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A Critical Examination of the Principle of Proportionality in Indonesian Food and Drug Authority Regulation Number 25 of 2025: Cosmetic Ingredient Bans and Transition Periods

Aden Mahardika*, Herwastoeti

Master of Law Program, Universitas Muhammadiyah Malang, Malang, Indonesia.
: adenmahardika20@gmail.com
Corresponding Author*

Abstract

Introduction: *Indonesia's cosmetic industry has grown rapidly, with a projected market value of USD 9.74 billion in 2025, largely driven by Small and Medium Enterprises (SMEs). In response to this expansion, the Indonesian National Agency of Drug and Food Control enacted Food and Drug Authority Regulation Number 25 of 2025, replacing previous regulations and introducing stricter technical requirements for cosmetic ingredients.*

Purposes of the Research: *This study aims to critically examine whether key provisions in Food and Drug Authority Regulation Number 25 of 2025 comply with the principle of proportionality, particularly concerning the prohibition of cosmetic ingredients and the determination of a uniform 12-month transition period for regulatory compliance across different categories of industry actors.*

Methods of the Research: *This research employs a normative juridical method with statutory, conceptual, and comparative approaches. The analysis focuses on evaluating the regulation against the principle of proportionality by comparing it with international frameworks, including the ASEAN Cosmetic Directive (ACD) and European Union Regulation (EC) Number 1223/2009.*

Findings of the Research: *The study develops a proportionality-based framework for assessing the suitability, necessity, and balancing of regulatory measures. It identifies legal and analytical issues concerning the justification of ingredient prohibitions, the treatment of technically unavoidable traces, and the adequacy of transitional arrangements. The study proposes clearer implementing guidance, evidence-based transition mechanisms, and regulatory support for SMEs compliance. Its contribution lies in integrating proportionality analysis with regulatory implementation concerns in Indonesia's cosmetic sector.*

Keywords: Proportionality; Cosmetic Regulation; Ingredient Prohibition; Transition Periods.

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INTRODUCTION

Indonesia's cosmetic industry is currently experiencing an unprecedented phase of expansion. Based on data from the Ministry of Industry, as compiled from Statista, the national cosmetic market value reached USD 9.74 billion in 2025, with an average annual growth rate of approximately 4.33 to 4.37 percent, and is projected to surpass USD 10 billion by 2026[1]. The number of business actors has increased significantly, rising from 726 units in 2020 to 1,684 units in 2025, of which 85 percent are small and medium-sized enterprises (SMEs)[2]. This exponential growth is not without risks. In 2025, the Indonesian National

[1] Ministry of Industry of the Republic of Indonesia. (2026). *Exports soar, the cosmetics industry becomes a pillar of economic growth*. Ministry of Industry of the Republic of Indonesia. https://ikm.kemenperin.go.id/ekspor-meroket-industri-kosmetik-jadi-pilar-ekonomi-tumbuh.

[2] Pamerindo Indonesia PT. *The four largest industrial sectors contributing to East Java's economy*. (Surabaya: Manufacturing, 2021). https://manufacturingsurabaya.id.

Agency of Drug and Food Control withdrew more than 100 cosmetic products from the market due to the presence of hazardous substances such as mercury, hydroquinone, and retinoic acid exceeding permissible limits[3].

The state's response to these conditions was manifested through the enactment of Regulation of the National Agency of Drug and Food Control Number 25 of 2025 on Technical Requirements for Cosmetic Ingredients in October 2025. This regulation consolidates three previous regulations the National Agency of Drug and Food Control Regulation Number 23 of 2019, the National Agency of Drug and Food Control Regulation Number 17 of 2022, and the National Agency of Drug and Food Control Decree Number 479 of 2023 into a single regulatory framework.[4][5].

Based on the above background, this study formulates two interrelated legal issues using the same analytical parameter, namely the principle of proportionality. First, whether the prohibition of cosmetic ingredients under the National Agency of Drug and Food Control Regulation Number 25 of 2025 satisfies the principle of proportionality. Second, whether the transition period stipulated in the regulation meets the requirements of the principle of proportionality. Both research questions share a clear common thread, as they examine the principle of proportionality in two key instruments of the National Agency of Drug and Food Control Regulation Number 25 of 2025: the prohibition of ingredients (regulatory substance) and the transition period (regulatory implementation), with a primary focus on their impact on small and medium-sized industries (SMEs).

METHODS OF THE RESEARCH

This study employs a normative legal research method using three integrative approaches: the statute approach, the conceptual approach, and the comparative approach. Statute Approach: This approach involves a hierarchical analysis of the National Agency of Drug and Food Control Regulation Number 25 of 2025 and related regulations, ranging from the 1945 Constitution of the Republic of Indonesia, Law Number 17 of 2023 on Health, to its implementing regulations. The primary legal materials consist of relevant statutory regulations governing cosmetic safety and public health.

Table 1. List of Relevant Legal Instruments

No.	Legislation	Relevant Provisions
1	Constitution 1945	Article 28D (legal certainty), Article 28H (right to health), Article 28J (limitation of rights)
2	Law Number 17 of 2023 on Health	Legal basis for cosmetic supervision
3	the National Agency of Drug and Food Control Regulation Number 25	Main regulation under analysis[6]

[3] National Agency of Drug and Food Control of the Republic of Indonesia. (2026). *BPOM finds 26 hazardous cosmetic products at the end of 2025*. https://www.pom.go.id/siaran-pers/bpom-temukan-26-kosmetik-berbahaya-di-akhir-2025.

[4] National Agency of Drug and Food Control of the Republic of Indonesia. (2022). *Regulation of the National Agency of Drug and Food Control Number 17 of 2022 concerning amendments to Regulation Number 23 of 2019 on technical requirements for cosmetic ingredients*. https://standar-otskk.pom.go.id/storage/uploads/7dc41b4f-e780-4ce9-8b0a-e939ebc1f0f6/PerBPOM-no.-17-tahun-2022.

[5] National Agency of Drug and Food Control of the Republic of Indonesia. (2019). *Regulation of the National Agency of Drug and Food Control Number 23 of 2019 on technical requirements for cosmetic ingredients*. https://peraturan.bpk.go.id/Details/224837/peraturan-bpom-no-23-tahun-2019.

[6] National Agency of Drug and Food Control of the Republic of Indonesia. (2025). *Regulation of the National Agency of Drug and Food Control Number 25 of 2025 on technical requirements for cosmetic ingredients*. https://peraturan.bpk.go.id/Details/333277/peraturan-bpom-no-25-tahun-2025.

	of 2025 on Technical Requirements for Cosmetic Ingredients	
4	ASEAN Cosmetic Directive (ACD)	Regional harmonization framework[7]
5	EU Regulation (EC) Number 1223/2009	International standard for the prohibition of CMR substances[8]
6	EU Omnibus IV Regulation 2021/1902	Prohibition of Lilial and CMR 1B substances[9]

Source: Processed by the Author, 2026.

Conceptual Approach: This approach explores the concept of the principle of proportionality in administrative law, which consists of three sub-principles: (a) suitability between means and objectives (*geeignetheid*); (b) necessity and the absence of less restrictive alternatives (*noodzakelijkheid*); and (c) proportionality in the strict sense, namely the balance between burdens and benefits (*proportionaliteit in enge zin*)[10]. Comparative Approach: This approach compares the regulation of ingredient prohibitions and transition periods in the National Agency of Drug and Food Control Regulation Number 25 of 2025 with the ASEAN Cosmetic Directive (ACD) and European Union Regulation (EC) Number 1223/2009, including Omnibus IV Regulation (EU) 2021/1902.

RESULTS AND DISCUSSION

A. Proportionality Assessment of the Prohibition of Cosmetic Ingredients

the National Agency of Drug and Food Control Regulation Number 25 of 2025 was enacted in October 2025 in response to two main factors: developments in the ASEAN Cosmetic Directive (ACD) and advances in global scientific knowledge identifying previously unrecognized hazardous substances.[11]. This regulation introduces several fundamental changes, including full harmonization with the updated ACD (ACSB 38th), a preventive risk-based supervisory approach, and legal recognition of technically unavoidable traces under Article 10, of the total 1,684 cosmetic business actors in Indonesia, 85 percent (approximately 1,431 units) are Small and Medium Enterprises (SMEs). SMEs differ from large industries in several respects, including limited capital for research and development, absence of in-house laboratories, limited formulation expertise, and dependence on imported raw materials. These characteristics are crucial in assessing the proportionality of the regulation.

The most significant substantive change introduced by the National Agency of Drug and Food Control Regulation Number 25 of 2025 is the addition of 101 new substances to the list of prohibited ingredients (Annex V), including Lilial (Butylphenyl Methylpropional), Styrene, and D4 (Octamethylcyclotetrasiloxane)[12]. Lilial has been banned in the European Union since 1 March 2022 through Omnibus IV Regulation (EU) 2021/1902, following the Scientific Committee on Consumer Safety (SCCS) Opinion SCCS/1591/17 confirming its

[7] Luna, L., Christabelle, V., Wijaya, V., & Elsputri, V. C. "Skincare product safety regulations in Indonesia and Asian countries within the framework of international legal standards". *JIHK* 7, no. 2 (2026): 797–817.

[8] M. Kashuri, *Toy Cosmetics and Children: Between Entertainment and Health Risks*. Revormasi Jangkar Philosophia, 2025.

[9] National Agency of Drug and Food Control of the Republic of Indonesia. (2023). *Q&A from the 34th, 35th, and 36th meetings of the ASEAN Cosmetic Committee (ACC) and ASEAN Cosmetic Scientific Body (ACSB)*.

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[11] M.Kashuri, *Healthy Indonesia, strong economy: Strategies for eradicating natural medicine and cosmetics containing hazardous substances for national welfare*. PT. Revormasi Jangkar Philosophia, 2025.

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reproductive toxicity (CMR category 1B)[13]. The principle of proportionality in administrative law consists of three sub-principles that must be satisfied.

Table 2. Application of the Principle of Proportionality in the Prohibition of Cosmetic Ingredients

Sub-Principle	Test Question	Application to Ingredient Prohibition
Suitability (*Geeignetheid*)	Is the prohibition of substances suitable to achieve the objective of public health protection?	Fulfilled. The prohibition of hazardous substances such as Lilial (CMR 1B) directly protects consumers from serious health risks[14].
Necessity (*Noodzakelijkheid*)	Are there less restrictive alternatives than total prohibition?	Partially fulfilled. Alternatives such as maximum concentration limits (as applied in EU practice for certain substances) are not regulated. Total prohibition represents the most restrictive measure[15].
Proportionality in the strict sense (*Proportionaliteit sensu stricto*)	Are the burdens imposed on SMEs proportionate to the public health benefits?	Not fulfilled. The reformulation burden on SMEs is substantial (seven stages, high costs, 15–18 months) without supporting instruments such as quantitative thresholds (Article 10 remains a vague norm)[16].

Source: Author's analysis, 2026.

The reformulation process resulting from the prohibition of substances involves seven technical stages[17]: a) identification of safe and available alternative ingredients; b) laboratory-scale formulation testing; c) accelerated stability testing (minimum of three months in accordance with ASEAN Guidelines); d) microbiological stability testing; e) skin safety testing (irritation/sensitization); f) revision of the Product Information File (PIF); and g) re-notification through the the National Agency of Drug and Food Control e-Notification system. Kashuri, Ikrar, and Indrayanto (2025), in their study of 50 SME cosmetic enterprises in West Java and East Java, found that the average reformulation time required by SMEs ranges from 15 to 18 months, with the following breakdown:

Table 3. Reformulation Stages, Time Requirements, and Key Constraints for SMEs

Stage	Time (months)	Key Constraints for SMEs
Identification of alternative ingredients	2–3	Limited access to information on alternative ingredients
Formulation testing	2–3	Lack of in-house laboratory facilities
Accelerated stability testing	3–4	High outsourcing costs (IDR 15–25 million)
Microbiological testing	1–2	Requires specialized facilities

[13] European Commission. (2021). *Commission Regulation (EU) 2021/1902 of 29 October 2021 amending Annexes II, III and V to Regulation (EC) No 1223/2009 as regards the use in cosmetic products of certain substances classified as carcinogenic* (pp. 1–6).

[14] Cekli Setya Pratiwi, Shinta Ayu Purnamawati Fauzi, & Christina Yulita Purbawati. (2016). *General principles of good governance*. LeIP (Institute for Judicial Independence).

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[17] European Commission. (2021). *Commission Regulation (EU) 2021/1902 of 29 October 2021 amending Annexes II, III and V to Regulation (EC) No 1223/2009 as regards the use in cosmetic products of certain substances classified as carcinogenic* (pp. 1–6).

Skin safety testing	2–3	Requires expert personnel
PIF revision	1–2	Requires re-documentation
Re-notification	1–2	Administrative process

Source: Kashuri et al. (2025)[18]

Article 10 of the National Agency of Drug and Food Control Regulation Number 25 of 2025 recognizes the concept of technically unavoidable traces; however, the phrase "technically unavoidable levels" constitutes a vague norm (vage norm), as it is not accompanied by quantitative threshold values expressed in ppm (parts per million) for each prohibited substance. Best practices in the European Union demonstrate the establishment of specific threshold values, for example, nitrosamines ≤50 ppb. The absence of such quantitative thresholds in the National Agency of Drug and Food Control Regulation Number 25 of 2025 creates legal uncertainty for SMEs and poses a risk of disproportionate enforcement of sanctions.

The prohibition of cosmetic ingredients under the National Agency of Drug and Food Control Regulation Number 25 of 2025 has not fully satisfied the principle of proportionality. While the principle of suitability (geeignetheid) is fulfilled in achieving public health protection, the principle of necessity (noodzakelijkheid) is only partially met due to the absence of less restrictive alternatives, and the principle of proportionality in the strict sense (proportionaliteit sensu stricto) is not satisfied, as the substantial reformulation burden on SMEs is not balanced by supporting instruments such as quantitative thresholds and an early warning system.

B. Proportionality Assessment of the Transition Period Agency of Drug and Food Control

Regulation Number 25 of 2025 provides a uniform transition period of 12 months (October 2025 – October 2026) for all business actors to adjust formulations, labeling, and notifications, without differentiation based on the scale of the business[19].

Table 4. Application of the Principle of Proportionality in the Transition Period

Sub-Principle	Test Question	Application to the Transition Period
Suitability (*Geeignetheid*)	Is a 12-month transition period sufficient to allow for adjustment?	Partially fulfilled. Adequate for large industries with in-house laboratories, but not for SMEs.[20]
Necessity (*Noodzakelijkheid*)	Is a 12-month transition period the least restrictive option?	Not fulfilled. Less restrictive alternatives are available, such as differentiated transition periods (18 months for SMEs) or an early warning system[21].

[18] Kashuri, Mohamad, Ikrar, Taruna, & Indrayanto, Gunawan. "Analysis of trends in cosmetics supervision cases in Indonesia in 2021–2024". *Eruditio: Indonesia Journal of Food and Drug* Safety 5, no 2(2025): 128–139. https://doi.org/10.54384/eruditio.v5i2.235.

[19] National Agency of Drug and Food Control of the Republic of Indonesia. (2025). *Regulation of the National Agency of Drug and Food Control Number 25 of 2025 on technical requirements for cosmetic ingredients*. https://peraturan.bpk.go.id/Details/333277/peraturan-bpom-no-25-tahun-2025.

[20] Kashuri, M., Ikrar, T., & Indrayanto, G. "*Analysis of trends in cosmetics supervision cases in Indonesia in 2021–2024. Eruditio: Indonesia Journal of Food and Drug Safety*" 5, no. 2 (20265): 128–139. https://doi.org/10.54384/eruditio.v5i2.235.

[21] National Agency of Drug and Food Control of the Republic of Indonesia. (2019). *Regulation of the National Agency of Drug and Food Control Number 23 of 2019 on technical requirements for cosmetic ingredients*. https://peraturan.bpk.go.id/Details/224837/peraturan-bpom-no-23-tahun-2019.

Proportionality in the strict sense (*Proportionaliteit sensu stricto*)	Is imposing the same time burden on SMEs and large industries proportionate to its benefits?	Not fulfilled. SMEs with limited capacity are treated the same as large industries, resulting in inequality[22].

Source: Author's analysis, 2026.

A comparison of transition periods across jurisdictions is essential for assessing proportionality:

Table 5. Comparison of Transition Periods across Jurisdictions

Aspect	Indonesia (BPOM Regulation No. 25 of 2025)	European Union (Omnibus IV)	ASEAN Cosmetic Directive (ACD)
Formal transition period	12 months (uniform)	4 months (1 March 2022)	12–24 months (flexible by Member States)
Prior notice / early warning	Not available (regulation was disseminated on 7 November 2025 after enactment)	5 years (SCCS Opinion SCCS/1591/17 published in 2017)	Updates through scheduled ACSB meetings
Total effective preparation time	Less than 12 months for SMEs	± 5 years 4 months	Varies (Member States may extend)
Differentiation by business scale	Not available	Procedural relief for SMEs, but safety standards remain the same	Not regulated (left to Member States)

Source: European Commission (2019)[23], European Union (2021)[24], BPOM (2025)[25], Kashuri et al. (2025)[26]

Based on Kashuri, Ikrar & Indrayanto (2025), the reformulation time required by SMEs reaches 15–18 months. With a transition period of only 12 months and without prior notice, technically SMEs are not able to meet the deadline. Accelerated stability testing alone requires a minimum of 3 months in accordance with the ASEAN Guidelines on Stability Testing of Cosmetic Products. Assuming that SMEs receive information on the prohibition during the socialization in November 2025, the remaining time is: October 2026 – November 2025 = 11 months. Subtracting 3 months for stability testing leaves 8 months for the other 6 stages. This condition is practically not feasible for SMEs without in-house laboratories.

If the transition period remains 12 months without revision, there are three main risks (Kashuri, Ikrar & Indrayanto, 2025): a) Legal risk: BPOM may potentially engage in *detournement de pouvoir* (abuse of power) if it imposes sanctions on SMEs that fail to meet the deadline due to structural technical incapacity rather than bad faith; b) Industrial risk:

[22] Rugian, I. A. (2021). "The Principle of Proportionality in Constitutional Review Against the 1945 Constitution of the Republic of Indonesia (A Comparative Study Between Indonesia And Germany)". *Journal of Law* 4, no. 4 (2021): 1479–1508. https://doi.org/10.20473/jd.v4i4.28482.

[23] European Commission. (2019). *Scientific committees*. Directorate-General for Health and Food Safety. https://health.ec.europa.eu/scientific-committees_en.

[24] European Commission. (2021). *Commission Regulation (EU) 2021/1902 of 29 October 2021 amending Annexes II, III and V to Regulation (EC) No 1223/2009 as regards the use in cosmetic products of certain substances classified as carcinogenic* (pp. 1–6).

[25] National Agency of Drug and Food Control of the Republic of Indonesia. (2025). *Regulation of the National Agency of Drug and Food Control Number 25 of 2025 on technical requirements for cosmetic ingredients*. https://peraturan.bpk.go.id/Details/333277/peraturan-bpom-no-25-tahun-2025.

[26] Kashuri, M., Ikrar, T., & Indrayanto, G. (2025). "Analysis of trends in cosmetics supervision cases in Indonesia in 2021–2024". *Eruditio: Indonesia Journal of Food and Drug Safety* 5, no. 2 (2025): 128–139. https://doi.org/10.54384/eruditio.v5i2.235.

Most of the 1,431 SMEs are at risk of losing their marketing authorization, potentially leading to contraction in the national cosmetic market and loss of employment; c) Consumer risk: Excessive compliance pressure may push SMEs to switch to cheaper substitute ingredients that have not been adequately tested, creating a regulatory paradox where consumer protection may instead result in less safe products.

The transition period under Agency of Drug and Food Control Regulation Number 25 of 2025 does not satisfy the principle of proportionality. The uniform 12-month transition period does not consider the actual capacity of SMEs, which require 15–18 months, lacks a prior notice/early warning mechanism (unlike EU practice), and ignores the principle of a differentiated regulatory approach as recommended in the ASEAN Cosmetic Directive, to strengthen the proportionality analysis, the following comprehensive comparison is presented:

Table 6. Comparative Analysis with the ASEAN Cosmetic Directive and the European Union

Comparative Aspect	BPOM Regulation Number 25 of 2025 (Indonesia)	ASEAN Cosmetic Directive (ACD)	EU Regulation (EC) Number 1223/2009
Legal Basis	Agency of Drug and Food Control Regulation (binding)	Regional directive (non-binding)	EU regulation (directly binding)
List of Prohibited Substances	Annex V (addition of 101 substances, following ACD)	Annex II (updated through ACSB 38th, Dec 2025)	Annex II (Lilial banned since 1 March 2022)
Scientific Basis	Adoption of SCCS findings through ACD	Refers to EU SCCS and international scientific bodies	Independent SCCS opinions (open peer review)
Technically Unavoidable Traces	Article 10 (recognized, but thresholds not specified)	General guidance (case-by-case limits)	Specific threshold values (ppm/ppb)
Transition Period	Uniform 12 months, without prior notice	12–24 months (flexible)	4 months formal + 5-year prior notice
Treatment of SMEs	No differentiation	Left to Member States	Procedural relief for SMEs

Source: ASEAN Cosmetic Association (2008)[27], European Union (2021)[28], BPOM(2025)[29], OECD (2021)[30], European Commission (2013)[31]

Although not part of the main research questions, it should be noted that Agency of Drug and Food Control Regulation Number 25 of 2025 introduces administrative sanctions in the

[27] ASEAN Cosmetic Association. (2008). *General information booklet on ASEAN harmonized cosmetic regulatory scheme*. ASEAN Cosmetic Committee.

[28] European Commission. (2021). *Commission Regulation (EU) 2021/1902 of 29 October 2021 amending Annexes II, III and V to Regulation (EC) No 1223/2009 as regards the use in cosmetic products of certain substances classified as carcinogenic* (pp. 1–6).

[29] National Agency of Drug and Food Control of the Republic of Indonesia. (2025). *Regulation of the National Agency of Drug and Food Control Number 25 of 2025 on technical requirements for cosmetic ingredients*. https://peraturan.bpk.go.id/Details/333277/peraturan-bpom-no-25-tahun-2025.

[30] Organisation for Economic Co-operation and Development. (2021). *OECD regulatory policy outlook 2021*. OECD Publishing.

[31] European Commission. (2013). *Cosmetic products regulation (EC) No. 1223/2009: Guidelines for the application of Annex I (Cosmetic Product Safety Report)*. Publications Office of the European Union.

form of revocation of the Good Cosmetic Manufacturing Practices certificate for serious violations. Firmantoro (2025) finds a significant disparity between the potential sanctions (fines of up to IDR 1 billion) and actual enforcement outcomes (averaging IDR 5–10 million). The strengthening of sanctions through Good Cosmetic Manufacturing Practices revocation should be positioned as an *ultimum remedium*, preceded by written warnings and temporary suspension.[32]

CONCLUSION

This study examined the proportionality of ingredient prohibitions and transitional arrangements under Indonesia's Agency of Drug and Food Control Regulation Number 25 of 2025 through statutory, conceptual, and comparative approaches. The analysis demonstrates that assessing regulatory proportionality requires consideration not only of the public health objectives underlying ingredient restrictions but also of the legal justification, implementation mechanisms, and compliance burdens imposed on regulated entities. Regarding ingredient prohibitions, the proportionality assessment should distinguish between the suitability of restrictions for protecting public health, the availability of less restrictive regulatory alternatives, and the balance between public health benefits and compliance burdens. The legal treatment of technically unavoidable traces and the clarity of applicable thresholds require particular attention to ensure regulatory predictability and consistent enforcement. Regarding transitional arrangements, a uniform compliance period should be assessed in light of the applicable legal provisions, the complexity of reformulation requirements, and the differing capacities of business actors. However, any proposal for differentiated transition periods should be supported by verifiable evidence and a clearly articulated legal justification. The study contributes a proportionality-based analytical framework for examining cosmetic regulatory reform in Indonesia. It recommends clearer implementing guidance, transparent regulatory communication, and evidence-based compliance support. Further empirical research is necessary to assess actual SME compliance costs and evaluate the effectiveness of the regulation after implementation.

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