

**SALES OF COSMETICS WITHOUT PERMISSION FROM
THE DRUG AND FOOD CONTROL AGENCY (BPOM) IN
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ABSTRACT

Cosmetics constitute a range of products utilized to enhance and maintain physical appearance. These products include make up, skincare, hair care, nail products, perfumes, and body care items. Cosmetics seem to have become a necessity for men and women to maintain their appearance. However, it is not uncommon to find that there is still a large number of cosmetics circulating that do not have permission from BPOM as the drug and food regulatory body, causing a lot of suspicion among the public. So special attention is needed regarding the distribution of cosmetics without permits based on statutory provisions. This research uses a normative juridical method, which is an approach to legal research that views law as a systematic structure of norms. So this research aims to see the extent to which legislation provides regulations regarding this problem. So it can be seen that the function and duties of BPOM as a drug and food regulatory agency must be able to be more optimal in carrying out its duties and functions. Considering its function, it can be a preventive measure in the circulation of unlicensed cosmetics among the public.

Keywords : Cosmetics; Permission; Health.

Journal History

Received	: April 26, 2024;
Reviewed	: May 30, 2024;
Accepted	: May 31, 2024;
Published	: May 31, 2024.

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INTRODUCTION

Development with the rapid rate of economic growth and lifestyle changes, along with advances in science and technology, demand for needs humans are increasing. Nowadays, cosmetics are starting to become a basic necessity especially for women. The definition of cosmetics is in accordance with the Regulation of the

ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

DOI: 10.30596/nomoi.v%vi%i.19375

Head of the Supervisory Agency RI Food and Drugs (BPOM) No. 23 of 2019 are the materials or preparations intended for use on external parts of the human body such as the epidermis, hair, nails, lips, etc external genital organs, or teeth and oral mucous membranes especially for cleaning, perfume, change appearance, and/or improve body odor or protect or look after body on good condition.

It is believed that the circulation and development of the beauty industry in Indonesia is quite rapid, so it has quite large potential for the market. In the current era of free trade, the flow of goods in and out has become smoother and is not hampered by a country's territorial boundaries. This is caused by weak supervision in the field of quality standardization of goods and product regulations, which results in many cosmetic products being distributed on the unregistered market and quality standards not being met, as well as the absence of distribution permits from the Food and Drug Supervisory Agency (BPOM).¹

The variety of cosmetic products circulating on the market is very diverse in terms of brands, types, function, as well as color and shape, so that often time give rise to confusion for consumers when choosing cosmetic products. According to Tranggono, cosmetics can be divided into: two categories based on their use on the skin: (1) skin care cosmetics (skin-care cosmetics), which aim for nurse, guard, and maintain condition skin; (2) make-up cosmetics (decorative or make up), which are used to beautify the face. Product Cosmetics have become an integral part of the daily routine, used by both women and men various age range.²

The large number of cosmetic products that have spread throughout society also makes it impossible for new problems to occur. So for carrying out the growth process of the business climate and all its developments, the Government and Regional Governments provide intellectual property rights to the products and designs of Micro, Small and Medium Enterprises in domestic and export business activities and encourage Micro, Small and Medium Enterprises to obtain certificate of intellectual property rights. The Regional Government fosters the business climate by establishing laws and regulations and policies covering aspects of funding, facilities and infrastructure, business information, partnerships, business licensing, partnership,

¹ Edtriana Meliza,, "Pelaksanaan Pengawasan Balai Besar Pengawasan Obat Dan Makanan (BPOM) Terhadap Peredaran Makanan Tanpa Izin Edar (TIE) Di Kota Pekanbaru Tahun 2012", *Jurnal Online Mahasiswa (JOM) Bidang Ilmu Sosial Dan Ilmu Politik*, (2014).

²Dwi Sukristiani, Hayatunnufus, dan Yuliana. "Pengetahuan Tentang Kosmetika Perawatan Kulit Wajah Dan Riasan Pada Mahasiswi Jurusan Kesejahteraan Keluarga Fakultas Teknik Universitas Negeri Padang.", *Journal of Home Economics and Tourism*, Vol. 7 No. 3 (2014). Pg. 2

ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

DOI: 10.30596/nomoi.v%vi%i.19375

business licensing, business opportunities, trade promotion, institutional support. SMEs become one of the important elements in the national economy. Such a position places the role of MSME as one of the pillars of developing a populist economic system as a manifestation of the national economic structure. Triggers the interest of parties who do not have the good faith to imitate the product which is then registered by the copycat which in the end the MSME can no longer use the product that has been registered by the copycat.³

Cosmetics now has become something need principal Which used every day Forcan maintain the appearance of both men and women. The need for products cosmetics the is opportunity big in sector business. Cosmetics No usedFor treat or prevent disease, so that cosmetics it's not drug. If There is cosmetics that are claimed to be able to treat/cure wounds, inflammation, infections or diseases other things and/or in its use it is inserted into the human body through injection, product the is a medicine and not a cosmetic.

As a consumer who uses cosmetic products, purchasing decisions are based on by Power pull product the. Expected that all product cosmetics Which used will improve appearance and beauty. However, the desire to look attractive with Cosmetic products are often not balanced by adequate understanding of the product the. As a result, sometimes use cosmetics can impact negative on skin. Cosmetics, be they facial skin care products or facial makeup cosmetics, have potential to have a positive or negative influence on the skin, depending on the ingredients used and way its processing.

Important For remembered that material Which used in product cosmetics must meet the criteria for safety, benefits and quality. Use of ingredients in products cosmetics are regulated in accordance with the Regulation of the Head of the Republic of Indonesia's Food and Drug Supervisory Agency Indonesia (BPOM RI) Number 23 of 2019. This regulation covers materials that may be used with certain restrictions and conditions, as described in Attachment I, Which covers substance active in product. Besides That, regulation This Also arrangepermitted ingredients as coloring agents (Appendix II), preservatives (Appendix III), sunscreen ingredients (Appendix IV), as well as ingredients that are prohibited from being used in cosmetic products (Attachment V).⁴

³ Eka N.A.M Sihombing, Kebijakan Afirmatif Bagi Usaha Mikro, Kecil, dan Menengah Di Bidang Kekayaan Intelektual (Affirmative Policy for Micro, Small, and Medium Enterprises in the Field of Intellectual Property), *Jurnal Rechtvinding*, Vol. 7, No. 3, December (2018).

⁴ Badan POM, "Mengenal Kosmetik Dan Peggunaannya", <https://bbpom-yogya.pom.go.id/705-judul-mengenal-kosmetik-dan-peggunaannya.html>, diakses tanggal 11 Februari 2024

By Because That, in formulation product cosmetics, there is a number material Which allowed with provision certain, at a time material Which forbidden used. Material-Materials included in the prohibited list are materials that are potentially dangerous to health humans, such as certain textile dyes (e.g., Rhodamine B, K3 red, metanil yellow), mercury, sour retinoic, And ingredients other Which forbidden its use in productcosmetics.

Based on this introduction, several formulations in this article begin from the negative impact of selling cosmetic products without BPOM permission, the consequences for cosmetic products sold without BPOM permission, and criminal sanctions for someone who sells them cosmetic products not permitted by BPOM. The purpose of this writing is to provide knowledge and insight to writers and readers about how important it is to choose cosmetic products that already have permission from BPOM. Apart from that, this research also aims For identify And analyze factors reason widespread product cosmetics without permission official in Indonesia as well as For analyze strategy enforcement law toproduct cosmetics that do not meet condition official permission.

METHOD

The research method used in this writing uses research methods normative juridical. This research method is the research method used to study a legal issue or problem by focusing on aspects of written law or norms law Which applies. Method This is approach in study law Which looking law as A structure systematic from norms. Approach This covers assessment to the principles, norms, and rules.⁵

In general, research that uses a normative legal approach aims to examine legal principles, legal systematization, and legal consistency. Method This normative juridical research leads to an analysis of the legal norms contained in statutory regulations and court decisions, as well as applicable legal norms in society. Apart from that, this research also pays attention to the level of relationship between one another rule with other rules in a way hierarchy.⁶

DISCUSSION

Impact Negative From Sale Product Cosmetics Without Permission BPOM

Public health is one of the main foundations of development efforts a country. Therefore, the need for health becomes very crucial, so make task Which very

⁵ Mukti Fajar dan Yulianto Achmad, *Dualisme Penelitian Hukum Normatif dan Empiris*, (Yogyakarta : Pustaka Fajar, 2017). p. 33

⁶ Bambang Sunggono, *Metode Penelitian Hukum*, (Jakarta : PT. Raja Grafindo, 2007). P.38

ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

DOI: 10.30596/nomoi.v%vi%i.19375

important for government For always ensure well-being its people. Health Also is A Right Asasi Man (HAM) Which must confirmed through implementation various program health in Indonesia, as mandated in charter opening Constitution Base Country Republic of Indonesia Year 1945.⁷

In in fact, Still there is a number of problem Which violate right public welfare, including those related to the legality of cosmetic products. Law Invite Number 36 Year 2009 about Health, together with regulation Which issued by the Cosmetic and Food Supervisory Agency (BPOM), establishing procedures cosmetics trade which includes licensing requirements from BPOM. However, there are still many cosmetic products circulating without obtaining official permission. Presence of cosmetic products without this permission is a problem that needs to be addressed immediately because it can cause losses for consumers, both financially and in terms of physical health consequences use illegal cosmetic products.

BPOM as a body that has supervision over a product should be able to carry out its functions as it should. BPOM Supervision Function Article 3 paragraph (1) Presidential Regulation Number 80 of 2017 In carrying out its duties of drug and food supervision, BPOM carries out the following functions:⁸

1. *Preparation of national policies in the field of drug and food control*
2. *Implementation of national policies in the field of drug control and*
3. *Preparation and determination of norms, standards, procedures and criteria in the field of Supervision Before Circulation and Supervision During Circulation*
4. *Implementation of Supervision Before Circulation and Supervision During Circulation*
5. *Coordination of the implementation of drug and food supervision with central and regional government agencies*
6. *Providing technical guidance and supervision in the field of drug and food control*
7. *Implementation of action against violations of statutory provisions in the field of drug and food control; h. Coordinating the implementation of tasks, coaching and providing administrative support to all organizational elements within the BPOM environment*

⁷ Desak Ayu Made Sintya Sattvika Putridan Ananda Chrisna D. Panjaitan, *Pertanggung jawaban Pidana Industri Farmasi Dan BPOM Terkait Pencemaran Obat Cair Dalam Hukum Kesehatan*, Vol. 17, No.1, Jurnal Yustitia (2023). Pg. 83

⁸ Peraturan Presiden Republik Indonesia Nomor 80 Tahun 2017 Tentang Badan Pengawasan Obat Dan Makanan.

ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

DOI: 10.30596/nomoi.v%vi%i.19375

8. *Management of state property/wealth which is the responsibility of BPOM*
9. *Supervision of the implementation of tasks within BPOM; Implementation of substantive support to all organizational elements within BPOM.*

And in carrying out this supervisory function, BPOM has the authority to implement and regulate supervision as regulated in article 4 of the Food and Drug Supervisory Agency Regulation Number 26 of 2017 concerning the Organization and Work Procedures of the Food and Drug Supervisory Agency:⁹

1. issue product distribution permits and certificates in accordance with standards and requirements for safety, efficacy/benefits, and quality, as well as drug and food testing in accordance with statutory provisions
2. carry out intelligence and investigations in the field of drug and food control in accordance with statutory provisions; And
3. Imposing administrative sanctions in accordance with statutory provisions.

The large number of cosmetic products circulating without official permission has caused losses both in material and immaterial terms for society. Therefore, it is necessary legal protection measures to protect consumers who have suffered loss as a result of use cosmetic products who does not own official permission.

A cosmetic that is said to be illegal is a cosmetic that does not have a distribution permit from the Food and Drug Supervisory Agency, whether made in Indonesia or from abroad and does not comply with the provisions of quality, safety and usefulness requirements and can be detrimental to the public. Meanwhile, legal cosmetics are cosmetics that meet the provisions of the Food and Drug Supervisory Agency, namely:¹⁰

A. Packaging

Cosmetic packaging must include label/marketing containing correct and complete information, including the name of the cosmetic, use, method of use, composition, name and country of producer, name and address of the applicant for notification, batch number, content size or. net weight, expiration date, warning/caution, and notification number.

B. Marketing Permit notification for cosmetics.

C. Expired.

⁹ Anggia, Rubby Permata, Syafril Syafril, and Z. Z. (2020). Pengawasan bpom dalam peredaran obat tradisional ilegal di kota padang. Diss. Universitas Bung Hatta.

¹⁰ Bahmid, Junindra Martua, and A. A. Peranan Badan Pengawas Obat Dan Makanan Dalam Memberikan Perlindungan Studi Di Kantor Cabang Badan Pengawas Obat Dan Makanan Badan Pengawas Obat Makanan (BPOM) Tanjung balai. *De Lega Lata: Jurnal Ilmu Hukum* (2020).

ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

DOI: 10.30596/nomoi.v%vi%i.19375

In article 2 of the decision of the Head of the Food and Drug Supervisory Agency of the Republic of Indonesia Number HK.00.05.4.1745 concerning cosmetics, it is stated that cosmetics distributed must meet the following requirements:

- a) Use materials that meet quality standards and requirements as well as other specified requirements.
- b) Produced using good cosmetic manufacturing methods.
- c) Registered with and obtained a distribution permit from the Food and Drug Supervisory Agency

Material losses can be financial losses, while immaterial losses can be includes feelings of disappointment, pain, or trauma experienced by the victim. Besides harm consumer, problem the Also potential harm country in a way whole. Case spread product cosmetics without permission official can hinder economic growth and lower investment levels, which in turn has an impact on capital inflows to the country. Therefore, solving this problem is very important important. By resolving this issue, consumers will feel protected and they can get compensation for the losses they experience. Consumers will too feel more believe self And comfortable If product Which they use has official certified and have permission circulate.¹¹

Consequence To Product Cosmetics Which For sale Without Permission BPOM

A distribution permit is a form of approval for food or cosmetic registration issued by BPOM so that product the in a way legitimate can circulated in region Indonesia. All cosmetic products that will be sold in Indonesia, whether originating fromfrom within the country or imported from abroad must go through registration for get number permission circulate Which issued BPOM. Where for BPOM number This registration is useful for monitoring products circulating on the market, so that if happen something problem will easy explored Who the culprit.¹²

BPOM has responsibility regarding the distribution of food and medicine in society through its role as an institution that controls both the government and the governmentnon-governmental organizations in carrying out supervisory functions. The state has a responsibility For ensure comfort And security product cosmetics

¹¹ Larashati Putri dan Moch Najib Imanullah. Perlindungan Konsumen Terhadap Produk Kosmetik Tanpa Izin Edar Dari Badan Pengawas Obat dan Makanan (BPOM). *Proceeding of Conference on Law and Social Studies*, Vol. 4. No. 1, (2023). Pg. 3

¹² Rezky Nur Amelia, Peran Balai Besar Pengawas Obat dan Makanan (BBPOM) Dalam Pengawasan Kosmetik Tanpa Izin Edar di Kota Makassar, (<http://eprints.unm.ac.id/10582/1/Jurnal.pdf>, diakses 11 Februari 2024).

ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

DOI: 10.30596/nomoi.v%vi%i.19375

Which circulating so that public protected from potency risk related health. By Because That, product cosmetics that do not meet the requirements in terms of usability, safety and quality must be prevented so that it doesn't circulate.

When consumer buy product cosmetics from perpetrator business, That means happen Transaction. This is in accordance with Article 1457 of the Civil Code which defines buying and selling as an agreement in which one party promises to provide goods, temporarily the other party promises to pay the agreed price. At the time of this agreement occurs, the parties involved have bound themselves, and this has legal consequences, in where party who violates agreement can be action taken law.

Business actors have an obligation to protect consumers from losses. They must provide honest, clear and accurate information about the products being sold, as well give instruction use Which Correct. Inclusion label on product Also required so that consumer can make decision Which appropriate about use product. If product cosmetics cause effect side, consumer entitled For file a complaint and give their views. The product being sold must also be fulfil standard quality Which has set For guard quality And security product.

The obligations of business actors, as stated in Article 7 letter a, aim to: prevent treatment Which No fair or harm consumer. Wrong One sign goodA business actor's intention is to use official channels and include a number registration from BPOM.

Although cosmetics No consumed like food or drug, ingredients Which used in making cosmetics must meet quality and safety standards. This matter important because the ingredients used in cosmetics can affect health skin and body as a whole. Therefore, it is important to ensure use The ingredients have been tested and are safe for the skin, as non-compliance may result damage on skin And even impact on organ vital And hormone in body.¹³

Efforts carried out by BPOM against business actors who violate marketing authorization standardscan implemented through a number of method that is:

Administratively, the initial action taken was to issue a warning letter to business actors by BPOM Officials. If the warning letter is not heeded, then will given letter warning hard. BPOM Also own authority For unplug permission in a way direct

¹³ Haqkiki Bintang Pratama, Zainudin Hasan, Adelya Putri Utami, Figo Putra Ranenda, *Akibat Hukum Penyalahgunaan Pemakaian Kosmetik Berbahan Kimia Dengan Edar Palsu Dan Tidak Mencantumkan Nomor Badan Pengawas Obat Dan Makanan (BPOM) (Studi di Pasar Simpung Bandar Lampung)*, Vol. 1, No. 2, (2023).. Pg. 140-152

ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

DOI: 10.30596/nomoi.v%vi%i.19375

If permission the issued by BPOM. If permission issued by institution other, BPOM entitled give letter recommendation Forrevocation or suspension of permits to the relevant agency that issued the permit. Action administrative final Which can done is closing business Which violate marketing authorization standards

- a. Legally, if a business actor has been subject to sanctions of destruction or confiscation but still don't pay attention, court proceedings will be carried out. The court will determine whether the business actor has an element of intent or unintentional action. Sanctions applied can be in the form of fines, probation, or imprisonment, which adjusted to the applicable law according to the type of violation done.

Administrative efforts as stated above are listed in article 54 number (2) Law of the Republic of Indonesia Number 7 of 1996 concerning Food with fines the highest is IDR 50,000,000 (fifty million rupiah); and Revocation of permits production or business license.¹⁴

Sanski Criminal For Somebody Which Sell Product Cosmetics No Allow BPOM

In the context of criminal liability, the first thing must be considered is the existence of a criminal act. Rules regarding the sale of cosmetics without a license BPOM is regulated in Law Number 36 of 2009 concerning Health ("UU 36/2009"). The conditions for cosmetics to be sold freely are regulated in Article 106, which written that :

- "(1) Pharmaceutical preparations and medical devices can only be distributed after obtaining permission circulate.*
- (2) Tagging And information preparation pharmacy And tool health must fulfil condition objectivity and completeness as well No misleading.*
- (3) Government authorized unplug permission circulate And instruct withdrawal from distribution of pharmaceutical preparations and medical devices that have obtained a distribution permit, which then proven not to meet quality and/or safety requirements and/or usefulness, can confiscated And annihilated in accordance with provision regulation legislation."*

That criminal sanctions against sellers of cosmetics without BPOM permission are more regulated carry on in Article 197 of Law 36/2009, which is written :

¹⁴ Ni Kadek Diah Sri Pratiwi, Made Nurmawati, Perlindungan Hukum Bagi Konsumen Terhadap Produk Kosmetik Import Tanpa Izin Edar Yang Dijual Secara Online., *Kertha Semaya: Journal Ilmu Hukum*, Vol. 7, No. 5 (2019). Pg. 12

ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

DOI: 10.30596/nomoi.v%vi%i.19375

“ Everyone who intentionally produces or distributes pharmaceutical preparations and/or medical devices that do not have an esar permit as intended in Article 106 paragraph (1) is punishable by imprisonment for a maximum of 15 (fifteen) years and a maximum fine Rp. 1,500,000,000.00 (one billion five hundred million rupiah). ”

So based on the description above it can be concluded that based on Article 106 of the Law 36/2009 that cosmetics must obtain a distribution permit from BPOM that meets all requirements standard completeness And objectivity. Penalty to they Which violate is withdrawal from circulation and imprisonment of fifteen years and a maximum fine of one billion five hundred million rupiah.

From a health law perspective, manufacturers and sellers who sell cosmetics do not BPOM is very firmly regulated in Law No. 36 of 2009 concerning Health (Health Law). In the Health Law, cosmetics are included in the type of preparation pharmacy. And in Article 98 paragraph (1), pharmaceutical preparations (including cosmetics) must be safe, Efficacious/useful, high quality and affordable. Also stated in Article 105 paragraph (2), producing cosmetics must meet the standards and requirements determined by Government.

Meanwhile, according to Article 106 paragraph (1), cosmetics must have a distribution permit before traded. The goal is For protect public from product cosmetics Which dangerous. So from That, produce And sell cosmetics Which No get certificate from BPOM is clear is a violation law.

Penalty for Which violate provision the Enough heavy. Producer or seller cosmetics Which No fulfil standard security, efficacy And quality can imprisoned 10 year and fined 1 billion rupiah (Article 196 of the Health Law). While the manufacturer or Cosmetics sellers who do not have a distribution permit can be jailed for 15 years and fined 1.5 Billion (Article 197 Health Law).¹⁵

CONCLUSION

As a smart consumer in choosing cosmetic products that are safe, useful, And quality, consumer can follow a number of step important. First, do inspection with method CLICK, Which is abbreviation from Packaging (ensure packaging in condition Good), Label (inspect information on label Which clear, complete, And No misleading), Permission circulate (ensure There is permission circulate from BPOM), And Expired (inspect expiration date).

¹⁵ *Jerat Hukum Bagi Produsen Kosmetik Tanpa Izin Edar BPOM*, (<https://patenku.id/jerat-hukum-bagi-produsen-kosmetik-tanpa-izin-edar-bpom/> diakses tanggal 12 Februari 2023)

ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

DOI: 10.30596/nomoi.v%vi%i.19375

In use product cosmetics, There is a number of matter Which need considered. Carefully read the information regarding use, descriptions and warnings listed on the packaging. Pay attention to physical or chemical changes in the product, such as color changes, smell, or consistency. Always use a clean cosmetic applicator, avoid using product cosmetics owned by person other, And No mix or dilute product withoutclear instructions. In addition, cosmetic products intended for the eyes are only permitted used in the eye area. If the consumer experiences a rash, redness, or swelling of the skin after using cosmetic products, immediately stop using the product and consult with a doctor.

For avoid risk And impact negative This, consumer recommended For always check the BPOM permit on the cosmetic products they want to buy. BPOM has a list product Which has get permission, And This Can become guide Which Good. Besides That, Be wary of prices that are too cheap and offers of cosmetic products from sources that are notclear.

There is a number of tips Which can help consumer in choose product cosmetics. First, always choose products that suit your skin type and condition. Avoid being tempted by Exaggerated claims in tempting advertising and promotions. Buy cosmetic products only from place official or shop on line official Which own ratings Good. Important Also For understand that cosmetic products that should only be used by medical personnel are not can sold online on line.

Let's be smart and wise consumers together in choosing use product cosmetics, so that We can reach results Which satisfying And guard our skin health.

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ISSN (Print) 2723-3413 - ISSN (Online) 2722-3663

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