



## Legal Protection for Consumers Who Use Thematic Cosmetics in Indonesia

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**Abstract** - Thematic Cosmetics are traditional cosmetics made from natural ingredients and are identical to a region and are in demand by the community. Due to this development, some communities try to make and sell thematic cosmetics without paying attention to BPOM permits. Therefore, this study aims to determine the legal protection for consumers who use thematic cosmetics, to find out the systematic registration of thematic cosmetics to obtain BPOM permits, and to find out the supervision of thematic cosmetics that applies in Indonesia. This study uses the Normative Juridical method, this literature study is a series of activities related to the stages of collecting literature data, understanding then recording, and processing research materials. Each province in Indonesia has a Food and Drug Supervisory Agency which is tasked with supervision, law enforcement, and guidance, BPOM supervises the quality of cosmetics starting from the registration and assessment stages, with the latest regulation, namely BPOM Regulation No. 21 of 2022 concerning Procedures for Submitting Cosmetic Notifications replacing Regulation No. 12 of 2020 which is considered no longer appropriate. The Food and Drug Supervisory Agency has the authority to supervise the circulation of each product and destruction of products that do not meet the requirements. Create standards and requirements related to product quality, safety, and benefits as well as inspection of production and distribution facilities and technical guidelines for laboratory assessment and testing.

**Keywords:** Illegal, Izin BPOM, Cosmetic Thematic

### I. INTRODUCTION

"Kosmetikos", derived from the Greek, means "skill of merias". Cosmetics are defined by the Regulation of the Head of BPOM RI Number 23 of 2019 as materials/goods used outside the body, namely, lips, skin, nails, hair and the outside of the genitals, organs, teeth and mucous membranes of the mouth, with the main purpose of being a cleaner; Deodorizer; changing appearance; Eliminate odor from the body or provide protection and keep the body fit.

Thematic cosmetics are a type of makeup with high attractiveness, produced using natural raw materials and representing a region. This is evident in various places such as Balinese cosmetics (scrubs and spas) and Javanese (palace traditional treatments) as well as Banjarmasin cold powder that comes with their respective themes. This thematic cosmetic is in great demand by the Indonesian people because it uses local natural ingredients (Baharudin, andreas. Badan POM, 2024). UU No. 8 Tahun 1999 Pasal 8 ayat (3) dan UU No. 39 Tahun 2009 Pasal 106 ayat (1) is legal protection for consumers who use Thematic Cosmetics

Some factors that influence the development of traditional cosmetics include:

1. Cultural factors
  - a. Ethnobotany
  - b. Cultural and religious beliefs
  - c. Influence of social media
2. Economic Factors
  - a. Price and Promotion:
  - b. Microeconomic Conditions
  - c. Environmental Awareness
3. Social factors
  - a. Social Media Influence
  - b. Celebrity and Influencer Influence
  - c. Tripartite Influence Model

because of this development, some people try to make and sell thematic cosmetics without paying attention to BPOM permits. In fact, this permit is very important so that the product is officially registered and safe for consumers to use. Even though it uses natural ingredients that have good benefits, it still requires permission from BPOM. To obtain a BPOM permit, cosmetic sellers must go through several stages, namely the pre-assessment stage, assessment, sampling, notification submission, and filling in business entity data.

Therefore, this study aims to determine the legal protection for consumers who use Thematic Cosmetics (Beauty Products), to find out the procedures for registering thematic cosmetics to obtain BPOM permits, and to find out the supervision of thematic cosmetics that applies in Indonesia. Then also, this study will have benefits such as readers will be able to analyze a product before it is used, especially thematic cosmetics and readers can also find out how important it is for a product to be officially registered with BPOM.

## **II. METHOD**

This research uses a normative juridical method this is a research method that focuses on analyzing applicable legal rules and norms, both written such as laws and regulations, and unwritten such as legal principles and customs. This method is used to determine how an issue is regulated in law and whether these rules fulfill legal objectives, such as justice or the protection of individual rights. This literature study is a series of activities related to the stages of collecting library data, understanding it and then recording it, as well as processing research materials.

Literature Review: Aspects and Methods

1. Laws and Regulations: This includes legal documents issued by legislative and government bodies, such as the Health Law, government regulations regarding cosmetics, and special BPOM regulations regarding standards and product registration procedures.
2. Academic Articles: Research articles published in academic journals, both domestic and international, which discuss legal issues related to cosmetics and consumer protection. These articles often provide empirical data and critical analysis.

Database or Repository Used

1. Indonesia: Indonesian National Law Library Database:
  - Access to various regulations, laws and other legal literature.
  - Indonesian Law Journal: Collection of articles and research from universities and research institutions in Indonesia.
  - BPOM Official Site: Information regarding regulations and policies related to registration and supervision of cosmetic products.
2. International:
  - Google Scholar: Freely accessible academic articles.

Literature Selection Criteria

- 1) Relevance: Literature is selected based on its relation to the research topic, namely consumer protection in the context of cosmetic products and BPOM regulations. The

sources selected should cover relevant legal aspects, such as product registration obligations and consumer safety.

- 2) Recency: Only literature published in the last few years is used, except for basic documents or legal foundations that are still relevant. This is important to ensure the analysis is based on current laws and practices.
- 3) Authority: The sources selected come from authors or institutions recognized in the legal field, such as academics, legal experts and government agencies. Work published in peer-reviewed journals or by reputable publishers is also given priority to ensure the reliability and quality of the information.

#### Identify Relevant Sources

- a) Establishing Criteria: The initial stage involves determining criteria for selecting literature, such as relevance to the topic (consumer protection and cosmetics), recency (year of publication), and authority (trustworthiness of the source).
- b) Initial Search: Conducting initial searches in databases such as Google Scholar, as well as local sources such as the Indonesian National Law Library Database and the Indonesian Law Journal to find relevant literature.
- c) Source Selection: Filter search results based on predetermined criteria, prioritizing peer-reviewed journals, books from leading publishers, and official government documents.

#### Document Collection

- a) Access and Collect: Download or gain access to relevant statutes, regulations, academic articles, legal cases, and legal commentaries.
- b) Organizing: Arrange collected documents by category (e.g., laws, academic articles) to facilitate further analysis.

#### Process of Understanding and Taking Notes

##### 1. Content Analysis

- a. Reading and Understanding: Thoroughly read the documents that have been collected to understand their content and context, especially those related to consumer protection and cosmetic regulations.
- b. Focus on Specific Aspects: Highlights specific elements of the literature, such as legal provisions on registration of cosmetic products, safety standards, sanctions for violations, and legal interpretation in related cases.

##### 2. Note taking and synthesis

- a. Note Key Points: Note key points and important quotes from each document for use in analysis and writing.
- b. Framework and Tools: Uses a framework that includes topic categorization (e.g., BPOM regulations, consumer protection), as well as tools such as observation tables and concept maps to combine information from various sources.
- c. Identify Patterns and Gaps: Look for general patterns in the data collected as well as identify gaps in the literature that may require further research.

##### 3. Verification and Validation

- a. Information Verification: filter the accuracy of information by comparing different sources.
- b. Source Validation: Guarantees that the sources used are authoritative and trustworthy, taking into account the credibility of the author and publisher.

### **III. RESULT AND DISCUSSION**

#### Legal Protection for Thematic Cosmetics Consumers, Regulatory Regulations and Circulation

As a result of CCI (Citra Cendikia Indonesia), most of the use of cosmetics in Indonesia is increasing every year. In 2015, the national cosmetics market reached 8.3%, or equivalent to Rp 13.9 trillion, up from 12.8 trillion in 2014. An increase of 9.67% occurred from 2010 to 2015. A total of 195 people answered the questionnaire distributed online, with 187 women and 8 men. This percentage shows that the majority of cosmetic users are women. The majority of customers are between 20 and 26 years old (Putri, A., 2018)

The following is a table of presentations of total cosmetics that have received BPOM distribution permits from 2018-2023.

Table.1 data analysis of product

Year	Total Products	Detailed analysis
2018	1063	This year, few people know about thematic cosmetic products
2019	3637	This year saw an increase in consumers after learning about the benefits of thematic cosmetics
2020	4543	This is increasing because some products are becoming easier for consumers to obtain
2021	1250	This year it seems to have decreased because several new products have appeared to compete with thematic cosmetics
2022	1103	Experienced another decline because consumers started using cosmetic products from doctors
2023	9238	Starting to experience a rapid increase because cosmetics are easily available among consumers in various places

*Indonesian Food and Drug Control Agency*

Every cosmetic consumer has legal protections such as, consumer legal protections are as follows:

a. Legal Protection for Thematic Cosmetics Consumers

Table 2. Legal protection for Thematic Cosmetics consumers

UU No. 8 Year 1999 Article 8 paragraph (3)	UU No. 36 of 2009 Article 106 paragraph (1)
Business actors are prohibited from trading damaged, defective or used and contaminated pharmaceutical and food preparations, with or without providing complete and correct information" and has been in effect since April 20, 2000.	Pharmaceutical preparations and medical devices can only be circulated after obtaining a distribution permit. In accordance with the content of the article, any health product that does not have a distribution permit is an illegal product because it does not obtain a distribution permit from the Food and Drug Control Agency (BPOM) and does not comply with laws and regulations

*Elizabet Devi Permatasari. 2020. Legal Protection for Consumers Against Illegal Cosmetic Products.*

The content of the Consumer Protection Law discusses more about business actors than the protection of their own consumers. Due to the fact that, in general, consumer losses

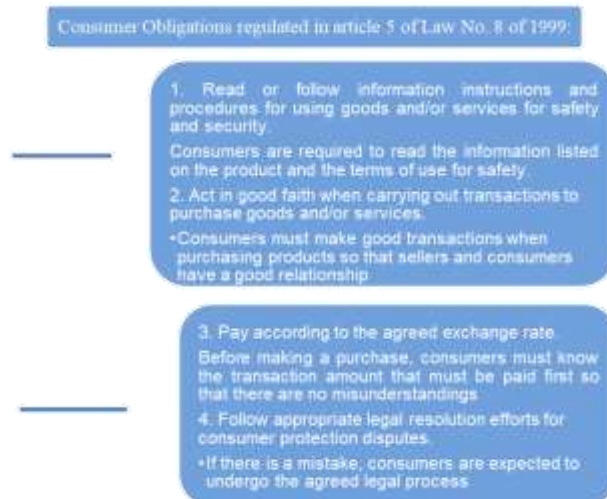
are the result of the seller's behavior, so it needs to be regulated so that consumers are not harmed. Consumer law and consumer protection law are two areas of law that are difficult to separate and differentiate their limits (Sari Htp et al., 2023)

The rights of consumers The rights of consumers are regulated in Article 4 of Law No.8 of 1999 Consumer Protection, as follows:



From the explanation table above, it can be seen that consumer rights are very useful and guarantee consumer comfort in using the thematic cosmetics used, so that consumers do not need to hesitate to use these products.

In addition to having Rights, consumers also have obligations regulated in Article 5 of Law No.8 of 1999 Consumer Protection, namely:



Rights and obligations are the basis for the relationship between commercial actors and consumers as stated in Article 4 (1) and (3) of Law No. 8 of 1999, one of the rights of consumers is:

1. The right to comfort, security and safety when using goods and/services;
2. The right to receive accurate, clear and truthful information about the condition and warranty of goods and/or services (Zai et al., 2021)

**b. Supervision regulations and their circulation**

In addition to consumer protection, regulations related to the supervision of the circulation of cosmetics include the following:

Table 3. Regulations related to supervision of the circulation of cosmetics

Regulations Related to Supervision of Cosmetics Circulation
1) The Head of the BPOM Agency has responsibility for the supervision of cosmetic products in accordance with Article 19 of the Regulation of the Minister of Health Number 63 of 2013 concerning Cosmetic Production Permits.
2) Every individual who is responsible for the inspection site by the supervisor has the right to refuse the inspection if the supervisor does not have an identification card or inspection warrant, in accordance with Article 20 of the Regulation of the Minister of Health Number 63 of 2013 concerning Cosmetic Production Permits.
3) Every cosmetic product in circulation must meet the standards of safety, benefits, quality, marking, and claims, and must be notified in accordance with Article 2 of the Decree of the Head of the Indonesian POM Agency Number HK.03.1.23.12.11.10052 of 2011 concerning Supervision of Production and Circulation of Cosmetics.
4) Supervision includes the inspection of cosmetic facilities and products in accordance with Article 3 of the Decree of the Head of the Indonesian POM Agency Number HK.03.1.23.12.11.10052 of 2011 concerning Supervision of Cosmetic Production and Circulation.
5) Supervision of cosmetic products involves aspects such as legality, safety, benefits, quality, marking, claims, promotion, and advertising according to Article 5 of the Decree
6) Inspections are carried out regularly to ensure the fulfillment of standards and requirements, and specifically to follow up on violations in accordance with Article 6 of the Decree of the Head of the Indonesian POM Agency Number HK.03.1.23.12.11.10052 of 2011 concerning Supervision of Cosmetic Production and Circulation.
7) In carrying out supervisory duties, the supervisory officer is authorized to inspect <ol style="list-style-type: none"><li>Any place suspected of being involved in the production, storage, transportation, and trade of cosmetics to take samples and examine everything related to those activities.</li><li>Examining documents or other records that are suspected to contain information about the production, storage, transportation, and trade of cosmetics, including the collection or excerpt of information from such documents.</li><li>Investigate the application of Good Manufacturing Practices (CPKB), as well as check the markings and claims listed on cosmetics.</li><li>Investigate promotions and advertisements related to cosmetics.</li><li>Taking samples for testing in the laboratory.</li></ol>
8) Monitoring the results of the recall and destruction of cosmetics that do not meet the requirements, in accordance with Article 8 of the Decree of the Head of the Indonesian POM Agency Number HK.03.1.23.12.11.10052 of 2011 concerning Supervision of Production and Circulation of Cosmetics.
9) If the results of the examination show that there is an alleged criminal act in the field of cosmetics, an investigation will be immediately carried out by investigators from the Food and Drug Supervisory Agency in accordance with Article 38 of the Decree of the Head of the Indonesian POM Agency Number HK.00.05.4.17.45 concerning Cosmetics.

*Fatma Riska Fitrianiingsih Dai, et al. 2019. Legal protection for consumers against the circulation of illegal cosmetics*

Producing/Distributing pharmaceutical preparations and/or medical devices that do not have a business license as intended in Article 197 Jo Article 106 paragraph (1) of Law of the Republic of Indonesia Number 36 of 2009 concerning Health as amended in Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation with the threat of imprisonment for a maximum of 15 (fifteen) years and a fine of a maximum of IDR 1 billion.

Second, namely producing or distributing pharmaceutical preparations that do not meet the standards and/or requirements for safety, efficacy or usefulness, and quality as intended in Article 196 Jo Article 95 paragraph (2) and paragraph (3) Republic of Indonesia Law Number 36 of 2009 concerning Health. This crime is punishable by a maximum imprisonment of 10 (ten) years and a maximum fine of IDR 1 billion.

Third, namely trading goods that do not meet or are not in accordance with the required standards and provisions of statutory regulations as intended in Article 62 paragraph (1) Jo Article 8 paragraph (1) letter a Republic of Indonesia Law Number 8 of 1999 concerning Consumer Protection. This crime is punishable by a maximum imprisonment of 5 (five) years or a maximum fine of Rp. 2 billion.

### **Thematic Cosmetic Registration Systematics to Obtain BPOM Permits**

The use of cosmetics aims to increase attractiveness, confidence and beautify oneself. Cosmetics available on the market are divided into two main categories based on the type of basic ingredients and the way they are processed:

- a. Traditional Cosmetics/Thematic Cosmetics are a type of cosmetics made from natural ingredients produced directly from fresh or dried ingredients, such as fruits and plants available around us.
- b. Modern cosmetics are cosmetics that are produced in factories or laboratories, where chemicals are added to extend their shelf life so that they do not spoil quickly (Fauzela, 2023)

Some of the regions in Indonesia that use natural cosmetics include: namely:

1. North Sumatra: The Batak tribe has a traditional treatment called oukup, which firms, brightens, and smoothes the skin through evaporation and fumigation techniques with a decoction of water infused with spices such as roots, lemongrass leaves, and pacoli.
2. Javanese: The traditional scrub known as ngadi saliro, popular among royal princesses, uses ingredients such as rice, kencur, turmeric, and jicama.
3. West Sumatra: The Minangkabau tribe has a steam bath ritual called batangeh, using spices such as lemongrass, pandanus, ylang ylang, betel, and cinnamon.
4. Bali: A traditional Balinese scrub, Herborist, is known to effectively remove dead skin cells, making the skin brighter, cleaner, smoother, and more moisturized, with a distinctive Balinese fragrance.
5. West Java: The Betawi tribe uses tangas oil to refresh and tighten the skin.
6. North Sulawesi: Minahasa Regency has a traditional spa called bakera, which uses natural ingredients such as suji leaves, balacai leaves, puring leaves, orange leaves, and cinnamon leaves (Monita, 2021)

The ingredients contained in cosmetics are regulated in the Regulation of the Head of the Indonesian POM Agency No. 23 of 2019, including materials that are allowed with restrictions and requirements for use, including dyes, preservatives, and sunscreen ingredients.

Every province in Indonesia has a Food and Drug Supervisory Center that is responsible for supervision, enforcement and coaching, this is due to the development of the cosmetics industry and business owners are required to comply with the rules (register their products with BPOM). Regulation, standardization, and certification of food and drug products is also the responsibility of BPOM (Febriani et al., 2022)



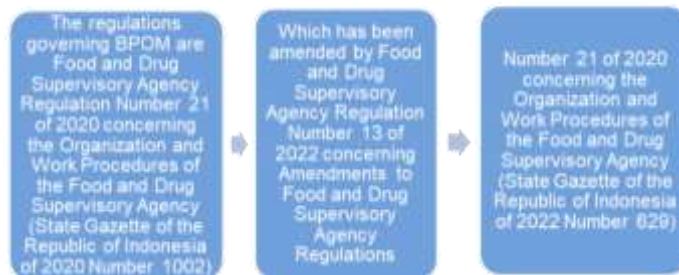


Chart 4. Regulations governing BPOM

BPOM supervises the quality of cosmetics from the registration and assessment stages, with the latest regulation being BPOM Regulation No. 21 of 2022 concerning Procedures for Submitting Cosmetic Notifications, replacing Regulation No. 12 of 2020 which is considered inappropriate.

a. Systematics of Thematic Cosmetics Registration

The thematic cosmetics registration system consists of two stages:

1. Pre-assessment stage
  - Lasts 10 working days,
  - Checking the completeness and authenticity of administrative and technical data on the registration form, as well as the authenticity of the documents included
2. Assessment stage
  - Lasts 30 working days,
  - Assess the quality, safety, and benefits of the product. For cosmetic products to enter the market, this is the first step that must be taken

After the pre-assessment and assessment stage, the supervision of cosmetic products on the market requires a sampling process for quality testing, with a sufficient method and number of samples to conduct thorough testing. BPOM also launched the BPOM Mobile application, which allows the public to check the quality and marketing status of cosmetic products online through *scan-barcodes* or cosmetic product numbers (R. N. Putri, 2022)

Sampling is a procedure in which a portion of a population is selected to represent it. The purpose of the sampling process is to obtain a suitable sample (sampling object) and be able to describe the population to be used for research (Basmatulhana et al., 2022)

The BPOM *mobile* application allows people to personally check all the goods used and consumed. The three functions of BPOM *mobile* are as follows:

1. Inspection of goods through *2D scan-barcode*,
2. Receive reports related to goods, and Provide up-to-date information on drug and food control (Nursaidr, 2019)



The submission of cosmetic notifications aims to register business entity data in the official BPOM account or submit administrative documents at the BPOM office. After the document verification is complete, the company uses the website to obtain an ID and password to submit a product notification.

Table 4. Notification submission process and how to fill in business entity data

Notification Submission Process	How to Fill in Business Entity Data
<ul style="list-style-type: none"><li>• Filling in the notification format on our site</li><li>• Receive a payment order (spb) through the system</li><li>• Get a notification number after document verification is complete</li><li>• BPOM provides a notification number within 14 working days, a sign that the product is in accordance with the provisions</li></ul>	<ul style="list-style-type: none"><li>• Applicant fills out the business entity registration form through the BPOM website</li><li>• The applicant can also go to the BPOM office to submit administrative documents in accordance with applicable regulations. After the document verification is complete, the applicant will receive a user ID and password to activate their account</li></ul>

Cosmetic companies can ensure that their products comply with applicable regulations and speed up the product notification process by following the registration and notification submission procedures that have been described (Hakim, 2022)

#### A. Thematic Cosmetics Licensing

Permits issued by the Government and BPOM are business licenses, production permits and import approvals;

- 1) Business License (IUI, TDI/SIUP): Granted by the Ministry of Industry or Regional Government, has the task of legality to start a business in the field of distributor, production, or trade
- 2) Production Permit: Based on Permenkes No. 1175/VIII/2010, granted by the Director General of Pharmaceuticals & Medical Devices of the Ministry of Health, overseeing the production of cosmetics to meet good cosmetic manufacturing practices (CPKB).
- 3) Distribution Permit: Based on the Regulation of the Head of BPOM No. Hk.00.05.1.23.3516, granted by BPOM, registering cosmetics so that products can be legally traded in Indonesia.
- 4) Import Approval: Based on Permenkes No. 14/2016, granted by the Ministry of Trade, businesses that bring in goods from abroad (additional goods), goods for market tests, and after-sales services are supervised with this permit (Fauzela, 2023)

#### Thematic Cosmetic Supervision Applicable in Indonesia

In ensuring the safety and quality of thematic cosmetics used by consumers, the Food and Drug Supervisory Agency has the authority to monitor the circulation of each product. This regulatory authority ensures that the public can confidently use thematic cosmetic products without worrying about potential dangers, such as ingredients that belong to the dangerous heavy metal class (mercury (Hg)/mercury). The use of thematic cosmetics that do not meet quality and safety standards can cause various harmful impacts on the skin, including the appearance of dark spots, irritation, allergies, brain and nervous system damage, as well as potential harm to the fetus and pregnant women. Like a Singaporean beauty blogger named

Bunbun experienced vomiting after consuming high doses at once and her whole body was filled with small spots of pus (Rahmawati et al., 2019)

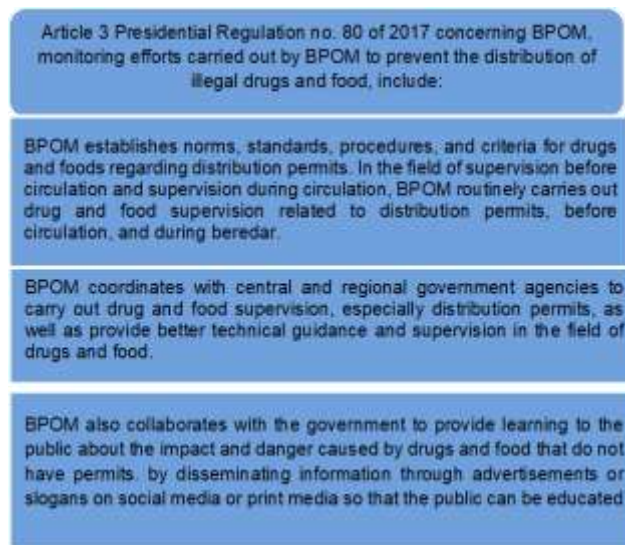


Chart 5. Article 3 of Presidential Regulation No. 80 of 2017  
(Zai et al., 2021)

Business owners have an important role in the circulation of cosmetics, where the Food and Drug Supervisory Agency increases security when cosmetic products will be distributed, including:

- 1) Registration, Assessment, and Quality and Safety Testing: Before circulating to the public, cosmetics must go through a process of registration, assessment, and testing of their quality and safety. Products with unsafe content will not obtain a registration number and will not be distributed in Indonesia.
- 2) Renewal and Inspection: Renewal and inspection are carried out on production and distribution methods, quality testing, and sampling.
- 3) Indonesian Cosmetic Codex Book: The Ministry of Health issues the Indonesian Cosmetic Codex Book to establish specifications and quality standards, which include descriptions and requirements for cosmetic ingredients
- 4) Improvement of Knowledge and Skills of the Workforce: Workers in the production and distribution of cosmetics need to improve their knowledge and skills in order to provide information about developments and progress in the field of cosmetics (Dai et al., 2019)

There are also Duties, Functions, and Authorities of the Food and Drug Supervisory Agency: Duties of BPOM:

- a) Evaluation of benefits, safety, quality, labeling, and laboratory analysis for drug distribution authorization, including traditional medicines, cosmetics, food, and medicinal ingredients.
- b) Local monitoring and supervision of manufacturing and distribution
- c) Laboratory sampling and testing
- d) Giving warnings to parties who have violated the stipulated provisions

Functions of BPOM :

As a supervisor, BPOM is responsible for eleven tasks, including policy formulation, policy implementation, procedure implementation, supervision implementation, coordination of supervision implementation, training, enforcement, goods management, supervision of the implementation of duties, and substance support related to drugs and food. According to

Presidential Decree Number 80 of 2017 concerning the Food and Drug Supervisory Agency, one of the eleven duties of BPOM is to conduct *premarket* (before distribution) *postmarket* (after distribution) supervision. *Premarket supervision* is carried out through licensing until the product is released to the market, starting from production permits to distribution permits, both for food and medicines, as well as thematic cosmetics. *Postmarket supervision* is carried out to ensure that industrial products are consistent and of high quality when the listed products are already available in the market.

Authority of BPOM:

- 1) Supervise the circulation and destruction of unqualified products. Create standards and requirements related to product quality, safety, and usefulness.
- 2) Inspection of production and distribution facilities and technical guidelines for laboratory assessment and testing (Dai et al., 2019)

#### IV. CONCLUSION

Based on the discussion above, several conclusions can be drawn, namely:

1. Thematic cosmetics are cosmetics that are safe to use in the community.
2. Thematic cosmetics are not only safe to use because they have good natural ingredients, the matic cosmetics also have BPOM permission.
3. The Food and Drug Supervisory Agency has the authority to monitor the distribution of each product, namely:
  - a. Supervise the distribution and destruction of products that do not meet the requirements.
  - b. Create standards and requirements related to product quality, safety and usability.
  - c. Inspection of production and distribution facilities as well as technical guidelines for laboratory assessment and testing.

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