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Review article: Comparison of cosmetic regulatory policies in various countries toward consumer protection



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ABSTRACT

Cosmetics are various products that enhance physical appearance and care for the skin, hair, and body. Cosmetic regulation refers to the rules and regulations imposed by a country's government or health regulatory agencies to regulate the production, marketing, and use of cosmetic products. The purpose of writing this journal is to compare the regulation of cosmetic products in Indonesia with the regulation of cosmetic products abroad, and it is hoped that people will be more aware and understand the regulation of cosmetic products that have been established. The literature method is used to conduct a review article, and the criteria chosen are based on the originality and relevance of the reading. The result of this writing is that the requirements regarding labeling in various countries are similar, such as composition, country of manufacture, product name, instructions for use, full name and address of the owner of the notification number (manufacturer), manufacturing batch number, expiration date, and special precautions that must be considered when using. Consumers must consider different regulations for cosmetic products in each country. These must be considered when making or selling cosmetic products: import and export regulations, limited ingredients, and safety testing of cosmetic products.

Keywords: Cosmetics, Export, Import, Labelling, Regulation

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INTRODUCTION

The cosmetics industry is one of the most traded products and continues to grow because many consumers know the importance of self-care. Along with the increasing consumer demand for cosmetic products, various brands, and variations are offered by the market, raising consumer protection issues (Aperta et al., 2023). Consumer protection is crucial in maintaining the welfare of consumers when choosing and using cosmetic products correctly, precisely, and safely. This is because cosmetics have the potential to affect skin health. Each country has policies to protect consumer rights and ensure product safety. For example, in ASEAN member countries, the content of cosmetic products and how these products are circulated (legal or illegal) can cause problems in health, economy, and society (Nurgiyanti & Fithriya, 2019).

Regulation can be defined as a process area that involves three state institutions, namely the judiciary, executive, and legislature, in the context of public administration. It also includes three essential aspects: regulatory drafting, implementation or enforcement, and adjudication. Regulations are made to control society with specific rules and add to the safety and quality of products made, such as packaging regulations. The packaging container must follow the type of product to be packaged. This aims to prevent leaks, explosions, product texture, and color changes and to avoid product migration. Different government entities worldwide regulate the manufacture and sale of cosmetic products (Ravi et al., 2016). In Indonesia, many beauty or cosmetic product entrepreneurs need to learn the regulations of their products, and duplicate products occur, which can endanger consumers.

The cosmetics regulations in each country may vary, and each has a specific authority that regulates cosmetic products. Some standard requirements often applied by many countries include safety testing, use of ingredients/composition, unambiguous labeling, restrictions on using hazardous ingredients, and product registration. This research aims to compare the regulation of cosmetics in

various countries with that of consumer protection. Hopefully, this research can provide a deeper understanding of how each country faces challenges related to the circulation of cosmetic products, both exports and imports, in the domestic market towards consumer protection.

RESEARCH METHOD

Methods

In writing this journal, the literature method was used, and it was published through a database in the form of a site that contains readings such as books, the official website of an agency, and journals to serve as a reference in making this review article. The criteria for articles are seen from the originality and relevance of reading, as for the years used to be used as literature, namely the last ten years.

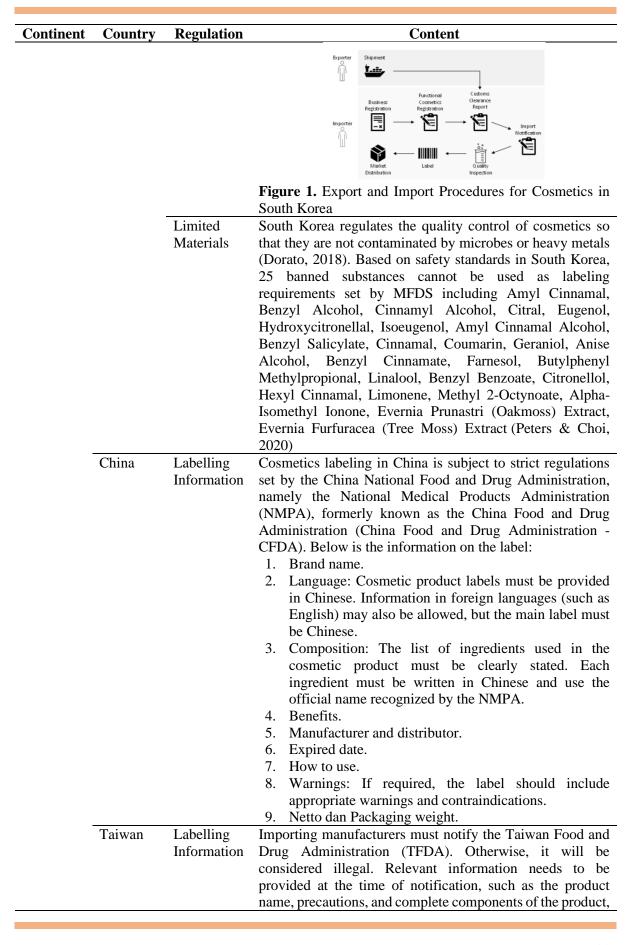
RESULT AND DISCUSSION

The following are the regulatory provisions set forth on several continents, shown in Table 1.

Table 1. The table of the regulatory provisions is set in four continents. **Continent** Country Regulation Content Asia India Labeling According to the Indian Drug and Cosmetic (D&C) Act, the information requirements are as follows: The outer label contains the net weight, while the inner label contains directions for use, warning indications, and the number of hazardous ingredients. The inner and outer labels include the product name and manufacturer's address. The manufacturing address (mfg), place of mfg, and pin code are included for small containers. The composition should be written down from 1% concentration to less than 1% (Ruhela et al., 2018). Malaysia Labeling Cosmetic products in Malaysia are authorized under the information Control of Drugs and Cosmetics Regulations (CDCR); companies that intend to manufacture, sell, supply, and import cosmetic products must notify that the product has been approved by the National Pharmaceutical Regulatory Agency (NPRA) under the ministry of health. Failure to do so will result in a fine of not more nor less than RM25,000 or imprisonment of not less than three years, and you may be penalized with both. Here are the details of the labeling requirements that must appear on the product packaging (*Ministry of Health Malaysia*, n.d.): 1. Product name and function. 2. Product usage instructions. 3. The product's ingredients list should be in descending order at the addition time. 4. Country of origin of the manufacturer. 5. Name, address, and contact number of the company holding the relevant license or certificate. Batch number of manufacture and Expiration date of the product. Special precaution warning. Labeling The information on the label is written in Japanese and must Japan be clearly and explicitly stated. The Japan Cosmetics information Association has compiled a Japanese version of the "Cosmetic Ingredient Label Name List" that meets the criteria of the Pharmaceutical Affairs Act for writing all ingredients on the marker. The following information must

be included on the label (Kemendag RI, 2021):

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Continent	Country	Regulation	Content
Continent	Arab	Regulation	to name a few. This notification serves as a record to help TFDA assign responsibility if there is a safety issue (TFDA, n.d.). From July 1, 2019 onwards, there are new requirements for labeling cosmetics, prohibited ingredients, and permitted colorants. The new regulations provide clear rules for labeling, including standardization of the display order of ingredients and font size of items that are mandatory on the label (Ministry of Health and Welfare of Taiwan, 2018): 1. Function. 2. Production and expiration dates are now mandatory information that must be included on labels. The aim is to help consumers identify and know product information, strengthening their rights. Some mandatory requirements still need to be implemented, such as compliance with good manufacturing practices for manufacturers and importers. For general cosmetics, the implementation date is expected to be set in July 2024. GCC Standardization Organization (GSO) is the regional standard in Saudi Arabia for product labeling or marking requirements. All cosmetic products must include the relevant Labeling information required by the GSO Standards and Technical Regulations specific to each product. The agency that manages cosmetic import requirements in Arabia is The Saudi Food and Drug Authority (SFDA) (International Trade Administration, 2022). Every cosmetic product must be labeled in Arabic or English or "Arabic and English" on the outer packaging with the following elements (Cotecna Saudi Arabia, 2020): 1. Name and Brand name. 2. The expiration date is given in the month and year for products expiring in less than 30 months or the phrase "Period After Opening" with the number of months of the product expiration if more than 30 months.
			 the product expiration if more than 30 months. List of ingredients that must conform to the international nomenclature for cosmetic ingredients Product function. Name and address of the manufacturer. Production date or batch number. Instructions for use and precautions. Country of manufacture. Volume.
		Limited Materials	Some banned and restricted ingredients in American cosmetics include bitonal, mercury compounds, vinyl chloride, and halogenated salicylanilides. Cosmetics must also not be contaminated with nitrosamines, 1,4-dioxane, or pesticide residues (Dorato, 2018).
Oceania	Australia	Labelling Information	The technical trade barriers applied in Australia to imported products are labeling and packaging (Widyantini, 2021). The Therapeutic Goods Administration (TGA) regulates

Continent	Country	Regulation	Content
			responsible for regulating therapeutic products, including beauty products or cosmetics. The information that must be included is as follows: 1. Brand name. 2. Language: using English. 3. Composition. 4. Benefits. 5. How to use. 6. Claims and Claim Labels: Claims about the product must be accurate and supported by valid evidence. Specific claims such as "paraben-free" or "hypoallergenic" must be scientifically substantiated. 7. Content (weight, volume). 8. Expired date. 9. Warning. 10. Name of Manufacturer or Importer: must include the name and address of the manufacturer or importer responsible for the product.
	New Zealand	Labelling Information	The cosmetics labeling regulations applied in New Zealand must comply with the European Union (EU) cosmetics regulations. The specificity of claims and nano ingredient regulations are the same, and cosmetic products sold in New Zealand must also comply with IFRA standards. The legal rules established by New Zealand have three categories called "related products." Cosmetic products must be appropriately labeled with the correct trade name, the active ingredients used must be quantitatively disclosed, and the product must be genuine, expired, batch number, dosage, frequency, instructions for use, and the name and address of the manufacturer.
Europe	Uni Europe	Labelling Information	Labeling should contain the trade name and address of the manufacturer responsible for marketing the product: product volume, precautions, identification of product reference number, and expiration date. Article 19 under Chapter VI of the EU Cosmetics Regulation 1223/2009 describes the label requirements in detail. Cosmetics can only be marketed if their containers and packaging contain information that cannot be washed off, is legible, and is printed in a visible font. Information that must be included on the product label includes: 1. Product Name. 2. Relevant information from the responsible person. 3. Product content information. 4. Shelf life. 5. Product usage. 6. Warning information is required to be identified. 7. Production batch number. 8. Product composition information. 9. Place of production: Choose one place where the product is always available.

Continent	Country	Regulation	Content
			10. The expiration date is divided into two types; for products with a shelf life of < 30 months, the shelf life date is written with "best consumed before the date." While products with a shelf life of > 30 months read, "the period is calculated after the product is opened and can be used without harming consumers."
		Importers of Indonesian cosmetic products to foreign countries	Importers of products into EU countries must be accountable for their products being safe to use; the EU has authoritative bodies responsible for enforcing compliance. In addition, manufacturers must have data on the safety assessment of products for health, as well as things to consider, such as the general toxicology of ingredients, chemical structure, and exposure levels; information on the composition must be written based on the national or remi language of each country. According to India's Drug and Cosmetic regulations, cosmetics may only be imported into India if the product is registered under these rules by a licensing authority designated by the central government (Ravi et al., 2016). Before the amendment, there was no regulation on cosmetics registration in India.
	Germany	Labelling Information	The Bundesinstitut für Risikobewertung (BfR) regulates cosmetic marking in Germany, translating to the Federal Institute for Risk Assessment. This agency is responsible for regulating and supervising cosmetic products in Germany to ensure the safety and quality of products sold on the market. The components contained in the label are: 1. Product name. 2. Language: Generally, cosmetic product labels in Germany must be provided in German. However, in some cases, labels in foreign languages, such as English, are also acceptable if the products are sold in specialty or duty-free shops. 3. Composition: The label should include a list of ingredients used in the cosmetic product. The ingredients should be written with familiar names and listed in quantity. 4. How to use. 5. Claim. 6. Net product. 7. Expired date. 8. Warning. 9. Benefit.
		Limited Materials	Azo dyes that may release one or more of the 22 aromatic amines listed in Annex 8 of the REACH Regulation, nonylphenols, and nonylphenol ethoxylates; and heavy metals, such as mercury, cadmium, and lead; chromium - the widely used chromium III may transform into the hazardous chromium VI variety under specific production and storage conditions; formaldehyde; nickel - may be present in metal trims and accessories, such as zippers, buttons, and jewelry;

Continent	Country	Regulation	Content
			polycyclic-aromatic hydrocarbons (PAHs), phthalates may
			be present in PVC components in purses and wallets.
America	United States	Labelling Information	The FDA controls US cosmetic labeling (Food and Drug Administration). The outer label contains ingredients and a net on the panel. The main display contains information (Ruhela et al., 2018). 1. Identity system.
			 Total net contents: expressed in ounces or pounds. Name and place of business: producer information and production address.
			4. Distributor statement: If the name and address are written instead of the agency's name, "Distributed by" should be given.
			5. Material Facts: Instructions for use.
			6. Warning and caution statement.
			7. Composition: written in descending order and, if retailed, added: "for professional use."
			Writing is required in English, except for products distributed only in the US and Puerto Rico.
		Limited	Some of the ingredients that are banned and restricted as
		Materials	ingredients in American cosmetics include bithionol, chlorofluorocarbon propellants, Chloroform, halogenated salicylanilides, hexachlorophene, mercury compounds, methylene chloride, prohibited cattle material, vinyl chloride, Zirconium-containing complexes. Cosmetics
			should also not be contaminated with nitrosamines, 1,4-
	Argentina	Labelling Information	dioxane, or pesticide residues (Dorato, 2018). IRAM (Instituto et al. y Certificación) is Argentina's Standardization and Certification body; in charge of handling cosmetic products in the market is the Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT). Here is some information that must be included in labeling in Argentina (Balbi & Sandoval, 2015). 1. Product name. 2. Brand.
			 Format/Variation. Description and Composition. Country of origin.
			6. Factory or warehouse address.7. File number.
	Canada	Labelling Information	An essential labeling requirement in Canada is that the displayed portion of the label, or Primary Display Panel (PDP), must have the following information (Government of Canada, n.d.):
			 Identity Statement Total Net Content. Other required cosmetic labeling information may be displayed on a section of the label other than the PDP, specifically the Information Panel. The Information Panel should include: Name and Place of Business.

Continent Country Regulation Content

- b. Warning and Prevention.
- c. Material Declaration.
- d. Product Name or Identity.
- e. The identity statement indicates the nature and use of the product. The product identity can be on the PDP in English or French if the other language is on one of the different panels.
- 3. Net quantity

Net quantity declarations provide the product content's weight, size, or numerical amount.

4. Business name

The cosmetic label must include the name and address of the manufacturer. Including the name and address must follow the Cosmetic Notification Form (CNF). If a product is manufactured or produced outside of Canada, there are several options for listing manufacturer or dealer identification.

- a. List of manufacturers outside Canada:
- b. List the Canadian importers, beginning with "Imported for/Importé pour" or "Imported by/Importé par."
- c. List the geographic origin of the product adjacent to the Canadian dealer.
- d. Warning and Prevention
- e. When a cosmetic product can be associated with avoidable harm, it can be sold under the condition that it includes a warning. These cosmetic warnings should explain how to use the product and when not to use it.

There are special regulations regarding warning statements for certain products, including:

- 1. Hair dye
- 2. Products containing mercury
- 3. Products in pressurized metal containers
- 4. Flammable products in pressurized metal containers
- 5. Mouthwash
- 6. Material declaration

Cosmetic labels must include an ingredient statement, with ingredients listed according to the INCI (International Nomenclature of Cosmetics Ingredients) name.

The regulation also allows designated Health Canada inspectors to check for other matters of concern when labeling.:

1. Cosmetic Product

The location where the cosmetic product is manufactured or stored. Product labeling includes any other written, printed, or pictorial material relating to the product. It ranges from the product's physical packaging to the content on the brand's website.

Continent Country Regulation **Content** 2. Expired Date There is currently no requirement to list expiry dates on Canadian cosmetic products. However, cosmetic companies are responsible for the safety of their products. Many brands include an expiry date to ensure their cosmetic products are used safely. 3. Language Canada is a bilingual French and English country; specific language requirements reflect this. The Consumer Packaging and Labeling Act Regulations explain which parts of the label must be included in French and English. These include: a. Product Identity b. Net quantity declaration c. Identity and place of business of the importer or producer The bill requires that all information on product labels be available in French and further stipulates that the French portion of such labels must be equal to or more prominent than any other language.

Labelling Information

In Indonesia, the circulation of products that are not legalized is very much found in cosmetic products. It can hurt health when using products without a distribution permit from BPOM (Food and Drug Supervisory Agency) because there is no guarantee for consumers that the product is suitable and safe to use. Taking care of BPOM takes a long time. It costs a lot of money, and producers use this as an excuse to implement traded products to remain suitable and safe by falsifying BPOM numbers or using BPOM numbers for other products (Heryansyach & Latumahina, 2022). Applying different regulations ensures that the products used are safe and properly labeled (Ravi et al., 2016). The following is the information that must be on the packaging label as stipulated in BPOM Regulation Number 30 of 2020 Article 5 of the Technical Requirements for Cosmetics Marking Regulation as follows:

- 1. Batch number.
- 2. Name of Cosmetics.
- 3. Notification number.
- 4. Size, content, or net weight.
- 5. 2D Barcode.
- 6. Name and complete address of the Notification Number Owner.
- 7. Expired date.
- 8. Warnings and cautions.
- 9. Benefit/usefulness.
- 10. How to use.
- 11. Composition.
- 12. Producing country.

In Indonesia, halal labeling on beauty product packaging must use raw materials declared halal, and permitted substances must be packaged, shipped, produced, and stored per the applicable Sharia law (Ningtyas & Harefa, 2022). Halal certification must be renewed annually using the exact mechanism and procedure. In manufacturing that does not extend halal certification, MUI does not guarantee that the industry can be held accountable for its halalness (Chairunnisyah, 2017). Including alcohol in cosmetic products is not considered unclean if alcohol made from plant fermentation is considered halal if it does not harm health. External beauty products do not restrict the use of alcohol if it is not made from khamr and does not cause harm (MUI, 2018). The writing of alcohol-free listed on

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the label is not specific to be 100% free of alcohol. After conducting trials, several samples were found to have evidence of alcohol in cosmetic products, from 2.48 x 10-4% - 4.96 x 10-4% (Albab & Mahfudh, 2020). The alcohol content found may be due to the fragrance of the cosmetics.

Based on the results of the discussion of labeling in the 15 countries above, Indonesia has the most labeling information among other countries, namely 12 information. This is a plus because packaging with an informative label can increase the selling value of the product (Khoirianingrum et al., 2018). Meanwhile, Taiwan has two requirements that must be included in the labeling: function and expiration date.

Import and Export

The halal industry in Indonesia continues to grow due to the increase in the world's Muslim population. The destination countries for exporting cosmetic products are Malaysia, Arabia, and the United Arab Emirates (Qoniah, 2022). Imported cosmetics sold online must have a distribution license, but cosmetic products imported by Indonesia are mostly unregistered and do not include the composition on the label. Table 2 shows beauty products exported to Indonesia:

	Table 2. Beauty products are exported to Indonesia.				
Export of Cosmetic Products from Outside to Indonesia					
Continent	Requirements				
Asia, America,	Foreign manufacturers that export beauty products to Indonesia include South				
and Europe	Korea, the USA, China, and Japan (Fatina et al., 2021). Products that will be				
	marketed must meet requirements such as:				
	1. Must have a distribution license				
	2. Imported cosmetics must use materials that meet requirements and				
	standards				
	3. Well-produced				
	4. Registered and licensed by BPOM				
	5. The label contains complete information about imported products and is				
	written in foreign and Indonesian languages. Article 22, paragraph 2 of				
	BPOM Decree Number HK.00.05.4.1745 states: "Writing labels in a				
	foreign language must be accompanied by information on how to use,				
	benefits, and other information in Indonesian" (Arimas & Suharta, 2014). If				
	exporters violate the rules set by Indonesia, they will be subject to penalties				
	such as:				
	6. Written reprimand				
	7. Seizure of beauty products from the market and stop media promotion				
	8. Termination of goods production activities				
	9. Distribution, storage, and import				
	10. Transporting and delivering products				
	11. Revoke the distribution and certification licenses listed in Article 8				
	paragraph (2) and Article 10 paragraph (1)				

Safety Test

Safety testing of cosmetic products is essential before products are marketed to consumers (Ermawati, 2018). The aim is to protect consumers and ensure that cosmetic products in circulation meet high safety standards. While regulations may vary from country to country, some standard safety tests include the following:

- 1. Toxicity Test: This test is carried out to assess the safety of a chemical compound, either the compound itself or the compound contained in other materials such as foodstuffs.
- 2. Sensitization Test: This test is conducted to identify the potential for the product to cause allergic or hypersensitivity reactions on the skin (BPOM RI, 2022).
- 3. Skin Irritation Test: This test assesses whether the cosmetic product can cause irritation or inflammatory reactions on human skin.

- 4. Patch Test: The patch test is used to identify potential allergic reactions on the skin by placing the product under a bandage on a small area of skin for some time.
- 5. Microbiology Test: This test assesses microbial contamination in cosmetic products to ensure the product is free from harmful microorganisms that can cause skin infections or other health problems.
- 6. Stability Tests: Real-time and accelerated tests are conducted with batches following established regulations to confirm the retest period of a substance or shelf life (BPOM RI, 2023).

Cosmetic safety regulations in each country may have specific requirements and different test methods. Some countries may also apply additional requirements related to the use of certain ingredients or product claims.

Limited Materials

Restricted ingredients in cosmetics refer to certain ingredients that are strictly regulated or even prohibited for use in the formulation of cosmetic products. These ingredients often pose potential risks to human health or the environment. Here are some examples of cosmetics with restricted ingredients that exist in Indonesia.

- 1. Mercury: Mercury or mercury compounds in cosmetics are prohibited in Indonesia as they harm health, especially the nervous system.
- 2. Hydroquinone: This ingredient is banned in specific concentrations because it is used as a skin whitener and can cause irritation and harm to the skin.
- 3. Lead: The use of lead in cosmetics is restricted as it can pose serious health risks, mainly if the product is used on a prolonged basis.
- 4. Phthalates: Some phthalates, such as diethyl phthalate (DEP) and dibutyl phthalate (DBP), are restricted due to potential negative impacts on hormonal health.
- 5. Methylisothiazolinone (MIT): This ingredient is restricted as it may cause allergic skin reactions.

Triclosan: As an antibacterial ingredient in cosmetic products, Triclosan is restricted because it can cause bacterial resistance.

CONCLUSION

In general, packaging labeling requirements in various countries have similarities such as product name, composition, country of manufacture, full name and address of the manufacturer, instructions for use, expiration date, and manufacturing batch number, as well as warnings of special precautions that must be observed when using the product. Each country's export and import procedures also have their country policies. Some countries impose additional requirements related to the use of certain prohibited ingredients. To market cosmetic products internationally, manufacturers must understand the safety regulatory requirements applicable in their target countries and ensure products have undergone appropriate safety testing before being introduced to the market. Stricter regulations will ensure that cosmetic products are tested and meet the set standards to protect consumers from the dangers of illegal cosmetics circulation. Good consumer protection can ensure the safety and quality of their products and increase consumer confidence in the cosmetics market. Therefore, the government's role in providing adequate consumer protection is crucial in supporting the sustainable growth of the beauty industry.

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