic regulations presents several challenges and opportunities for the industry. Harmonizing these regulations could help streamline the process and improve market access, but it would require significant cooperation and coordination among regulatory bodies worldwide (Figure 1).

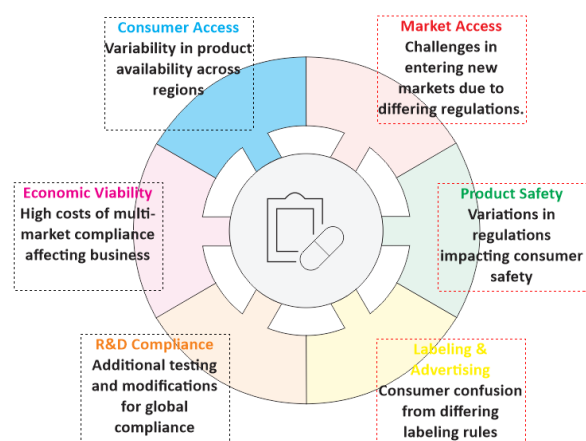


Figure 1. Global Cosmetic Regulation Challenges

Harmonization of Cosmetic Regulation

Regulatory harmonization refers to the process of aligning technical regulations and standards among different jurisdictions or authorities to ensure consistency and compatibility (US Food and Drug Administration, 2019). WHO (World Health Organization (WHO), 2025), asserted that harmonizing technical requirements for medicine regulation, encompassing legislation, technical guidelines, and procedures, forms the basis for successful collaboration. Effective implementation of medicine regulation necessitates the comprehensive consideration of all major aspects.

Cosmetic regulatory harmonization involves aligning and coordinating regulations across jurisdictions to ensure consistency while reducing barriers to trade and investment. By standardizing rules and requirements, this process enhances efficiency and facilitates smoother interactions among businesses, governments, and other stakeholders across borders (Regulatory harmonization from class: Intro to Public Policy Definition, 2025).

ASEAN Harmonization

The ASEAN Harmonized Cosmetic Regulatory Scheme, encompassing the ASEAN Cosmetic Directive (ACD), was established in September 2003 by the ASEAN countries, comprising 11 member states, including Malaysia, Thailand, Vietnam, Myanmar, Cambodia, Laos, Singapore, Indonesia, the Philippines, Brunei, and Timor-Leste. This framework aims to enhance cosmetic safety and quality across the region while facilitating the free movement of compliant cosmetics within ASEAN member states. The ACD was fully implemented on January 1, 2008. (REACH24H, 2025). The URL of the Health Sciences Authority (HSA) of the Singapore Government provides a complete document of the ACD (HSA (Health Science Authority) Government of Singapore, 2024). It serves as a collaborative initiative among ASEAN countries, aimed at achieving regulatory consistency for cosmetic products, which aims to reduce technical barriers to trade within the region, making it easier for companies to market their products across different ASEAN countries. The ACD is comprised of eight sections, i.e., (1) Definition and examples of cosmetic products, (2) Regulated Ingredients: Prohibited, Restricted, and Allowed Substances in the ASEAN Cosmetic Directive, (3) Labelling requirements, (4) Good manufacturing practices. (5) Safety assessment, (6) Adverse event reporting, (7) Documentation, and (8) Limits of contaminants. It aims to establish a harmonized set of rules for cosmetics within ASEAN member countries. While the ACD establishes a common framework, each ASEAN member country concurrently implements its specific national regulations. In practice, this indicates that cosmetic products must comply with both the ACD and the specific national regulations of each member state.

European Union harmonized regulatory framework

The European Union (EU) implemented a unified regulatory system for cosmetic products through Regulation (EC) No 1223/2009, enforced since July 2013, to uphold product safety and streamline market access across EU member states (The European Commission, 2009), (The European Union, 2013). Cosmetic products must comply with the broader REACH requirement, a broader regulation that applies to all chemicals (EUR-Lex, 2006). Commission Regulation (EU) 2024/996 modifies and revises the provisions of this regulation (The European Commission, 2024). The European Commission Joint Research Centre (JRC) has issued guidelines for the implementation of Regulation (EC) No 1223/2009, covering (1) the evaluation and verification of analytical techniques for cosmetics and (2) proposed measures for their standardization (Vincent, 2015).

EU Cosmetics Regulation is founded on the principle of free movement, granting cosmetics that comply with the regulation immediate and unrestricted access to the EU market. The system relies on in-market control with strong post-market surveillance, considered more effective for fast-moving consumer goods than pre-market approval. As part of EU Single Market – which ensures the free flow of goods, capital, people, and services – cosmetic product require consistent legislation across member states, including harmonized labelling, packaging, and safety regulations to enable the free movement of products throughout Europe (Cosmetic Europe, n.d.).

South America Mercosur Cosmetic Regulations

MERCOSUR, the Southern Common Market (Mercado Común del Sur), was established in 1991 by the Treaty of Asunción. It consists of Brazil, Argentina, Uruguay, and Paraguay, with Venezuela, currently suspended since 2017 (Biorius, 2025), (MERCOSUR, 2025). MERCOSUR's Resolution has been integrated into the regulatory frameworks of its member states. Uruguay and Paraguay follow identical guidelines, while Brazil and Argentina apply slight modifications. The region's cosmetics legislation is shaped by multiple Resolutions issued by the Grupo Mercado Común (GMC), MERCOSUR's executive body, for example, prohibited substances are described by Resolution GMC n°62/14, Restricted substances: Resolution GMC n°48/10 and n°24/11, Authorized dyes: Resolution GMC n°16/12, etc (Biorius, 2025).

Discussion on the Harmonization of Cosmetic Regulation

Harmonization of cosmetic regulations, whether within the EU or ASEAN or MERCOSUR, brings several key advantages i.e. (1) Enhanced market access and trade: Simplifies trade and reduces barriers for manufacture, (2) Improved consumer safety: Ensures high safety standards and protects consumer, (3) Increased clarity and efficiency: Streamlines processes for manufacturers and regulators, (4) Boosted innovation and competitiveness: Fosters R&D and creates a level playing field, (5) Improved regulatory efficiency: Reduces duplication of efforts and facilitates cooperation, and (6) Enhanced consumer trust: Builds trust in the safety and quality of the cosmetic products.

Several factors present challenges to achieving global regulatory harmonization (Méndez and Trejo, 2020): (1) Shifts in political landscapes; (2) Expertise within regulatory bodies, as some agencies lack specialists in all relevant fields; (3) Regional policies, since each country operates under its regulatory framework; (4) Limited resources, with agencies facing constraints related to personnel, funding, and infrastructure; (5) Technological limitations, as insufficient resources hinder the adoption of advanced systems; (6) Economic considerations, including the fees and financial requirements imposed by agencies for evaluating processes and services; and (7) National identity, which can impede harmonization when external directives are perceived as conflicting with domestic policies or national interests.

Besides those seven obstacles, Dong et al. (2023) indicated that a certain Regional Standard (e.g., European standard) is not fully applicable to people in another region; they identified the necessity of increasing allergen detection efficiency in the Han population via European standardized testing. Ethnic differences become important considerations for assessing products of the global cosmetic industry. These results demonstrated variations in skin sensitivity, reflected in both objective assessments and subjective reports, among different ethnic groups when exposed to standard positive materials (Lee et al., 2014). This suggests that the worldwide harmonization of cosmetics regulations might not be fully applicable. A further challenge to global harmonization lies in the requirement for Halal certification, particularly for countries with predominantly Muslim populations.

STRATEGIES FOR HARMONIZING REGULATION

Leveraging Technology

Regulation has a significant impact on technological innovation in the cosmetic industry, ensuring safety, driving compliance, and fostering research and development. Although such regulations can pose challenges, they also create opportunities for innovation that can lead to safer and more effective cosmetic products (Ferreira et al., 2022). Achieving harmonization of Cosmetic Regulations through technology adoption involves developing and implementing targeted strategies to create consistent regulatory standards for cosmetics utilizing technology. Achieving regulatory compliance and consistency across regions can be realized through technological solutions, such as developing digital platforms and databases, applying artificial intelligence (AI) and blockchain technology, strengthening regional and international collaborations, and standardizing New Approach Methodologies (NAMs).

Digital Platforms and Databases

Online platforms can be developed to provide regulators and manufacturers with easy access to the latest global regulations, ingredient restrictions, and safety assessments. This online information hub will help manufacturers stay informed and compliant with the constantly changing global regulatory landscape. Furthermore, databases can be created to describe approved ingredients, testing methods, safety data, cosmetovigilance, and test results, preventing redundant efforts and errors while speeding up product approvals.

The URL of the Health Science Authority of Singapore provides the ASEAN Cosmetic Directive (ACD), comprised of eight documents that can be freely downloaded (HSA (Health Science Authority) Government of Singapore, 2024): (1) Definition and examples of cosmetic products; (2) Prohibited, restricted, and permitted ingredients Annexes of the ASEAN Cosmetic Directive (Updated July 2024; (3) Labelling requirements; (4) Good manufacturing practices; (5) Safety assessment; (6) Adverse event reporting; (7) Documentation; and (8) Contaminants limits. However, Document (2) of the ACD lacks descriptions of the analytical methods employed. The Indonesian Food and Drug Authority (BPOM) has developed a database that describes cosmetics in the Indonesian market, containing harmful substances and are freely

accessible (Direktorat Standardisasi Obat Tradisional, 2024).

The EU has common cosmetic legislation and Regulations that can be freely downloaded (The European Commission, 2024), (The European Commission, 2009). These regulations outline the prohibited substances in cosmetics, the restricted ingredients permitted under specific conditions, and the approved colorants for cosmetic formulations. However, they do not include analytical methods for evaluating these substances. In order to support the implementation of Regulation (EC) No 1223/2009, the Cosmetic Products Notification Portal (CPNP) was developed as a free online system. Once a cosmetic product is registered in the CPNP, no additional notification is required at the national level within EU member states (The European Commission, 2025a), Market Surveillance (The European Commission, 2025b), Regulations, Catalogues of nanomaterials, and other related links on the nanomaterials for cosmetics are provided by this URL of the EU (The European Commission, 2025c).

The FDA provides digital platforms outlining Prohibited & Restricted Ingredients in Cosmetics (US Food and Drug Administration, 2022e), Colour Additives Permitted for Use in Cosmetics (US Food and Drug Administration, 2022a), and Product Testing of Cosmetics (US Food and Drug Administration, 2022d) to ensure the safety of cosmetic ingredients and products. This resource features six digital platforms (Table II), offering detailed information and guidelines accessible through interactive topic selections as follows.

Table II. Resources on the Safety Substantiation of Cosmetics

No.	Regulatory Topic
1.	Animal testing
2.	Cruelty free/not tested on animals
3.	Guidance for industry: safety of nanomaterials in cosmetic products
4.	Investigational new drug applications (INDs)-determining whether human research studies can be conducted without an IND
5.	Potential contaminants
6.	Cosmetic science and research

The cosmetics industry operates within a critical framework of safety and regulatory compliance. A strong cosmetics ingredients

database is indispensable for navigating this complex landscape. Digitizing ingredient information, when available online, empowers companies to ensure the safety and regulatory compliance of their formulations. This includes identifying and avoiding banned substances, verifying adherence to specific safety requirements for each target market, and ultimately building a robust compliance strategy. With official digital platforms and databases, researchers can quickly verify whether an ingredient is approved for use in a particular country market or flagged as potentially hazardous. Digital platforms and databases accelerate the formulation process and reduce the risk of regulatory penalties from non-compliant ingredients.

Unfortunately, the currently available digital platforms for cosmetics published by regulators, as described above, do not provide a complete set of standardized chemical analysis methods for all prohibited and restricted ingredients. Manufacturers should first develop and standardize methods for ingredients not detailed in the databases because this process will be costly and time-consuming. Therefore, it is advisable to include them in the new edition of the databases.

Artificial Intelligence (AI) and Machine Learning (ML)

Grech et al. (2024) highlighted the broad and transformative role of AI in the cosmetics industry, encompassing virtual try-ons, tailored product suggestions, robotic-assisted procedures, and advancements in ethical testing. AI offers advancements in assessing cosmetic ingredients, contributing to greater safety and effectiveness. Additionally, under EU regulations, AI-driven *in silico* models hold significant potential to replace traditional animal testing methods, such as the Local Lymph Node Assay and the Guinea Pig Maximization Test (The European Commission, 2009). However, it needs to be strictly validated before routine application for each of the compounds. This commitment to ethical standards corresponds with the growing public interest in animal-friendly products. Although AI provides substantial benefits, issues surrounding personal data safeguards, transparency in consent, and the influence on beauty norms remain pressing considerations. Pandya and Padma (2024) aimed to assess the application of AI-driven marketing tools within the Indian cosmetics industry and their subsequent effects on consumer behaviour.

AI can be leveraged to analyse extensive regulatory datasets, enabling the identification of similarities, inconsistencies, and potential avenues for harmonization across jurisdictions. The pharmaceutical regulatory process is time-consuming due to its complexity and frequent updates. Traditional methods are considered slow, but AI has presented promise in other pharmaceutical areas. By integrating AI with human expertise, the industry can streamline the regulatory process, allowing for more strategic approval planning (Patil et al., 2023). In addition, Fu et al. (2024) examined the role of artificial intelligence in drug regulation, highlighting its potential to drive greater oversight, efficiency, and innovation, ultimately contributing to improved global public health.

Ajmal et al. (2025) also provide an overview of AI-driven tools utilized in regulatory processes, including DocShifter, Veeva Vault, RiskWatch, Freyr SubmitPro, Litera Microsystems, and cortical.io etc. Their study explores the benefits and drawbacks of using these technologies in regulatory processes. This article examines AI and machine learning in reshaping pharmaceutical regulatory affairs, highlighting their role in streamlining operations, expediting outcomes, and maintaining adherence to safety regulations. Machine learning (ML) algorithms are capable of predicting potential safety and regulatory issues based on ingredient composition and intended use, thereby facilitating proactive risk management.

Singh et al. (2024) described and discussed how AI, ML, and omics technologies are revolutionizing chemical risk assessment by offering new ways to understand toxicity, predict risks, and manage them. This integration, as highlighted in their review, helps predict cancer risk by analysing genomic instability and provides a comprehensive framework for mitigating health risks and informing public health policies. Their review also provides the URLs of various free and commercial toxicity prediction tools for assessing carcinogenicity, genotoxicity, and mutagenicity. The FDA's draft guidance outlines recommendations for leveraging AI in regulatory assessments, focusing on drug and biological product safety, efficacy, and quality (U.S. Department of Health and Human Services FDA, 2025); although it primarily focuses on pharmaceuticals, its principles may also be relevant to cosmetics regulations. Kang et al. (2023) utilized ML algorithms to evaluate the

irritation and corrosivity risks of 545 liquid chemicals. Their XGBoost-based models, incorporating physicochemical descriptors, yielded accuracy (0.73–0.81), sensitivity (0.71–0.92), and positive predictive value (0.65–0.81). Qiao et al. (2024) developed a novel method for detecting allergens in cosmetics with greater accuracy. They combined two cell types, HaCaT and THP-1, and analysed gene expression changes in THP-1 cells following exposure to various chemicals. By applying multiple machine learning techniques to this data, they found that the Random Forest and voomDQDA models were the most effective, both achieving 100% accuracy in allergen identification. This innovative approach, integrating cell culture with advanced data analysis, presents a promising avenue for improving cosmetic safety testing while potentially reducing the reliance on animal testing.

While AI and ML provide powerful predictive models, real-world validation through experiments is crucial to ensure accuracy and reliability. Predictions must be tested against empirical data to confirm their effectiveness and refine models for better precision. Experimental validation is essential for identifying biases, unexpected variables, and limitations that purely computational approaches might overlook. The integration of advanced technological approaches with empirical investigation is critical to ensuring reliable risk assessments and evidence-based decision-making.

Blockchain Technology

Blockchain operates as a distributed digital ledger, maintaining records across a network of multiple computers. Blockchain technology is unique; it operates without a central authority (decentralized). Once information is recorded on it, it cannot be altered (immutable). Strong encryption protects the data, and its transparent nature fosters trust among participants. These features make it valuable for improving the efficiency and traceability of ingredients and products throughout the supply chain, ensuring authenticity and compliance with safety and sustainability standards (Centobelli et al., 2022).

Although blockchain technology is still evolving, beauty brands have rapidly recognized its potential to enhance customer interactions and strengthen brand credibility. It is applicable across diverse domains, including (1) tracking product movement across the supply chain, (2) verifying authenticity, (3) optimizing loyalty programs, (4) integrating non-fungible tokens (NFTs) to combine

branding with artistic expression, and (5) utilizing big data for tailored product development. Blockchain is driving a shift toward more consumer-focused retail strategies, enabling shoppers to make informed purchases, engage with adaptable loyalty programs, and access customized product offerings (Ryder, 2021).

The Drug Supply Chain Security Act (DSCSA) is a federal law enacted by the US FDA to enhance the safety and traceability of prescription drugs within the American supply chain. Furthermore, (US Food and Drug Administration, 2024b) establishes measures to develop an interconnected digital system for tracking designated prescription medications at the package level throughout the supply chain, which aims to protect the U.S. drug distribution network by preventing the infiltration of unsafe pharmaceuticals, identifying any that may enter the system, and facilitating swift action to remove them, ensuring patient safety. Payandeh et al. (2024) published a review paper on the Supply Chain Traceability Blockchain (STBB). It concludes that STBB has the potential to revolutionize supply chain traceability, providing numerous benefits while also highlighting areas for future research and development.

Currently, the use of blockchain technology in the global cosmetics industry faces several challenges, including high implementation costs and complexity, scalability issues that affect transaction speed, technical barriers due to a lack of expertise, difficulties integrating with existing systems, regulatory uncertainties, and the need to balance data transparency with privacy.

Strengthening Regional and International Collaborations

This section highlights key international and regional collaborations among cosmetics regulatory authorities that examines their initiatives to address challenges across global and regional cosmetics safety and regulatory frameworks. Furthermore, it summarizes and analyses various cooperation models established within the cosmetics and pharmaceutical sectors.

Founded in 2007, the International Cooperation on Cosmetics Regulation (ICCR) (2025), is a voluntary alliance comprising cosmetics regulatory authorities from Brazil, Canada, Chinese Taipei, the European Union, Israel, Japan, the Republic of Korea, and the United States. This serves as a collaborative platform dedicated to enhancing global consumer protection by advancing regulatory alignment and reducing

obstacles to international trade. Some of the latest key documents released by ICCR include (International Cooperation on Cosmetics Regulation (ICCR), n.d.): (1) Revised Annex listing validated alternatives to animal testing for cosmetics (August 2024), (2) Updated Annex detailing international cosmetic standards (July 2024), and (3) Supplementary Annex on international cosmetic standards (July 13, 2023). Unfortunately, documents (2) and (3) do not yet provide completed standardized methods of chemical analysis for common prohibited and restricted ingredients in cosmetics.

Driven by the globalization of the cosmetics market, the FDA actively participates in international cosmetic regulatory activities. The FDA collaborates with regulatory authorities in other countries through the ICCR (US Food and Drug Administration, 2022c). Some important issues have been considered for the collaborations, including (1) Ingredient Nomenclature, (2) Color Additives, (3) Animal Testing and the Development of Alternatives, and (4) Ultraviolet (UV) Filters (Sunscreens).

The (ASEAN-Australia-New Zealand Free Trade Area Economic Cooperation Support Programme, 2021) facilitates the implementation of the ASEAN Cosmetic Directive (ACD) (HSA (Health Science Authority) Government of Singapore, 2024) by promoting harmonized and effective regulatory practices within the cosmetics industry. Through its initiatives, AANZFTA supports ASEAN member states in enhancing their regulatory frameworks and aligning them with international standards. For ensuring effective governance of the cosmetics industry within the AANZFTA framework, a structured and collaborative approach is recommended. This approach encourages regional cooperation, strengthens regulatory capacities, and improves the consistency of cosmetic standards across member states.

The Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC) was formed as a cooperative network to oversee cosmetics market surveillance across EU member states. Its aims to promote a unified and coherent approach to addressing consumer product safety issues, particularly in the cosmetics sector. One of the critical areas of cooperation is the communication of serious undesirable effects (SUE) attributable for cosmetics use. Key objectives of the PEMSAC are coordinating activities, exchanging information, developing joint projects,

and exchanging expertise and best practices (The European Commission, 2025a).

The International Collaboration for Cosmetics Safety (ICCS) (International Collaboration on Cosmetic Safety (ICCS), 2025), (International Collaboration on Cosmetic Safety (ICCS), 2024) is a global partnership of cosmetic manufacturers, suppliers, industry associations, and animal protection groups. Collectively, they advocate for the adoption of non-animal methods in cosmetic safety testing. The ICCS supports this effort by advancing scientific research, offering education and training, as well as engaging with regulatory bodies to guarantee the safety of cosmetic products and their ingredients.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) believes that countries should work together to improve their drug regulations. This collaboration aims to strengthen regulatory systems, foster regulatory reliance, and ensure timely patient access for innovative therapies. Some key points i.e., Strengthening Regulatory Systems, Regulatory Reliance and Convergence, Harmonization Initiatives, Pilot Projects and Innovative Systems, and Public Health Commitment should be considered (International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), 2024). USP White Paper (USP White Paper, 2023) also discusses the importance of regulatory and pharmacopeial convergence, harmonization, and global cooperation in enhancing the resilience of the medicines supply chain. The paper underscores the critical need for ongoing collaboration and harmonization efforts among regulatory authorities to improve the resilience and efficiency of the global medicines supply chain.

Regional and international collaborations in the field of cosmetics or pharmaceutical regulations in common can provide the following benefits i.e.: (1) Harmonization of the Regulations and Reduced Trade Barriers, (2) Enhanced Consumer Safety, (3) Improved Regulatory Efficiency, and (4) Increased Trust and Confidence. Collaboration facilitates the sharing of scientific knowledge and expertise, leading to more standardized and strong safety assessments and better-informed regulatory decision-making. Harmonized standards help ensure that cosmetic products meet consistent safety and quality requirements across different regions, enhancing consumer protection worldwide.

Standardizing NAMs (New Approach Methodologies)

While the global cosmetics industry increasingly embraces scientifically advanced, cruelty-free safety assessments, replacing outdated animal testing, the EU's progressive adoption of non-animal methods is created by the recognition that certain complex systemic effects still present testing challenges (Pistollato et al., 2021). The UK took a pioneering step in 1998 by becoming the first country to prohibit animal testing for cosmetic products. Over the following two decades, several nations gradually eliminated animal testing and restricted the sale of newly tested cosmetics, eventually leading to comprehensive legal bans. The EU, for instance, initiated a phase-out process in 2004, progressively limiting the production and sale of animal-tested cosmetics. By March 2013, a full prohibition was implemented across the EU. Despite these advancements, animal testing for cosmetics remains a requirement in certain regions (Aida Cosmetics, 2025). New Approach Methodologies (NAMs) are defined as *in vitro*, *in chemical*, or *in silico* methods, applied individually or in combination, that strengthen chemical safety assessments by providing more protective and relevant models, thereby contributing to the replacement of animal testing (Sewell et al., 2024).

Table III. OECD Test Guidelines (TGs) for Non-Animal Cosmetic Testing

Code	Test Method Description
TG 430	Transcutaneous Electrical Resistance (TER) test method for skin corrosion
TG 431	Reconstructed human Epidermis (RhE) test methods for skin corrosion
TG 435	In vitro membrane barrier test method for skin corrosion
TG 439	Reconstructed human Epidermis (RhE) test methods for skin irritation
TG 442C	In chemico skin sensitisation assays addressing protein binding
TG 442E	In vitro skin sensitisation assays addressing dendritic cell activation
TG 428:	Skin absorption: in vitro method
TG 432:	3T3 Neutral Red Uptake (NRU) phototoxicity test
TG 495:	In chemico test method based on reactive oxygen species (ROS) and photostability
TG 498:	In vitro phototoxicity - Reconstructed human Epidermis (RhE) phototoxicity test method

The OECD (Organisation for Economic Co-operation and Development, 2025) provides internationally recognized guidelines for testing chemicals using New Approach Methodologies (NAMs), including cosmetics (Table III). These guidelines are part of the OECD Test Guidelines for the Testing of Chemicals, which cover various non-animal testing methods. The PDF files of the testing methods can be freely downloaded from the OECD website and the ICCR Cosmetics (International Cooperation on Cosmetics Regulation (ICCR), 2024).

GARD™ (Genomic Allergen Rapid Detection) is a cutting-edge technology platform, with GARD™ skin being its most advanced application for assessing skin-sensitizing chemicals. This assay utilizes a dendritic cell-like cell line, effectively simulating the immunological processes that initiate and regulate skin sensitization (Johansson et al., 2019). A spectrophotometric assay for skin sensitization potential based on MIE measurement—the ProtReact assay has developed by Ferreira et al. (2023). ProtReact is a cheaper, faster, simpler, and more accessible alternative for the Direct Peptide Reactivity Assay (DPRA); and the ProtReact assay and DPRA give similar results. The implementation of the Triangular Approach as a validation method for NAM skin sensitization has been reviewed and discussed (Natsch et al., 2021). Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) published a Report of the ICCVAM) Validation Workgroup in March 2024 (ICCVAM, 2024).

Several review articles on alternative animal models have been published. Nabarretti et al. (2022) offer a focused review of current in vitro models for evaluating cosmetic safety, specifically addressing irritation, corrosion, sensitization, mutagenicity, genotoxicity, and phototoxicity. Their work serves as a guide for selecting the most appropriate tests. A broader overview of both in vitro and ex vivo alternative models used in cosmetic safety assessments was also introduced by Barthe et al. (2021). Their review covers regulatory compliance, genotoxicity, skin sensitization, irritation, endocrine properties, and dermal absorption, and further examines model limitations and emerging technology. Silva and Tamburic (2022) provide a state-of-the-art review of alternative testing methods, also known as NAMs, focusing on assessing the safety of cosmetic ingredients and

products. Increasing public awareness appears crucial for fostering support toward the development and regulatory acceptance of NAMs. Moreover, the application of NAMs offers a more cost-effective, rapid, human-relevant, and ethical approach to the safety evaluation of naturally derived cosmetic materials (Manful et al., 2024).

Alongside NAMs, the cosmetic industry requires validated state-of-the-art analytical techniques for quality control, enabling the exploration, understanding, optimization, and evaluation of cosmetic product performance at the nano, micro, and macroscopic levels. Recent developments have reviewed in chromatography, spectroscopy methods, and biosensors for cosmetics analysis. The inherent complexity of cosmetic formulations, along with the possibility of trace unauthorized additives, posed challenges to the application of specific analytical technologies (Rico et al., 2024). Pre-treatment methods for cosmetics have been summarized, which are intended to enhance analytical capabilities and refine detection and regulatory approaches in the industry (Du et al., 2024). All chemical methods used in cosmetic analysis must be validated following the latest official regulations. Without proper validation, the integrity of the evaluation data cannot be unequivocally confirmed.

Discussion on Leveraging Technology

The successful implementation of technology towards global harmonization necessitates indispensable cooperation among national regulators, academics, and industry stakeholders. This partnership is crucial for facilitating the collaborative validation of New Approach Methodologies (NAMs), which may integrate AI and ML, across diverse national conditions to ensure their broader applicability. Furthermore, the collaboration is also essential for developing analytical methods and standardizing chemical analysis techniques to detect and quantify newly prohibited chemical ingredients in cosmetics. In order to achieve these objectives, it is required to organize routine workshops and/or training sessions concerning NAMs or new chemical analysis techniques for (newly) prohibited substances. Cosmetic regulations for individual countries or regions should be provided in both English and their respective national language to streamline access for the database platform.

POLICY RECOMMENDATION

Adopting an Adaptive Regulatory Framework

The European Union's Cosmetic Products Regulation (EC) No 1223/2009 demonstrates the principles of an adaptive regulatory framework within the cosmetics industry. This regulation is designed to ensure the safety of cosmetic products while allowing for flexibility and adaptation to new scientific and technological developments. Key features demonstrating its adaptive nature include periodic reviews and updates, the establishment of scientific committees, a notification system, and adaptation to technological advancements (Ferreira et al., 2022). See the previous section for discussions on EU Cosmetic Regulations.

Adopting an adaptive cosmetics regulatory framework involves several key steps to ensure that regulations remain effective and responsive to new information and technological advancements (ASEAN-Australia-New Zealand Free Trade Area Economic Cooperation Support Programme, 2021). These include (Benneer and Wiener, 2019): (1) Assessment of current regulations; reviewing current standards, technical regulations, and conformity assessment procedure (2) Stakeholder engagement; all relevant stakeholders, including industry representatives, consumer groups, and regulatory bodies should be involved in the discussion, (3) Development of adaptive mechanisms; allowing for periodic review and updates of regulations must be designed, (4) Implementation of monitoring systems; strong monitoring and data collection systems must be established for gathering information on the performance and impact of the regulations, (5) Capacity building; investing in the training and capacity-building initiatives for regulatory authorities to ensure they are equipped to manage and implement adaptive regulations effectively, (6) Pilot testing and feedback must be performed before full-scale implementation; conducting pilot tests of the new regulatory framework to identify potential issues and gather feedback from stakeholders, and (7) Continuous improvement; ensuring the regulations remain relevant and effective over time.

These steps ensure that regulations remain effective, responsive to technological advancements, and aligned with evolving industry and consumer needs. By fostering flexibility and adaptability, such a framework can enhance regulatory efficiency, promote innovation, and ensure the safety and quality of cosmetic products in a rapidly changing landscape.

Promoting Sustainable Practices

Several key strategies could be recommended to promote sustainable practices in the harmonization of cosmetic regulation consisting: (1) Eco-design, which prioritizes minimizing environmental impact throughout a product's lifecycle by utilizing sustainable raw materials, optimizing energy efficiency in production, and designing for recyclability (Quantis, 2025), (2) Life Cycle Assessment (LCA) helps understand the environmental impact of cosmetic products. It concerns at the whole process, from the raw materials come from to the condition when the product is thrown away. This helps find ways to make the product more environmentally friendly at every stage of the product's full life cycle (Cosmetic Europe's Strategic Project Team 'Sustainable Development', n.d.), (3) Sustainable Packaging, prioritizes minimizing waste by applying recyclable, biodegradable, and reusable materials. Innovative packaging design can significantly lower the environmental impact of cosmetic products (Quantis, 2025), (4) Regulatory Alignment, foster consistent sustainability standards across regions by harmonizing definitions, criteria, and labelling requirements for sustainable products (Cosmetic Europe's Strategic Project Team 'Sustainable Development', n.d.), (5) Transparency and Reporting, promote corporate transparency regarding sustainability practices and require reporting on environmental and social impacts. This fosters consumer trust and drives industry-wide improvements (Cosmetic Europe's Strategic Project Team 'Sustainable Development', n.d.), (6) Stakeholder Collaboration, foster collaboration among regulators, industry, and NGOs to share best practices and develop shared sustainability goals (Quantis, 2025), and (7) Consumer Education, by educating consumers about the importance of sustainability in cosmetics and empowering them to make eco-friendly choices. The demand for sustainable products and encourage companies to adopt greener practices can be shaped (Quantis, 2025).

Sasounian et al., (2024) review emphasized the cosmetic industry's shift towards sustainability. Their study explored sustainable ingredients derived from diverse sources, including plants, animals, microorganisms, cell cultures, and recycled materials. It further evaluated the benefits and challenges associated with these ingredients. This evaluation served as the basis for discussing the development of

innovative, sustainable cosmetic products designed to meet consumer demands. Making traditional cosmetics can harm the environment, thus the industry is looking for eco-friendly options. Nhani et al., (2024) reviewed the latest trends and future ideas for sustainable cosmetics, focusing on new technologies and using waste materials. It also shows how nanotechnology can produce cosmetics more sustainable by using tiny carriers to improve how well natural ingredients from waste work, stay stable and get absorbed by the skin. The abovementioned strategies aim to minimize environmental impact, foster industry-wide sustainability standards, and empower consumers to make eco-friendly choices.

By implementing these measurements, the cosmetic industry is able to align with global sustainability goals, reduce its ecological footprint, and contribute to a more environmentally responsible future. L'Oréal, the world's leading beauty company, is partnering with IBM (NYSE: IBM) to explore more sustainable cosmetic formulations. The collaboration will leverage IBM's generative AI expertise to analyse formulation data and identify opportunities to reduce energy and material waste through the use of sustainable raw materials (IBM, 2025).

Enhancing Capacity Building

Enhancing capacity building for harmonizing cosmetic regulation involves several key strategies, including (1) Training and Education, implement comprehensive training programs for regulators, industry, and other relevant parties. This includes workshops, seminars, and online courses on best practices, regulatory standards, and new technologies (ERIA Economic Research Institute for ASEAN and East ASia, 2016); (2) International Collaboration, foster partnerships between countries and international organizations to share knowledge, resources, and expertise (Azatyan, 2024); (3) Technical Assistance, offering technical assistance to countries with less developed regulatory systems. This can involve sending experts to help develop and implement regulatory frameworks, conducting assessments, and providing ongoing support (Azatyan, 2024); (4) Standardization of Practices, encourage the adoption of standardized regulatory practices and guidelines across various regions to ensure consistency and reliability in cosmetic regulation (ASEAN-Australia-New Zealand Free Trade Area Economic Cooperation Support Programme, 2021); (5) Resource Allocation,

ensure adequate resources are allocated for regulatory activities, including funding, personnel, and infrastructure. This can help build robust regulatory systems capable of supporting harmonization efforts (Azatyan, 2024);

(6) Stakeholder Engagement, engage with all relevant stakeholders, including industry representatives, consumer groups, and non-governmental organizations, to gather input and build consensus on regulatory harmonization efforts (ERIA Economic Research Institute for ASEAN and East ASia, 2016); and (7) Monitoring and Evaluation, implement systems to monitor and evaluate the effectiveness of capacity-building initiatives. This can help identify areas for improvement and ensure that efforts are achieving the expected outcomes (Azatyan, 2024).

These strategies aim to build robust regulatory systems, foster global cooperation, and ensure consistent and reliable cosmetic regulation across regions. By implementing these measures, countries can strengthen their regulatory frameworks, promote harmonization, and ultimately ensure the safety and quality of cosmetic products for consumers worldwide.

Encourage Industry-Agency Collaboration

Harmonizing cosmetic regulations requires strong collaboration between industries and regulatory agencies. This can be achieved through several key strategies: 1) establishing regular dialogue and open communication channels fosters trust and allows for collaborative problem-solving; 2) creating joint working groups comprising members from both sides enables focused discussions on specific issues, such as ingredient safety, labelling, and sustainability; 3) promoting transparency through information sharing on regulatory changes, compliance requirements, and industry trends keeps all stakeholders informed; 4) implementing joint training programs and workshops can enhance understanding of regulations and best practices, aligning expectations and improving compliance; and 5) employing feedback mechanisms allows industry stakeholders to contribute to regulatory development, ensuring practicality. These collaborative efforts lead to harmonized regulations that protect consumers while supporting a thriving cosmetics industry.

Tanaka and Lopez (2024) conclude that fostering strong collaborations among industry, academia, and government is essential for driving innovation in medical devices, with a positive

outlook for future partnerships that can address public health needs effectively. Moreover, the scope of these collaborations may be extended to pharmaceutical products, which encompass cosmetics. Through university partnerships, the cosmetic industry can achieve greater efficiency in developing and validating NAMs and other chemical analyses of new novel ingredients for their purposes.

To streamline compliance, collaboration among manufacturers, regulators, universities, and industry stakeholders is important as well. This collaborative approach enables early identification of potential regulatory obstacles during product development, fostering faster innovation without sacrificing safety. Cosmetic manufacturers face the complex but crucial task of balancing innovation with regulation. Successfully navigating compliance while driving innovation requires understanding the regulatory landscape, fostering collaboration, and embracing emerging technologies. A proactive approach to regulation will be essential for ensuring product safety and efficacy, and meeting the demands of increasingly discerning consumers as the industry evolves (Hale Cosmeceuticals Inc, 2024) (Figure 2).

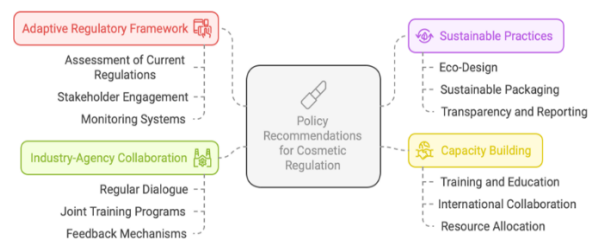


Figure 2. Policy Recommendations for Cosmetic Regulations

Future Prospective

In the upcoming years, the landscape of cosmetic regulation is anticipated to evolve significantly through the integration of digital innovations, strengthened safety protocols, and expanded global alignment. Regulatory agencies are increasingly leveraging tools like artificial intelligence (AI) and blockchain to modernize oversight processes, enhance data transparency, and streamline regulatory workflows. Simultaneously, broader societal expectations, particularly regarding ethical sourcing, environmental sustainability, and consumer well-being, are influencing how regulations are designed and implemented. In order to keep effective in this dynamic context, future regulatory systems must

embrace flexibility, support continuous technological integration, and foster open channels for cross-border collaboration. These forward-looking strategies will be critical in ensuring that cosmetic regulation keeps pace with industry innovation and global public health priorities.

CONCLUSIONS

The current diversity in cosmetic regulatory frameworks presents substantial challenges for uniform compliance and international trade, yet it also offers opportunities for region-specific innovation. Achieving alignment across these varied systems requires sustained cooperation among policymakers, scientific communities, and industry leaders to build trust and consensus on best practices. Rather than adopting a one-size-fits-all approach, successful harmonization should respect local contexts while pursuing global standards that uphold safety, transparency, and equity. Furthermore, acknowledging differences in technical capacity and cultural norms is essential to ensure the inclusiveness and effectiveness of any regulatory integration. Ultimately, a globally responsive regulatory ecosystem grounded in collaboration, mutual recognition, and scientific rigor will ultimately benefit all stakeholders by enabling safer products, more efficient oversight, and responsible industry growth.

REFERENCES

Aida Cosmetics (2025). Animal testing & cosmetics. <https://ada-cosmetics.com/expert-stories/animal-testing-cosmetics>

Ajmal, C. S., Yerram, S., Abishek, V., Nizam, V. P. M., Aglave, G., Patnam, J. D., et al. (2025). Innovative approaches in regulatory affairs: leveraging artificial intelligence and machine learning for efficient compliance and decision-making. *AAPS J* 27, 22. <https://doi.org/10.1208/s12248-024-01006-5>

Alves, P. L. M., Nieri, V., Moreli, F. de C., Constantino, E., de Souza, J., Oshima-Franco, Y., et al. (2024). Unveiling new horizons: advancing technologies in cosmeceuticals for anti-aging solutions. *Molecules* 29. <https://doi.org/10.3390/molecules29204890>

ASEAN-Australia-New Zealand Free Trade Area Economic Cooperation Support Programme (2021). Desk research on good regulatory practice in the cosmetics industry. <https://aanzfta.asean.org/uploads/2022/0>

1/Desk%20Research%20on%20Good%20Regulatory%20Practice%20in%20the%20Cosmetics%20Industry.pdf

Azatyán, S. (2024). Update From WHO: Global perspective on regulatory harmonization and convergence to support reliance. *CMC Strategy Forum, North America*. https://www.casss.org/docs/default-source/wcbp/2024-speaker-presentations/azatyán-samvel-world-health-organization-2024.pdf?sfvrsn=5f5fc760_6

Barthe, M., Bavoux, C., Finot, F., Mouche, I., Cuceu-Petrenci, C., Forreryd, A., et al. (2021). Safety testing of cosmetic products: overview of established methods and new approach methodologies (nams). *Cosmetics* 8. <https://doi.org/10.3390/cosmetics802005>

Beg, M. R. (2020). Cosmetic-regulations, research & marketing challenges and global compliance: An overview. *OSF Preprints*. <https://doi.org/10.31219/osf.io/d8tzu>

Benbear, L. S., and Wiener, J. B. (2019). Adaptive regulation: instrument choice for policy learning over time.

Biorius (2025). South America mercosur cosmetic regulations, regulatory context MERCOSUR. <https://biorius.com/cosmetic-regulations/south-america-mercosur>

Biorius (2022). Comparison between the US and EU cosmetics regulations. <https://biorius.com/cosmetic-news/comparison-between-the-us-and-eu-cosmetics-regulations>

Biro Hukum dan Organisasi, BPOM RI (2025). Jaringan dokumentasi dan informasi hukum Badan Pengawas Obat dan Makanan RI (Legal documentation and information network of the Indonesian Food and Drug Authority). <https://jdih.pom.go.id>

Centobelli, P., Cerchione, R., Vecchio, P. Del, Oropallo, E., and Secundo, G. (2022). Blockchain technology for bridging trust, traceability, and transparency in circular supply chain. *Information and Management* 59, 103508. <https://doi.org/10.1016/j.im.2021.103508>

Cosmetic Europe (n.d.). Understanding the cosmetic regulation. <https://cosmeticseurope.eu/cosmetics-industry/understanding-cosmetics-regulation>

Cosmetic Europe's Strategic Project Team 'Sustainable Development' (n.d.). Good

- sustainability practice (GSP) for the cosmetic industry. https://www.cosmeticseurope.eu/files/4214/6521/4452/GSP_Brochure.pdf
- Cuross, B. (2024). Differences European Vs US cosmetic regulation (MoCRA). *CosmeticScientist.com*. <https://cosmeticscientist.com/differences-european-vs-us-cosmetic-regulation-mocra>
- Dahiya, R., Dubey, S., and Dahiya, S. (2022). Current global regulations for nanocosmeceuticals. In *Nanocosmeceuticals* (pp 483-510). Academic Press, Elsevier. <https://doi.org/10.1016/B978-0-323-91077-4.00016-8>
- Dela Cosmetics (2024). Understanding the regulatory differences in cosmetic manufacturing. <https://dela.pl/en/understanding-the-regulatory-differences-in-cosmetics-manufacturing-europe-vs-asia>
- Direktorat Standardisasi Obat Tradisional, S. K. dan K. (2024). Database kosmetik mengandung bahan berbahaya (Databases of cosmetics containing hazardous ingredients). <https://standar-otskk.pom.go.id/otskk-db/kategori/database-kosmetik-mengandung-bahan-berbahaya>
- Dong, C., Liu, F., Liao, Z., Lin, L., Wang, R., Du, J., et al. (2023). Analysis of adverse reactions of cosmetics in Chinese han population in recent five years. *Clin Cosmet Investig Dermatol* 16, 2419–2428. <https://doi.org/10.2147/CCID.S418591>
- Du, X. N., He, Y., Chen, Y. W., Liu, Q., Sun, L., Sun, H. M., et al. (2024). Decoding cosmetic complexities: a comprehensive guide to matrix composition and pre-treatment technology. *Molecules* 29, 411. <https://doi.org/10.3390/molecules29020411>
- ERIA Economic Research Institute for ASEAN and East ASia (2016). “Capacity-building measures by third parties,” in *harmonization of standards and mutual recognition agreements on conformity assessment in Indonesia, Malaysia, Thailand, and Viet Nam*. ERIA Research Project Report 2015-14, ed. E. D. Scoles, 18–21. http://www.eria.org/RPR_FY2015_No.15_C_hapter_5.pdf
- EUR-Lex (2006). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH). *Document 02006R1907-20221217*. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20221217>
- Faster Capital (2025). Beauty industry regulations: global harmonization: challenges in standardizing beauty regulations. <https://www.fastercapital.com/content/Beauty-industry-regulations--Global-Harmonization--Challenges-in-Standardizing-Beauty-Regulations.html>
- Ferreira, I., Brites, G., Silva, A., Caramelo, F., Oliveiros, B., Neves, B. M., et al. (2023). Development of an in chemico high-throughput screening method for the identification of skin sensitization potential. *Arch Toxicol* 97, 2441–2451. doi: 10.1007/s00204-023-03550-z
- Ferreira, M., Matos, A., Couras, A., Marto, J., and Ribeiro, H. (2022). Overview of cosmetic regulatory frameworks around the world. *cosmetics* 9. doi: 10.3390/cosmetics9040072
- Fu, L., Jia, G., Liu, Z., Pang, X., and Cui, Y. (2024). The applications and advances of artificial intelligence in drug regulation: a global perspective. *Acta Pharm Sin B*. doi: 10.1016/j.apsb.2024.11.006
- Grech, V. S., Kefala, V., and Rallis, E. (2024). Cosmetology in the era of artificial intelligence. *Cosmetics* 11. doi: 10.3390/cosmetics11040135
- Hale Cosmeceuticals Inc (2024). Balancing innovation and regulation in cosmetic manufacturing. <https://www.halecosmeceuticals.com/blog/balancing-innovation-and-regulation-in-cosmetic-manufacturing>
- Hale Cosmeceuticals Inc. (2024). Globalization challenges in cosmetic manufacturing. <https://www.halecosmeceuticals.com/blog/globalization-challenges-in-cosmetic-manufacturing>
- HSA (Health Science Authority) Government of Singapore (2024). ASEAN cosmetic directive. <https://www.hsa.gov.sg/cosmetic-products/asean-cosmetic-directive>
- IBM (2025). IBM and L’Oréal to Build First AI Model to Advance the Creation of Sustainable Cosmetics. *Artificial intelligence generative ai research and innovation*.

- <https://newsroom.ibm.com/2025-01-16-ibm-and-loreal-to-build-first-ai-model-to-advance-the-creation-of-sustainable-cosmetics>
- ICCVAM (2024). Validation, qualification, and regulatory acceptance of new approach methodologies. doi: <https://doi.org/10.22427/NICEATM-2>
- International Collaboration on Cosmetic Safety (ICCS). (2024). The international collaboration for cosmetics safety (ICCS): accelerating global adoption of animal-free safety science for cosmetic product and ingredient safety assessment. <https://seac.unilever.com/files/accelerating-global-adoption-of-animal-free-safety-science-for-cosmetic-product-and-ingredient-safety-assessment-final.pdf>
- International Collaboration on Cosmetic Safety (ICCS) (2025). International collaboration on cosmetic safety and the cosmetic ingredient review commit to progress sharing of information and collaboration. *Cosmetic Ingredient Review*. <https://www.iccs-cosmetics.org/iccs-and-icr-commit-to-a-working-partnership-to-progress-sharing-of-information-and-collaboration>
- International Cooperation on Cosmetics Regulation (ICCR) (2024). ANNEX inventory of validated alternatives to animal testing applicable for cosmetic products and their ingredients in all iccr regions. *Alternatives to animal testing/Report (table) / Final 2024-08-01-TFDA*. https://www.iccr-cosmetics.org/downloads/topics/2024-08_updated%20annex%20of%20inventory%20of%20validated%20alternatives%20to%20animal%20testing%20applicable%20for%20cosmetics.pdf
- International Cooperation on Cosmetics Regulation (ICCR) (2025). What is ICCR? <https://www.iccr-cosmetics.org/about-us>
- International Cooperation on Cosmetics Regulation (ICCR) (n.d.). International cooperation on cosmetics regulation. 2025. <https://www.iccr-cosmetics.org>
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) (2024). Collaboration, convergence, and regulatory reliance. <https://www.ifpma.org/areas-of-work/strengthening-regulatory-systems/collaboration-convergence-and-regulatory-reliance>
- Johansson, H., Gradin, R., Johansson, A., Adriaens, E., Edwards, A., Zuckerstätter, V., et al. (2019). Validation of the GARD™skin assay for assessment of chemical skin sensitizers: ring trial results of predictive performance and reproducibility. *Toxicological Sciences* 170, 374–381. doi: 10.1093/toxsci/kfz108
- Kang, Y., Kim, M. G., and Lim, K. M. (2023). Machine-learning based prediction models for assessing skin irritation and corrosion potential of liquid chemicals using physicochemical properties by XGBoost. *Toxicol Res* 39, 295–305. doi: 10.1007/s43188-022-00168-8
- Kittisak, A. (2023). Challenges and strategies for inventory management in small and medium-sized cosmetic enterprises: a review. *International Journal of Information Technology and Computer Science Applications* 1, 71–77. <https://doi.org/10.58776/ijitcsa.v1i2.30>
- Lee, E., Kim, S., Lee, J., Cho, S. A., and Shin, K. (2014). Ethnic differences in objective and subjective skin irritation response: an international study. *Skin Research and Technology* 20, 265–269. doi: 10.1111/srt.12111
- LPPOM MUI (2023). 2026, Cosmetics must be halal. <https://halalmui.org/en/2026-cosmetics-must-be-halal>
- Manful, M. E., Ahmed, L., and Barry-Ryan, C. (2024). Cosmetic formulations from natural sources: safety considerations and legislative frameworks in the European Union. *Cosmetics* 11, 72. doi: 10.3390/cosmetics11030072
- Méndez, M. de la L., and Trejo, A. H. (2020). Barriers and challenges for global regulatory harmonization. *Informa connect*. <https://informaconnect.com/barriers-global-regulatory-harmonization>
- MERCOSUR (2025). MERCOSUR in brief. <https://www.mercosur.int/en/about-mercotur/mercotur-in-brief>
- Morel, S., Sapino, S., Peira, E., Chirio, D., and Gallarate, M. (2023). Regulatory requirements for exporting cosmetic products to Extra-EU countries. *Cosmetics* 10. doi: 10.3390/cosmetics10020062
- Nabarretti, B. H., Rigon, R. B., Burga-Sánchez, J., and Leonardi, G. R. (2022). A review of alternative methods to the use of animals in

- safety evaluation of cosmetics. *Einstein (Sao Paulo)* 20, eRB5578. doi: 10.31744/einstein_journal/2022RB5578
- Natsch, A., Landsiedel, R., and Kolle, S. N. (2021). A triangular approach for the validation of new approach methods for skin sensitization. *ALTEX* 38, 669–677. doi: 10.14573/altex.2105111
- Nayak, M., Sreedhar, D., Prabhu, S. S., and Ligade, V. S. (2021). Global trends in cosmetics use-related adverse effects: a bibliometric analysis of literature published during 1957–2021. *Cosmetics* 8. doi: 10.3390/cosmetics8030075
- Nhani, G. B. B., Di Filippo, L. D., de Paula, G. A., Mantovanelli, V. R., da Fonseca, P. P., Tashiro, F. M., et al. (2024). High-tech sustainable beauty: exploring nanotechnology for the development of cosmetics using plant and animal by-products. *Cosmetics* 11. doi: 10.3390/cosmetics11040112
- OECD (Organisation for Economic Co-operation and Development) (2025). Guidelines for the testing of chemicals. <https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/test-guidelines.html>
- Pandya, J., and Padma, S. (2024). The study of artificial marketing tools used in Indian cosmetic industry and its impact on consumer behaviour. <http://jier.org>
- Patil, R. S., Kulkarni, S. B., and Gaikwad, V. L. (2023). Artificial intelligence in pharmaceutical regulatory affairs. *Drug Discov Today* 28. doi: 10.1016/j.drudis.2023.103700
- Payandeh, R., Delbari, A., Fardad, F., Helmzadeh, J., Shafiee, S., and Ghatari, A. R. (2024). Unravelling the potential of blockchain technology in enhancing supply chain traceability: a systematic literature review and modelling with ISM. *Blockchain: Research and Applications*, 100240. doi: 10.1016/j.bcra.2024.100240
- Pistollato, F., Madia, F., Corvi, R., Munn, S., Grignard, E., Paini, A., et al. (2021). Current EU regulatory requirements for the assessment of chemicals and cosmetic products: challenges and opportunities for introducing new approach methodologies. *Arch Toxicol* 95, 1867–1897. doi: 10.1007/s00204-021-03034-y
- Precision Stability Storage (2024). Understanding FDA cosmetic regulation for the cosmetic industry. <https://precisionstabilitystorage.com/understanding-fda-cosmetic-regulations>
- Qiao, W., Xie, T., Lu, J., and Jia, T. (2024). Development of machine learning models for the prediction of the skin sensitization potential of cosmetic compounds. *PeerJ* 12, e18672. doi: 10.7717/peerj.18672
- Quantis, A. B. C. (2025). Transforming the beauty industry: six sustainability trends to expect in 2025. <https://quantis.com/news/the-6-key-sustainability-highlights-of-2025>
- REACH24H, S. (2025). Cosmetics notification in ASEAN: a comprehensive guide to the regulatory process. <https://www.reach24h.com/en/service/cosmetic-service/cosmetics-notification-in-asean.html>
- Regulatory Harmonization from class: intro to public policy definition (2025). *Fiveable Inc.* <https://library.fiveable.me/key-terms/introduction-to-public-policy/regulatory-harmonization>
- Rico, F., Mazabel, A., Egurrola, G., Pulido, J., Barrios, N., Marquez, R., et al. (2024). Meta-analysis and analytical methods in cosmetics formulation: a review. *Cosmetics* 11. doi: 10.3390/cosmetics11010001
- Ryder (2021). Beauty and the blockchain: How blockchain technology is changing the beauty industry. *Ryder System, Inc.* <https://www.ryder.com/en-us/insights/blogs/e-comm/blockchain-beauty>
- Sasounian, R., Martinez, R. M., Lopes, A. M., Giarolla, J., Rosado, C., Magalhães, W. V., et al. (2024). Innovative approaches to an eco-friendly cosmetic industry: a review of sustainable ingredients. *Clean Technologies* 6, 176–198. doi: 10.3390/cleantechnol6010011
- Sewell, F., Alexander-White, C., Brescia, S., Currie, R. A., Roberts, R., Roper, C., et al. (2024). New approach methodologies (NAMs): identifying and overcoming hurdles to accelerated adoption. *Toxicol Res (Camb)* 13. doi: 10.1093/toxres/tfae044
- Silva, R. J., and Tamburic, S. (2022). A State-of-the-art review on the alternatives to animal testing for the safety assessment of cosmetics. *Cosmetics* 9. doi: 10.3390/cosmetics9050090
- Singh, A. V., Bhardwaj, P., Laux, P., Pradeep, P., Busse, M., Luch, A., et al. (2024). AI and ML-based risk assessment of chemicals: predicting carcinogenic risk from chemical-

- induced genomic instability. *Frontiers in Toxicology* 6. doi: 10.3389/ftox.2024.1461587
- Skin Consult BV (2025). 15 Major challenges of cosmetics manufacturers and how to solve them. <https://skinconsult.com/en/blog/major-challenges-cosmetics-manufacturers>
- Su, Z., Luo, F. Y., Pei, X. R., Zhang, F. L., Xing, S. X., and Wang, G. L. (2020). Final publication of the “regulations on the supervision and administration of cosmetics” and new prospective of cosmetic science in China. *Cosmetics* 7, 1–17. doi: 10.3390/cosmetics7040098
- Tanaka, M. L., and Lopez, O. (2024). Outlook on industry-academia-government collaborations impacting medical device innovation. *J Eng. Sci Med Diagn Ther* 7. doi: 10.1115/1.4063464
- The European Commission (2025). Cosmetic product notification porta. https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-product-notification-portal_en
- The European Commission (2009). Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. *Official Journal of the European Union L 342/59*. <https://eur-lex.europa.eu/eli/reg/2009/1223/oj/eng>
- The European Commission (2024). Commission regulation (EU) 2024/996 of 3 April 2024 amending regulation (ec) no 1223/2009 of the European Parliament and of the Council as regards the use of vitamin a, alpha-arbutin and arbutin and certain substances with potential endocrine disrupting properties in cosmetic products. *Official Journal of the European Union*. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_20240096
- The European Commission (2025a). Market surveillance. https://single-market-economy.ec.europa.eu/sectors/cosmetics/market-surveillance_en
- The European Commission (2025b). Nanomaterials. https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-products-specific-topics/nanomaterials_en
- The European Union (2013). Commission Regulation (EU) No 658/2013 of 10 July 2013 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. *Official Journal of the European Union L 190/38*. Retrieved from: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0658>
- U.S. Department of Health and Human Services FDA (2025). Considerations for the Use of artificial intelligence to support regulatory decision-making for drug and biological products guidance for industry and other interested parties. *Draft Guidance*. <https://www.fda.gov/media/184830/download>
- US Food and Drug Administration (2019). Regulatory harmonization and convergence. <https://www.fda.gov/vaccines-blood-biologics/international-activities/regulatory-harmonization-and-convergence>
- US Food and Drug Administration (2022a). Color additives permitted for use in cosmetics. *Regulated Products*. <https://www.fda.gov/cosmetics/cosmetic-ingredient-names/color-additives-permitted-use-cosmetics>
- US Food and Drug Administration (2022b). Cosmetics guidance & regulation. <https://www.fda.gov/cosmetics/cosmetics-guidance-regulation>
- US Food and Drug Administration (2022c). Overview of international activities for cosmetics. <https://www.fda.gov/cosmetics/cosmetics-international-activities/overview-international-activities-cosmetics>
- US Food and Drug Administration (2022d). Product testing of cosmetics. *Regulated Products*. <https://www.fda.gov/cosmetics/cosmetics-science-research/product-testing-cosmetics>
- US Food and Drug Administration (2022e). Prohibited & restricted ingredients in cosmetics. *Regulated Products*. <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics>
- US Food and Drug Administration (2024a). Cosmetics & U.S. Law. <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/cosmetics-us-law>
- US Food and Drug Administration (2024b). Drug supply chain security act (DSCSA). <https://www.fda.gov/drugs/drug-supply->

- chain-integrity/drug-supply-chain-security-act-dscsa
- US Food and Drug Administration (2025). Modernization of cosmetics regulation act of 2022 (MoCRA). <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra>
- USP White Paper (2023). Advancing regulatory and pharmacopeial convergence, harmonization, and global cooperation to improve medicines supply chain resiliency. https://www.usp.org/sites/default/files/USP_2023_Advancing%20Regulatory%20and%20Pharmacopeial%20Convergence%20Harmonization%20and%20Global%20Cooperation%20to%20Improve%20Medicines%20Supply%20Chain%20Resiliency.pdf
- Ustyenko, R. (2023). Trends and innovations in cosmetic marketing. *Economic & Education* (8). 12-17. <https://doi.org/10.30525/2500-946X/2023-3-2>
- Van der Burg, A. (2023). The 40 key differences between us and eu cosmetics regulation and how MoCRA impacts this. *SkinConsult BV*. <https://skinconsult.com/en/blog/differences-us-eu-cosmetics-regulation>
- Veeva Systems (2019). 4 Quality & regulatory challenges facing the cosmetics industry and how to avoid them. <https://www.industries.veeva.com/hubfs/Veeva%20-%204%20Challenges%20Cosmetics%20Whitepaper%20Mar%202019.pdf>
- Vincent, U. (2015). Implementation of regulation (EC) No 1223/2009 of the European Parliament and of the Council. European Union. doi: doi:10.2787/412553
- World Health Organization (WHO) (2025). Regulation and prequalification. <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/harmonization>