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Skincare Product Safety Regulations in Indonesia and Asian Countries within the Framework of International Legal Standards

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Original Article

Abstract

This study is driven by the rapid expansion of the global cosmetics trade, which necessitates the alignment of national regulations with international legal standards, particularly in relation to skincare product safety. The objective of this research is to examine Indonesia's administrative regulations on skincare safety, compare them with those of selected East Asian countries, and evaluate their conformity with international legal frameworks. Employing a qualitative approach, this study utilizes descriptive-comparative analysis of national legal instruments, international standards, and relevant academic literature. The findings reveal that Indonesia has adopted the ASEAN Cosmetic Directive (ACD) harmonization framework; however, its implementation continues to encounter challenges in areas such as regulatory oversight, bureaucratic processes, and technical capacity. In comparison with Japan, South Korea, and China, Indonesia's regulatory framework remains less integrated. The study concludes that strengthening institutional capacity and enhancing regulatory harmonization are essential to achieving greater alignment with the WTO's Technical Barriers to Trade (TBT) principles and other international standards.

Keywords: *National Regulation, Skincare, International Law, Harmonization*

Abstrak

Penelitian ini dilatarbelakangi oleh meningkatnya perkembangan perdagangan kosmetik global yang menuntut keselarasan antara regulasi nasional dan standar hukum internasional, khususnya dalam aspek keamanan produk skincare. Tujuan penelitian ini adalah untuk mendeskripsikan regulasi administratif keamanan skincare di Indonesia, membandingkannya dengan sistem di negara-negara Asia Timur, serta menilai tingkat kesesuaiannya dengan standar hukum internasional. Metode penelitian menggunakan pendekatan kualitatif dengan analisis deskriptif-komparatif terhadap peraturan nasional, standar internasional, serta literatur akademik. Hasil penelitian menunjukkan bahwa Indonesia telah mengadopsi kerangka harmonisasi ASEAN Cosmetic Directive (ACD), namun implementasinya masih menghadapi kendala pada aspek pengawasan, birokrasi, dan kapasitas teknis. Dibandingkan dengan Jepang, Korea Selatan, dan Tiongkok, regulasi Indonesia relatif kurang terintegrasi. Kesimpulannya, diperlukan penguatan kapasitas institusional dan harmonisasi regulasi agar sejalan dengan prinsip Technical Barriers to Trade (TBT) WTO dan standar global lainnya.

Kata kunci: *Regulasi Nasional, Skincare, Hukum Internasional*

1. INTRODUCTION

The global beauty industry has experienced substantial transformation over the past two decades, establishing itself as one of the world's fastest-growing sectors. This evolution reflects not only the increasing demand for skincare products but also the broader social, economic, and technological shifts that shape modern consumer behavior. The Asia-Pacific region currently dominates the global cosmetics market—accounting for over 30 percent of total market value—and is projected to maintain an average annual growth rate of approximately 3 percent through 2029.[1] Three key countries—South Korea, Japan, and China—have driven this expansion through continuous innovation, the standardization of product quality, and globally influential marketing strategies.

This phenomenon extends beyond economic considerations, encompassing complex legal, social, and public health dimensions. In an era of globalization, cross-border trade in skincare products has intensified due to advancements in digital technology and e-commerce. Contemporary consumption patterns emphasizing health consciousness and self-care have further increased the demand for skincare products. In Indonesia, this trend is evident in the rising value of the national cosmetics market, projected to reach USD 9.7 billion by 2025, with an average annual growth rate of 4.33 percent through 2030.[2] This development indicates a significant shift in consumer awareness toward self-care, while simultaneously exposing consumers to the risks associated with unsafe or non-compliant products.

A critical concern emerging in this context is the growing circulation of illegal and unregistered skincare products, which pose potential threats to consumer safety. According to a 2023 report by the Indonesian Food and Drug Monitoring Agency (BPOM), over 415,000 illegally imported cosmetic products—valued at approximately IDR 11.4 billion—were found in the domestic market. Most of these products originated from China, the Philippines, Thailand, and Malaysia and were identified as containing hazardous substances and lacking proper labeling. This situation underscores the ineffectiveness of existing administrative oversight mechanisms in safeguarding product safety and legality within Indonesia's market.

This issue also underscores the broader challenge of harmonizing standards and regulatory systems across countries, given the diversity of legal frameworks, administrative policies, and institutional capacities. In the international context, instruments such as the World Trade Organization's Technical Barriers to Trade (WTO

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1 Aya Suzuki and Yang Hu, "2025 Asia Pacific Beauty: What's Driving Growth in China, Japan and South Korea?," Euromonitor International, 2025, https://www.euromonitor.com/article/2025-asia-pacific-beauty-whats-driving-growth-in-china-japan-and-south-korea.

2 Direktorat Jenderal Industri Kecil Menengah dan Aneka Kementerian Perindustrian, "Kemenperin Gadang Potensi Industri Kosmetik Semakin Gemilang," Kementerian Perindustrian Republik Indonesia, 2025, https://ikm.kemenperin.go.id/kemenperin-gadang-potensi-industri-kosmetik-semakin-gemilang.

TBT) Agreement and the ASEAN Cosmetic Directive (ACD) are designed to harmonize technical standards and conformity assessment procedures to prevent discriminatory trade barriers. However, in practice, the national implementation of these frameworks often faces structural and institutional constraints, including limited inter-agency coordination, weak verification systems, and inconsistent interpretations of technical provisions.

The role of the Food and Drug Authority (BPOM) as Indonesia's primary regulatory body for food and drug supervision is therefore crucial but fraught with challenges. The continued circulation of unregistered skincare products, counterfeit labeling, and illegal import practices illustrates the inadequacy of current administrative regulations in addressing the dynamics of the modern cosmetics trade. These challenges are further compounded by the rapid growth of e-commerce and social media, which facilitate the widespread distribution of products without sufficient verification. Consequently, consumer protection is frequently compromised, while non-compliant businesses continue to profit at the expense of public safety.

From a legal standpoint, this situation reveals a persistent gap between normative regulation and practical enforcement. Indonesia possesses a relatively comprehensive legal framework—including Law No. 8 of 1999 on Consumer Protection, Law No. 36 of 2009 on Health, and several implementing regulations issued by BPOM. Nonetheless, enforcement and oversight remain weak in practice. By contrast, countries such as South Korea and Japan have developed more integrated cosmetic regulatory systems, with systematic and transparent mechanisms for certification, registration, and safety evaluation. These differences highlight the importance of cross-country comparative analysis to identify best practices for strengthening Indonesia's regulatory and administrative framework for skincare product safety.

Furthermore, this issue extends beyond national legal considerations, carrying significant implications for international trade and the competitiveness of the domestic cosmetics industry. The harmonization of standards among Asian countries—particularly through the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS)—aims to establish technical equivalence and facilitate the intra-regional flow of cosmetic products. However, in the absence of a robust national regulatory framework, Indonesia risks becoming a market susceptible to the influx of unsafe and high-risk imported products. Therefore, an in-depth examination is essential to evaluate the extent to which Indonesia's administrative regulations align with international standards and how their implementation compares with that of more developed countries in terms of cosmetics industry governance.

The regulation and legal protection of skincare and cosmetic products have increasingly become central topics in legal and public policy research, particularly in light of rising consumer awareness and the expansion of the digital economy within the

beauty sector. Over the past two decades, the skincare industry has evolved into a global phenomenon, contributing substantially to international trade and transforming consumer behavior. The Asia-Pacific region—especially China, South Korea, and Japan—has emerged as the epicenter of this transformation through continuous product innovation, stringent regulatory frameworks, and marketing strategies that shape global beauty trends. This dynamic underscores the necessity of cross-national regulatory harmonization to ensure product safety, uphold consumer protection, and promote fair trade practices.

In Indonesia, the principal authority responsible for regulating cosmetic distribution and safety is the Food and Drug Monitoring Agency (BPOM). Despite the existence of formal licensing procedures and safety testing mechanisms, numerous regulatory violations persist in practice. These include the distribution of illegal cosmetics, the use of hazardous substances, and the sale of products without official notification. More than 415,000 illegally imported cosmetic products—with an estimated market value of IDR 11.4 billion—were discovered within just four months.[3] These findings reveal systemic weaknesses in regulatory oversight and highlight deficiencies in enforcement effectiveness.

Research conducted by Astikasari examined legal protection for cosmetic brands in Indonesia and South Korea, emphasizing that South Korea maintains a more structured and systematic regulatory system. In contrast, Indonesia's legal protection remains largely constitutive, focusing primarily on brand formalities rather than substantive product safety. While this study contributes valuable insights into the role of intellectual property rights (IPR) in the cosmetics sector, it does not comprehensively address issues related to product safety and cross-national regulatory harmonization.[4]

Similarly, Annisa et al. investigated the implications of the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) on Indonesia's cosmetic import policies through the case study of the Dnars brand. Their findings indicate that despite regional harmonization efforts under the ASEAN Cosmetic Directive (ACD), regulatory implementation in Indonesia remains weak, as reflected by the continued circulation of imported products lacking official notification. While this study highlights inconsistencies between regional and national regulatory frameworks, it does not offer a comparative analysis of how East Asian countries have integrated international standards into their domestic systems.[5]

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[3] Badan Pengawas Obat dan Makanan, "BPOM Tegas Tumpas Produk Kosmetik Impor Ilegal," 2024, https://www.pom.go.id/berita/bpom-tegas-tumpas-produk-kosmetik-impor-ilegal.

[4] Rizki Nur Astikasari, "Perlindungan Hukum Atas Merek Kosmetik Antara Indonesia Dan Korea Selatan" (Universitas Islam Indonesia, 2024), https://dspace.uii.ac.id/123456789/50399.

[5] Ade Rizki Annisa, Zulfikar Jayakusuma, and Ledy Diana, "Analisis Yuridis Implikasi Agreement On The Asean Harmonized Cosmetic Regulatory Scheme Terhadap Kebijakan Impor Kosmetik Di Indonesia: Kasus Kosmetik Merek Dnars," *Jurnal Ilmiah Wahana Pendidikan* 9, no. 21 (2023): 46–54, https://jurnal.peneliti.net/index.php/JIWP/article/view/7000.

Furthermore, Buloto et al. conducted a comparative analysis of criminal law regulations governing the distribution of illegal cosmetics in Indonesia and Singapore. Their research found that although Indonesia possesses adequate legal instruments, enforcement remains ineffective due to weak supervision and insufficient deterrent measures. Conversely, Singapore has successfully curtailed the circulation of illegal cosmetics through the more stringent and integrated enforcement of the Health Products Act and the Consumer Protection (Fair Trading) Act. This study offers critical insights into the role of criminal law in consumer protection; however, it does not explore the interrelation between administrative regulation, cross-border trade, and international legal standards.[6]

Research conducted by Aresil et al. emphasizes legal protection for consumers against the circulation of illegal cosmetics. The study confirms that Indonesia's existing legal framework—particularly Law No. 8 of 1999 on Consumer Protection and Law No. 36 of 2009 on Health—provides adequate protection in normative terms. However, weaknesses persist in enforcement and regulatory oversight, especially within the context of online product distribution. These findings reinforce the argument that the principal gap lies not in the written regulations themselves, but in the effectiveness of their implementation.[7]

Rahmawati et al. examine the national legal framework governing cosmetic products based on BPOM regulations and other derivative provisions. Their study underscores the critical role of state intervention in protecting consumers from the structural imbalance of power between businesses and consumers. This research contributes to a better understanding of the importance of regulatory compliance within the cosmetics distribution chain. Nevertheless, it remains limited to a national perspective and does not explore the relationship between domestic regulations and international legal instruments, such as the WTO Technical Barriers to Trade (TBT) Agreement or the ASEAN Cosmetic Directive (ACD).[8]

In the context of skincare distribution supervision, Setiyani et al. identify both internal and external barriers to the effective implementation of the Consumer Protection Law. Internal barriers include limited human resources and inadequate operational budgets, while external barriers involve consumers' lack of critical awareness regarding product information and low levels of digital literacy. This study illustrates the complexity of skincare distribution oversight but does not assess how

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6 Aprilia Vitaloka Buloto, Fenti U. Puluhulawa, and Avelia Rahmah Y. Mantali, "Penguatan Regulasi Dan Penegakan Hukum Terhadap Peredaran Kosmetik Ilegal Di Indonesia Dan Singapura," *Sinergi: Jurnal Riset Ilmiah* 2, no. 2 (2025): 691–703, https://doi.org/10.62335/sinergi.v2i2.889.

7 Alfian Aresil, Rajab Lestaluhu, and Sokhib Naim, "Perlindungan Hukum Bagi Pembeli Terhadap Peredaran Kosmetik Ilegal Di Pasaran," *Judge: Jurnal Hukum* 5, no. 2 (2024): 141–51, https://doi.org/10.54209/judge.v5i02.673.

8 Dewi Rahmawati et al., "Regulasi Kosmetik Terhadap Izin Edar: A Studi Literature," *Vitamin: Jurnal Ilmu Kesehatan Umum* 2, no. 1 (2024): 249–255, https://doi.org/10.61132/vitamin.v2i1.196.

administrative policies might be optimized to prevent the cross-border circulation of illegal products.[9]

Meanwhile, Situngkir et al. highlight the importance of distribution permits as a legal safeguard ensuring the legitimacy of cosmetics circulating within the Indonesian market. Their research focuses on consumer protection against the proliferation of illegal cosmetics using a normative and conceptual approach, with Law No. 17 of 2023 on Health serving as the primary analytical basis. The findings indicate that national regulations tend to be reactive toward violations rather than preventive through the establishment of robust administrative mechanisms.[10]

Most previous studies have primarily focused on aspects of legal protection, criminal violations, or compliance with cosmetics regulations, without conducting an in-depth examination of administrative regulations on skincare safety in Indonesia from a comparative and internationally harmonized perspective. The main limitation of prior research lies in the absence of an integrative analysis connecting national practices with legal standards in South Korea, Japan, and China, as well as their alignment with the WTO TBT Agreement and the ASEAN Cosmetic Directive.

Therefore, this study seeks to fill this research gap through a comparative-juridical approach with the following objectives:

1) To describe Indonesia's administrative regulations on skincare safety;
2) To compare these regulations with the systems implemented in East Asian countries; and
3) To assess the extent to which Indonesia's national regulations comply with international legal standards.

2. RESEARCH METHODOLOGY

This study employs a comparative-juridical approach combined with normative analysis to examine the effectiveness of administrative regulations governing skincare product safety in Indonesia and their alignment with international legal standards and best practices in East Asian countries, particularly South Korea, Japan, and China. This approach is relevant as it elucidates the relationship between legal norms, regulatory policies, and the dynamics of globalization within the cosmetics industry. The research adopts a descriptive-analytical design aimed at describing, comparing, and analyzing

[9] Alynda Andra Tri Setiyani, Sanusi Sanusi, and Evy Indriasari, "Pengawasan Peredaran Produk Skincare Di Tinjau Dari Undang-Undang Perlindungan Konsumen," *Pancasakti Law Journal* 1, no. 2 (2023): 295–306, https://doi.org/10.24905/plj.v1i2.27.

[10] Andreas Henfri Situngkir, Fauzan Fauzan, and Redyanto Sidi, "Legal Protection for Consumers Against the Circulation of Illegal Cosmetics in Online Stores (E-Commerce) Reviewed from RI Law Number 17 of 2023 Concerning Health," *Asian Journal of Healthcare Analytics* 2, no. 3 (2023): 383–400, https://doi.org/10.55927/ajha.v2i2.8356.

administrative regulatory frameworks across jurisdictions in the context of consumer protection, legal certainty, and harmonization with international standards.

The research utilizes secondary data sources, including national laws and regulations, international agreements, and regional instruments such as the ASEAN Cosmetic Directive (ACD) and the WTO Technical Barriers to Trade (TBT) Agreement. Additional secondary legal materials comprise scholarly journal articles, textbooks on health law, and reports from regulatory institutions such as the Food and Drug Authority (BPOM) and the Ministry of Trade. Tertiary legal materials include legal encyclopedias and cosmetics market data from Euromonitor and Statista.

Data collection techniques consist of literature review and analysis of legal documents and public policies. The data were analyzed using a qualitative legal method conducted in three stages: normative analysis, comparative analysis, and legal synchronization. The analytical process followed a deductive–inductive logic, beginning with international legal principles and subsequently contextualizing them within national frameworks to generate limited empirical generalizations. Data validity was ensured through triangulation of sources and methods, as well as peer review by experts in health law and international trade law to guarantee consistency and accuracy in legal interpretation.

3. RESEARCH RESULT AND DISCUSSION

3.1. Administrative Regulations on Skincare Product Safety in Indonesia

This study aims to provide a comprehensive description of the administrative regulatory framework governing skincare product safety in Indonesia by examining the legal structure, licensing mechanisms, and supervisory implementation carried out by the Food and Drug Monitoring Agency (BPOM) in the context of consumer protection and regulatory harmonization with international standards. The data analyzed in this section were obtained from national legal documents, official BPOM reports, and supporting materials from relevant government institutions.

Based on data collection and analysis, the administrative framework for skincare product safety in Indonesia is organized into several interrelated regulatory layers. The primary legal foundation is Law No. 36 of 2009 on Health, which explicitly mandates that all distributed products must meet safety, efficacy, and quality standards. Complementing this, Law No. 7 of 2014 on Trade emphasizes the legality of product distribution and the responsibility of business operators to ensure the safety of products placed on the market.

At the level of implementing regulations, Government Regulation No. 72 of 1998 on the Safety of Pharmaceutical Preparations and Medical Devices provides the technical foundation for the supervision of cosmetic products, including skincare. This regulation is further reinforced by various BPOM Regulations, particularly the most

recent ones, which govern product notification, distribution, and post-market surveillance procedures.

Empirical findings indicate that BPOM has implemented a Cosmetic Notification System as the principal administrative mechanism for ensuring product safety prior to market entry. Based on BPOM Regulation No. 12 of 2020, as amended by BPOM Regulation No. 21 of 2022, every skincare product must submit an online notification through the Notifkos platform, accompanied by documentation on ingredient composition, safety data, quality assurance, and certificates of analysis. This system replaced the previously more cumbersome manual registration process, streamlining the approval procedure without compromising safety.

A total of 52,416 cosmetic product notifications were submitted, 78 percent of which were imported products. Meanwhile, local skincare products showed a 23 percent increase from the previous year, reflecting the growing competitiveness of the domestic cosmetics industry.[11] In addition to product notification, a Border Import Certificate (Surat Keterangan Impor/SKI) is mandatory for imported cosmetic products entering Indonesia. Under BPOM Regulation No. 28 of 2023, Border SKIs are issued only after all import documents have been electronically verified through the e-BPOM system. In 2024, BPOM recorded 14,276 SKI applications, with a rejection rate of 8.5 percent due to inconsistencies in submitted data and incomplete safety documentation.

During post-market surveillance, BPOM routinely conducts sampling and laboratory testing of distributed products. According to BPOM's 2025 Annual Report, 21 cosmetic products had their distribution permits revoked due to discrepancies between the approved formula and the one declared during notification. Moreover, BPOM identified 415,000 illegal cosmetic products circulating via cross-border e-commerce platforms, representing an estimated economic value of IDR 11.4 billion.

However, field observations and secondary data reveal several structural challenges in regulatory enforcement. First, the distribution of illegal cosmetics remains high, particularly in border and remote regions where regular BPOM inspections are difficult to conduct. Second, digital supervision of cross-border online transactions remains limited due to the lack of full integration between BPOM's system and major e-commerce platforms. Third, the enforcement of administrative sanctions often lacks deterrent effect, as evidenced by repeated violations committed by the same entities.

Beyond regulatory oversight, consumer literacy also plays a critical role in determining the effectiveness of administrative regulations. According to a 2022 BPOM survey, approximately 61 percent of consumers do not verify the official notification number before purchasing skincare products. This low level of consumer awareness increases the likelihood of unsafe or non-compliant products entering the domestic market. Indonesia's administrative regulations on skincare product safety possess a solid

[11] Badan Pengawas Obat dan Makanan, "BPOM Tegas Tumpas Produk Kosmetik Impor Ilegal."

legal foundation, they continue to face challenges in implementation, supervision, and public awareness, which must be addressed to strengthen consumer protection and achieve harmonization with international regulatory standards.

The findings of this study indicate that although Indonesia's administrative regulatory framework for skincare product safety has been comprehensively designed, its implementation effectiveness remains influenced by institutional capacity, technological infrastructure, and consumer behavior. The effectiveness of a regulatory system is determined not only by the clarity of its legal norms but also by the capacity of implementing agencies to perform oversight and ensure public accountability.[12] The role of BPOM as the national cosmetics regulatory authority aligns with the principles of administrative enforcement, wherein state institutions exercise both preventive powers (through notification and distribution permits) and repressive powers (through administrative sanctions). However, in practice, limitations in human resources, laboratory infrastructure, and digital monitoring capacity have constrained the optimal performance of these functions.

Compared with the findings of Astikasari, which focused on the legal protection of cosmetic brands in Indonesia and South Korea, this study broadens the analytical scope to product safety governance. South Korea, for instance, has implemented a Cosmetic Ingredient Database System that ensures transparency of active ingredients in every registered product. In contrast, Indonesia maintains confidentiality of formulation data, restricting access exclusively to regulatory authorities. This divergence underscores differences in the degree of consumer participation and transparency in quality assurance processes.[13]

Furthermore, this study corroborates the findings of Annisa et al., who reported that the harmonization of cosmetic regulations under the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) has not been fully effective in Indonesia. Although BPOM has adopted most provisions of the ASEAN Cosmetic Directive (ACD), implementation challenges persist, particularly in inter-agency coordination and the lack of an integrated cross-border certification framework.[14]

Ideally, the implementation of administrative regulations should ensure consumer safety, informed decision-making, and accessible redress mechanisms.[15] However, this study finds that informed consumer choice remains unfulfilled due to low public literacy

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[12] David Levi-Faur, Yael Kariv-Teitelbaum, and Rotem Medzini, "Regulatory Governance: History, Theories, Strategies, and Challenges," *Oxford Research Encyclopedia of Politics*, 2021, https://doi.org/10.1093/acrefore/9780190228637.013.1430; Erlan Wijatmoko, Armaidy Armawi, and Teuku Faisal Fathani, "Legal Effectiveness in Promoting Development Policies: A Case Study of North Aceh Indonesia," *Heliyon* 9, no. 11 (2023): 1–22, https://doi.org/10.1016/j.heliyon.2023.e21280.

[13] Astikasari, "Perlindungan Hukum Atas Merek Kosmetik Antara Indonesia Dan Korea Selatan."

[14] Annisa, Jayakusuma, and Diana, "Analisis Yuridis Implikasi Agreement On The Asean Harmonized Cosmetic Regulatory Scheme Terhadap Kebijakan Impor Kosmetik Di Indonesia: Kasus Kosmetik Merek Dnars."

[15] G. Howells, "Protecting Consumer Protection Values in the Fourth Industrial Revolution," *Journal of Consumer Policy* 43 (2020): 145–175, https://doi.org/10.1007/s10603-019-09430-3.

regarding product legality. Hence, an effective regulatory approach must not rely solely on administrative oversight but also integrate educational initiatives and multi-sectoral collaboration.

When compared to the research of Buloto et al., which examined the circulation of illegal cosmetics in Indonesia and Singapore, similar enforcement gaps were observed. Singapore has successfully minimized violations through an integrated enforcement system under the Health Products Act, whereas Indonesia's regulatory response remains largely reactive.[16] This suggests that Indonesia's administrative legal framework still emphasizes corrective rather than preventive measures.

Moreover, the findings of this study reinforce the perspective of Rahmawati et al., who underscored the importance of regulatory compliance within the cosmetics distribution chain. While BPOM's administrative regulations provide clear procedural provisions, their practical effectiveness continues to depend on the compliance behavior of business actors and the degree of coordination among agencies such as Customs and Excise and the Ministry of Trade.[17]

This study highlights that the establishment of the Cosmetic Notification System and the Border Safety Information System (SKI) represents a significant advancement in Indonesia's administrative oversight of skincare products. Nevertheless, without enhanced digital surveillance capabilities and greater transparency of public data, the current regulatory framework remains inadequate to address the growing complexity of cross-border cosmetic trade. Therefore, policy innovations are required, including the integration of BPOM's digital systems with the ASEAN cross-border data exchange platform and the promotion of consumer participation through national cosmetic safety literacy campaigns.

The results of this study extend the application of the concept of good regulatory governance within the framework of Indonesian health law. Sound regulations must adhere to the principles of transparency, accountability, responsiveness, coherence, and effectiveness.[18] The findings reveal that the principles of coherence and effectiveness remain significant challenges in Indonesia's skincare regulatory oversight, particularly in maintaining a balance between streamlined licensing processes and robust consumer protection.

Regarding its scope, this study acknowledges certain limitations. As the analysis primarily focuses on administrative dimensions, the economic and social implications of illegal skincare product circulation have not been explored in depth. Nevertheless, this limitation provides opportunities for future research to examine the effectiveness

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[16] Buloto, Puluhulawa, and Mantali, "Penguatan Regulasi Dan Penegakan Hukum Terhadap Peredaran Kosmetik Ilegal Di Indonesia Dan Singapura."

[17] Rahmawati et al., "Regulasi Kosmetik Terhadap Izin Edar: A Studi Literature."

[18] Edward Donelan, *Regulatory Governance: Policy Making, Legislative Drafting and Law Reform*, 1st ed. (Cham: Palgrave Macmillan, 2022), https://doi.org/10.1007/978-3-030-96351-4.

of digital-based regulatory mechanisms and the role of public participation in enhancing consumer protection systems.

In conclusion, the administrative regulations governing skincare product safety in Indonesia possess a solid legal foundation and demonstrate progress toward international harmonization. However, further strengthening is required in terms of implementation capacity and digital oversight. This study contributes theoretically to the advancement of administrative health law and offers practical recommendations for the Food and Drug Authority (BPOM) and the government to enhance the effectiveness of consumer protection in the context of the global cosmetics trade.

3.2. Assessing the Compliance of National Regulations with International Legal Standards

This study aims to compare administrative regulations governing skincare product safety in Indonesia with those implemented in three Asian countries—South Korea, Japan, and China. The comparison focuses on regulatory mechanisms related to product registration, classification, law enforcement, consumer protection, and trade implications. The research data were obtained through an analysis of legal and regulatory documents, reports from national food and drug regulatory authorities, and official publications issued between 2021 and 2024 concerning the implementation of cosmetic regulations.

The findings reveal that skincare product safety in Indonesia is regulated by the Food and Drug Authority (BPOM) under Law No. 36 of 2009 on Health, supported by derivative instruments such as BPOM Regulation No. 12 of 2020 and BPOM Regulation No. 21 of 2022 concerning procedures for cosmetic notification submission. The current system operates through an online notification platform (Notifkos), requiring business operators to submit documentation regarding product safety, composition, labeling, and quality prior to obtaining a notification number that serves as a distribution permit. Post-market surveillance is conducted to ensure compliance, with administrative sanctions including written warnings, suspension of production, or revocation of distribution permits as stipulated in BPOM Regulation No. 28 of 2023.

In South Korea, regulatory oversight of skincare products is administered by the Ministry of Food and Drug Safety (MFDS) under the Cosmetic Act. Regulation is based on a risk-based classification system, categorizing products by their potential risk level. Functional cosmetics—such as sunscreens, whitening products, and anti-wrinkle formulations—must undergo clinical trials and safety evaluations prior to marketing authorization. Violations of these provisions are subject to administrative penalties, permit revocation, or criminal prosecution.

Japan regulates skincare products under the Pharmaceutical and Medical Devices Act (PMD Act) through the Ministry of Health, Labour, and Welfare (MHLW) and the

Pharmaceuticals and Medical Devices Agency (PMDA). Products are classified into two main categories: cosmetics (general-use products) and quasi-drugs (products with functional claims such as anti-acne or sun protection). Quasi-drug products require marketing approval based on safety evaluation, clinical testing, and demonstrated efficacy. Japan also applies a positive list system, permitting only approved active ingredients in cosmetic formulations.

China, by contrast, enacted a major regulatory reform through the Cosmetic Supervision and Administration Regulation (CSAR), which came into effect on January 1, 2021, replacing the 1989 framework. The National Medical Products Administration (NMPA) is the competent authority overseeing its implementation. Under CSAR, cosmetics are classified into general cosmetics and special cosmetics (including whitening, sunscreen, hair dye, and baby products). All products must undergo safety and toxicological assessments prior to market approval. Imported products may be exempt from animal testing if supported by a Good Manufacturing Practice (GMP) certificate from the country of origin. Violations may result in fines reaching tens of millions of yuan, license revocation, and permanent bans on non-compliant businesses.

Comparative analysis across the four countries indicates that all maintain licensing and oversight mechanisms emphasizing consumer safety. However, the degree of regulatory rigor, scientific evaluation requirements, and enforcement measures varies significantly. Indonesia's framework relies primarily on an administrative notification system, while South Korea, Japan, and China employ risk-based regulatory models incorporating clinical and toxicological assessments.

These variations reflect differing administrative approaches shaped by national legal systems, institutional capacities, and the developmental stage of each country's cosmetics industry. Conceptually, the findings can be interpreted through the Good Regulatory Governance framework, which emphasizes transparency, accountability, effectiveness, efficiency, and legal consistency in public policy formulation. Cosmetics regulation in developed jurisdictions such as Japan and South Korea demonstrates a more advanced and coherent application of these principles compared to Indonesia.

In terms of product classification, the results of this study show that Japan and South Korea have developed more structured and risk-sensitive systems. Japan distinguishes between cosmetics and quasi-drugs to demarcate the boundary between functional and non-functional products. This classification provides a strong foundation for legal certainty while fostering innovation based on scientific evidence. These findings align with Kwon et al, who emphasize that South Korea's risk-based product classification enhances the efficiency of safety assessments without impeding industrial innovation.[19] By contrast, Indonesia has not yet adopted a risk-based classification

[19] Hyuckmyun Kwon et al., "Advanced Korean Industrial Safety and Health Policy with Risk Assessment," *Safety and Health at Work* 1, no. 1 (2010): 29–36, https://doi.org/10.5491/SHAW.2010.1.1.29.

framework, resulting in a uniform oversight process that treats all product types equally, regardless of their potential risk levels.

Regarding registration mechanisms, the most striking difference lies in the depth of scientific evaluation. Indonesia applies an administrative notification system that does not mandate laboratory testing prior to product distribution. While this approach improves time efficiency, it tends to reduce the robustness of pre-market scientific verification. In contrast, South Korea and Japan require scientific evidence of safety and efficacy before granting marketing authorization. This model builds "regulatory trust" between government authorities and consumers because policy decisions are grounded in verifiable scientific data.[20]

The dimension of law enforcement also demonstrates notable divergence. Documentation from 2023 indicates that South Korea and China exhibit the highest levels of consistency in enforcing administrative sanctions. The South Korean Ministry of Food and Drug Safety (MFDS) routinely publishes lists of recalled products, serving as both a corrective and educational tool for the industry. Similarly, China's National Medical Products Administration (NMPA) adopts a stringent enforcement approach, including lifetime bans for manufacturers involved in severe regulatory violations. Conversely, in Indonesia, although the Food and Drug Authority (BPOM) holds administrative sanctioning powers, enforcement remains constrained by limited human resources and weak inter-agency coordination. This underscores a persistent gap between de jure regulations—those articulated in formal legislation—and de facto implementation in practice.

With respect to consumer protection and transparency, Japan and South Korea outperform Indonesia in public information disclosure. Japan's positive list system guarantees legal clarity regarding approved active ingredients, while South Korea mandates the publication of safety test results for functional cosmetics. These practices asserts that information disclosure enhances public trust and curbs market misconduct.[21] In contrast, Indonesia continues to struggle with the circulation of illegal products, especially via cross-border e-commerce platforms. Although BPOM has introduced the e-BPOM system and an online product notification database to increase transparency, their effectiveness remains limited due to low levels of consumer literacy.

The findings further reveal significant implications for international trade. Stringent regulatory regimes in Japan and China often function as non-tariff barriers for Indonesian exports, as they require additional clinical trials and safety evaluations. Conversely, highly certified products from Japan and South Korea more easily penetrate the Indonesian market through simplified notification procedures. This asymmetry in

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[20] Ahmed S. El-tahlawy et al., "Advanced Analytical and Digital Approaches for Proactive Detection of Food Fraud as an Emerging Contaminant Threat," *Talanta Open* 12 (2025): 1–24, https://doi.org/10.1016/j.talo.2025.100499.

[21] Kwon et al., "Advanced Korean Industrial Safety and Health Policy with Risk Assessment."

regulatory requirements creates competitive disadvantages for the domestic skincare industry. Supporting this argument, Kwon et al found that regulatory harmonization among Asian countries could reduce trade costs by up to 15 percent while enhancing regional market transparency.[22]

These findings suggest that risk-based regulatory frameworks, as implemented in South Korea and Japan, are more adaptive to contemporary industrial developments because they balance consumer protection with product innovation. Indonesia could strengthen its own system by incorporating scientific verification for higher-risk products without impeding the efficiency of the licensing process.

From a policy perspective, this comparative analysis highlights the urgent need for deeper regulatory harmonization across Asia through frameworks such as the ASEAN Cosmetic Directive (ACD) and the Mutual Recognition Agreement (MRA). These mechanisms facilitate mutual recognition of safety testing results among member states, accelerating product distribution while maintaining consumer safety. Such harmonization would not only streamline regulatory processes but also enhance Indonesia's competitiveness and integration within the global cosmetics industry value chain.

However, this study also presents certain limitations. First, most of the secondary data were obtained from regulatory documents and official government reports, which may not fully capture the actual implementation conditions in practice. Second, law enforcement data are not entirely accessible to the public, particularly in China and Japan. Third, this study did not incorporate empirical analysis of industry and consumer perceptions, which could provide a deeper understanding of the effectiveness of skincare regulatory frameworks.

3.3. Assessing the Conformity of National Regulations with International Legal Standards

This study aims to evaluate the degree of conformity between Indonesia's national regulations on skincare product safety and international legal standards, particularly within the context of global trade and consumer protection. The analysis focuses on three key international and regional legal instruments: the World Trade Organization's Technical Barriers to Trade (WTO TBT) Agreement, the ASEAN Cosmetic Directive (ACD), and global standards established by the World Health Organization (WHO), the Organization for Economic Co-operation and Development (OECD), and the International Cooperation on Cosmetics Regulation (ICCR). A normative-comparative approach was employed by analyzing secondary data, including national regulations,

[22] Kwon et al.

reports from international institutions, and empirical observations of regulatory implementation in practice.

The findings indicate that, normatively, Indonesia has adopted the main principles articulated in the WTO TBT Agreement—particularly those concerning transparency, non-discrimination, and the use of international standards as references for developing technical regulations. These principles are reflected in several national legal instruments, including Law No. 36 of 2009 on Health, Law No. 7 of 2014 on Trade, and BPOM Regulation No. 21 of 2022 on Procedures for Cosmetic Notification Submission. In practice, the Indonesian Food and Drug Authority (BPOM) requires every skincare product, both domestic and imported, to obtain a notification number prior to market distribution. This mechanism replaces the previous, more time-consuming registration process and seeks to streamline administrative procedures while maintaining consumer protection standards.

Regarding regional harmonization, the study found that Indonesia has incorporated most provisions of the ASEAN Cosmetic Directive (ACD) into its national regulatory framework. The ACD harmonizes cosmetic standards among ASEAN member states through technical guidelines, including the ASEAN Cosmetic Ingredient List, the List of Prohibited Substances, and the Good Manufacturing Practices (GMP) guidelines. BPOM functions as the National Regulatory Authority (NRA) responsible for implementing ACD provisions via the Online Cosmetic Notification System (Notifkos). However, implementation challenges remain. According to the 2023 BPOM report, inconsistencies in technical interpretations of active ingredients and variations in administrative procedures among ASEAN countries have led to delays in cross-border product notification approvals.

Field observations further reveal that approximately 23% of skincare products sold online in Indonesia in 2024 lacked BPOM notification numbers. Most of these unregistered products were imported from China and South Korea through cross-border e-commerce channels, indicating weak post-market surveillance in the digital marketplace. Additionally, the limited number of accredited testing laboratories and toxicology experts, particularly in eastern Indonesia, has resulted in inconsistencies in product safety verification. Several laboratories in the region have yet to achieve ISO/IEC 17025 accreditation, as recommended by the OECD.

In terms of compliance with global standards, Indonesia has partially adopted the WHO Guidelines for the Safety of Cosmetics and OECD recommendations on non-animal (alternative) testing methods. However, Indonesia's pre-market safety evaluation system remains largely administrative and lacks a comprehensive risk-based assessment. By contrast, trading partners such as Japan, South Korea, and China require mandatory toxicological testing and scientific dossier reviews prior to granting marketing

authorization. This disparity in testing and evaluation practices poses potential non-tariff barriers to international cosmetics trade.

Moreover, the study found that Indonesia is not yet an active member of the International Cooperation on Cosmetics Regulation (ICCR), despite the organization's critical role in advancing global regulatory harmonization and developing new science-based safety assessment methods. The absence of full membership restricts Indonesia's participation in international policy formulation related to cosmetics regulation. The study concludes that while Indonesia's national regulations are conceptually consistent with international legal standards, significant challenges persist in terms of technical implementation, institutional capacity, and cross-jurisdictional harmonization.

The findings of this study demonstrate that the conformity of national regulations with international legal standards depends not only on the written content of the regulations (de jure) but also on the consistency of their implementation in practice (de facto). A country's success in aligning national regulations with international standards is determined by three main factors: the clarity of normative frameworks, the effectiveness of regulatory institutions, and the degree of openness to multilateral oversight.[23] Although Indonesia has made notable normative progress, it continues to face challenges in the latter two dimensions.

Compliance with the principles of the WTO Technical Barriers to Trade (TBT) Agreement can be observed in BPOM's efforts to maintain non-discriminatory treatment toward imported products. However, in practice, potential technical barriers remain due to inconsistencies between national requirements and international confirmation procedures. For instance, the WTO reported in 2022 that Indonesia's cosmetic product notification process lacked full transparency and did not incorporate the cross-border public consultation mechanism mandated under Article 2.9 of the TBT Agreement. These findings suggest that, while Indonesia's legal framework does not directly conflict with TBT principles, the level of administrative transparency requires further enhancement.

Regulatory harmonization within the ASEAN framework serves as a transitional phase toward broader legal integration.[24] The implementation of the ASEAN Cosmetic Directive (ACD) in Indonesia has contributed to standard alignment at the regional level but has not yet eliminated administrative barriers among member states. For example, each ASEAN country continues to require domestic product notifications even for

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[23] Caroline E. Foster, "Regulatory Coherence," in *Global Regulatory Standards in Environmental and Health Disputes: Regulatory Coherence, Due Regard, and Due Diligence* (Oxford: Oxford Academic, 2021), 51–88, https://doi.org/10.1093/oso/9780198810551.003.0003%0A; Peter Mumford, "Regulatory Coherence: Blending Trade and Regulatory Policy," *Policy Quarterly* 10, no. 4 (2014): 1–7, https://doi.org/10.26686/pq.v10i4.4512.

[24] Xavier Fernández-i-Marín and Jacint Jordana, "The Emergence of Regulatory Regionalism: Transnational Networks and the Diffusion of Regulatory Agencies within Regions," *Contemporary Politics* 21, no. 4 (2015): 417–434, https://doi.org/10.1080/13569775.2015.1010776; Moch Faisal Karim, Adelia Putri Irawan, and Tirta Nugraha Mursitama, "Regulatory Regionalism and the Limits of ASEAN Banking Integration: The Case of Indonesia," *Politics* 44, no. 3 (2021): 420–36, https://doi.org/10.1177/02633957211061233.

cosmetics already registered in another member country. This limitation directly affects the competitiveness of the national industry. Small and medium-sized enterprises (SMEs) in Indonesia continue to face obstacles in entering the ASEAN market due to the necessity of repeated notification submissions. Consequently, this study confirms that procedural harmonization should be the next strategic priority to enhance the effectiveness of the ACD in supporting regional cosmetic market integration.

Regarding compliance with WHO, OECD, and ICCR standards, the study identifies several implementation gaps. Both the WHO and OECD emphasize a risk-based approach and the reduction of animal testing through the adoption of alternative scientific methods. However, Indonesia's safety assessment framework remains primarily administrative rather than scientific. This gap is further evidenced by the absence of a comprehensive toxicological assessment system within BPOM that integrates with the OECD eChemPortal international database. Integration with such databases could expedite evaluation processes and strengthen the credibility of safety test results. This finding is consistent with the research of Rodriguez-Manzano et al. which demonstrates that countries with limited laboratory infrastructure tend to rely on administrative verification rather than full scientific assessment.[25] Therefore, it can be concluded that Indonesia's compliance with international standards remains largely normative rather than substantive.

Furthermore, the rapid expansion of cross-border digital trade (cross-border e-commerce) has intensified the challenges associated with implementing international legal frameworks. The World Trade Organization (WTO), through its E-commerce Work Programme (2022), reported a notable increase in the circulation of illegal cosmetic products online, including within Indonesia. The finding that approximately 23% of online cosmetic products lack official notification numbers underscores the persistent weaknesses of the country's digital oversight mechanisms. This phenomenon highlights the limited jurisdictional reach of national regulations in governing cross-border digital activities, thereby necessitating enhanced international cooperation—such as data-sharing mechanisms among regulatory authorities.[26]

This study confirms that aligning national regulations with international legal standards has a direct and significant impact on regulatory credibility, consumer protection, and the competitiveness of the national cosmetics industry. Effective harmonization not only mitigates the risk of trade disputes within the WTO framework but also strengthens consumer confidence in domestic products. Moreover, regulatory compliance is a key determinant in attracting foreign investment in the cosmetics sector,

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[25] Jesus Rodriguez-Manzano et al., "Innovative Diagnostic Technologies: Navigating Regulatory Frameworks Through Advances, Challenges, and Future Prospects," *The Lancet Digital Health* 6, no. 12 (2024): 934–43, https://doi.org/10.1016/S2589-7500(24)00242-5.

[26] Peer Zumbansen, "Manifestations and Arguments: The Everyday Operation of Transnational Legal Pluralism," in *The Oxford Handbook of Global Legal Pluralism*, ed. Paul Schiff Berman (Oxford: Oxford Academic, 2020), 230–262, https://doi.org/10.1093/oxfordhb/9780197516744.013.23%0A.

as multinational corporations tend to favor jurisdictions with stable, transparent, and internationally aligned regulatory systems.

However, this study acknowledges several limitations. First, restricted access to empirical data concerning the implementation of the ASEAN Cosmetic Directive (ACD) and the WTO Technical Barriers to Trade (TBT) Agreement at the national level has necessitated a greater reliance on secondary data sources. Second, the perceptions of industry stakeholders and international institutions regarding the effectiveness of Indonesia's regulatory system were not included in this analysis. Third, due to the absence of standardized quantitative indicators for measuring regulatory compliance, the evaluation presented in this study is primarily descriptive and qualitative in nature.

4. CONCLUSION

This study aims to describe the administrative regulations governing skincare safety in Indonesia, compare them with regulatory systems in East Asian countries, and assess their degree of compliance with international legal standards. The findings indicate that Indonesia has established a relatively comprehensive legal framework through Law No. 36 of 2009 on Health, various BPOM (Food and Drug Authority) regulations, and the adoption of the ASEAN Cosmetic Directive (ACD). However, the effectiveness of implementation remains constrained by limited oversight capacity, regulatory overlaps among agencies, and inadequate resources at the regional level.

The comparative analysis shows that East Asian countries such as Japan, South Korea, and China have developed more stringent and integrated regulatory systems, particularly in areas such as active ingredient safety testing, post-market surveillance, and product information transparency. In contrast, Indonesia continues to rely primarily on an administrative approach centered on pre-distribution notification and routine surveillance. This highlights a persistent gap between national regulations and international best practices.

The study confirms that Indonesia has taken meaningful steps toward aligning its regulatory framework with the World Trade Organization's Technical Barriers to Trade (TBT) principles and the harmonization objectives of the ASEAN Cosmetic Directive. Nevertheless, further efforts are required to strengthen the implementation of non-discrimination principles, promote transparency through open scientific data, and establish a cross-border surveillance system responsive to the dynamics of digital trade.

This research provides valuable insights for policymakers and scholars seeking to enhance cosmetic safety governance in alignment with global developments. However, its primary limitation lies in the scope of empirical data, which focuses mainly on national-level regulations and does not encompass all administrative regions. Accordingly, future research is recommended to conduct broader cross-regional comparative studies employing a more extensive empirical approach, including an

analysis of the economic and social impacts of skincare safety regulation implementation in Indonesia.

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