



## LEGAL IMPACT ON SKINCARE BRAND OWNERS WHO VIOLATE BPOM REGULATIONS

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### ABSTRACT

*This research analyzes the legal impact on skincare brand owners who violate BPOM regulations. The focus of the research is on legal sanctions applied to skincare brand owners who do not meet product safety and quality standards. The results show that skincare brand owners who violate BPOM regulations can be subject to administrative, criminal, and civil sanctions. This research aims to provide a better understanding of the legal consequences for skincare brand owners who violate BPOM regulations. In addition, this research uses a normative juridical approach by examining applicable laws and regulations, such as Law Number 36 of 2009 concerning Health, Law Number 8 of 1999 concerning Consumer Protection, and BPOM regulations related to the circulation of cosmetic products. Secondary data from court decisions, regulations, and legal literature are also analyzed to strengthen the study. With this approach, the research is able to systematically map the forms of legal liability that must be faced by skincare brand owners who violate the provisions. The findings of this study emphasize the importance of skincare manufacturers' compliance with BPOM regulations as a form of protection for consumers and public health. Violations of regulations not only have implications for consumer losses, but can also damage brand reputation and cause financial losses due to lawsuits. Therefore*

**Keywords:** Legal Impact, Skincare Brand Owners, BPOM Regulation, Legal Sanctions

## 1. INTRODUCTION

The skincare industry in Indonesia has grown rapidly in recent years, with many products being offered to consumers. However, this development is also accompanied by increasing cases of regulatory violations by some skincare brand owners. The Food and Drug Supervisory Agency (BPOM) as a food and drug safety supervisory agency, has established various regulations to ensure the safety and quality of skincare products circulating in the market. Unfortunately, there are still many cases of regulatory violations committed by skincare brand owners, such as the use of hazardous ingredients, inappropriate product labeling, and unproven product claims. These violations can endanger consumer health and damage public trust in the skincare industry.

Therefore, it is necessary to analyze the legal impact on skincare brand owners who violate BPOM regulations. This research aims to provide a better understanding of the legal consequences for skincare brand owners who violate BPOM regulations, as well as to increase awareness and compliance of the skincare industry with applicable regulations.

In the legal context, violations of BPOM regulations by skincare brand owners do not only affect administrative aspects, but can also have criminal and civil consequences. Law Number 36 of 2009 concerning Health, Law Number 8 of 1999 concerning Consumer Protection, as well as other provisions relating to the safety of cosmetic products, provide a legal basis for the government to take action against violators. Sanctions can include revocation of distribution licenses, administrative fines, and imprisonment if violations are proven to seriously endanger public health.

In addition, non-compliance with BPOM regulations also has the potential to lead to lawsuits from consumers who feel harmed. In some cases, consumers can file claims for compensation for physical, psychological, and financial losses they experience due to the use of skincare products that do not meet safety standards. This emphasizes the importance of skincare brand owners to understand and comply with every provision stipulated in BPOM regulations as a form of legal responsibility as well as business ethics.

Therefore, this research is not only relevant from an academic point of view, but also has practical significance for business actors in the skincare industry. With a comprehensive understanding of the legal impact of violating BPOM regulations, it is hoped that skincare brand owners will be more careful in producing and marketing their products, and be able to build consumer confidence in a sustainable manner. This research also makes an important contribution to strengthening the system of supervision and law enforcement in the field of cosmetic product safety in Indonesia.

## RESEARCH METHODE

This research method uses normative legal research methods. The approaches used include a statutory approach, which involves examining all laws and regulations relevant to the legal issues being studied. Second, a case approach is applied by analyzing legal cases that are relevant to the research problem and have resulted in final and binding court decisions. Third, a conceptual approach is used, which is based on legal doctrines and scientific views that have developed in the discipline of law. The legal materials used in this research consist of primary legal materials, including laws and court decisions, and secondary legal materials, such as scientific journals, legal textbooks, and other relevant legal literature. The collection of legal materials was done through a literature study, where primary and secondary sources were systematically collected. These materials were then critically screened by identifying and retaining only those that were relevant, credible, and valid, ensuring that the discussion was supported by authoritative legal sources.

## **2. RESULT AND ANALYSIS**

### **A. Types of Legal Sanctions That Can Be Applied Against Skincare Brand Owners Who Violate BPOM**

In the realm of violations of the Food and Drug Administration (BPOM) regulations in Indonesia, skincare brand owners can be subject to various forms of legal sanctions.

The first sanction that can be applied is administrative sanctions, which are actions from BPOM against non-criminal violations. The form can be in the form of revocation of distribution permits, which means that the product is prohibited from being marketed again. In addition, BPOM can also impose administrative fines, the amount of which depends on the level of violation. An official warning can also be issued, demanding that the brand owner make corrections within a certain time. The amount of administrative fines imposed can vary according to the level of violation, which is between IDR 1,000,000 to IDR 500,000,000 for minor to medium violations, and more than IDR 500,000,000 if the violation is considered severe or poses a risk to public health. Other factors that affect the amount of the fine are the frequency of the violation, the level of impact on consumers, and the corrective measures that have been taken. Therefore, it is highly recommended to always refer to the latest regulations or contact BPOM for accurate information.

In addition to administrative aspects, brand owners can also be sanctioned in the civil realm. This sanction focuses more on compensation to consumers who are harmed. If skincare products are proven not to meet safety or quality standards, consumers have the right to claim compensation. In this case, civil sanctions also include the obligation for manufacturers to recall unqualified products and refund consumers. This sanction aims to provide protection to consumers and recover losses experienced. Damage claims cover both physical impacts and financial losses. Brand owners must also accept back products that are proven to be dangerous or defective and refund the money in a transparent manner. If disputes arise, consumers can take legal action through the courts. The court will examine the evidence and determine whether the manufacturer is liable for the losses suffered by consumers. In addition to individuals, companies as legal entities may also be subject to civil sanctions, which reinforces collective responsibility in maintaining product quality. Reputational impact is also a significant consequence of civil sanctions, as information about lawsuits or compensation can tarnish the company's image in the public eye. This reputational damage has the potential to reduce consumer confidence and disrupt business sustainability.

Civil sanctions also act as a means of education for the public, especially consumers, so that they understand their rights to the products they consume. With this understanding, consumers will be more active in reporting violations found. This encourages business actors to increase responsibility for their products to avoid legal risks. Furthermore, civil sanctions reflect corporate social obligations. Through the fulfillment of compensation and willingness to accept product returns, brand owners demonstrate a commitment to consumer safety and welfare. This strengthens the relationship between producers and consumers and raises awareness of the importance of compliance with applicable regulations.

The next type of sanction is criminal sanctions, which are applied to serious violations such as producing or distributing products without a distribution permit from BPOM. This sanction is applied as a form of strict law enforcement and aims to provide a deterrent effect to industry players. Serious violations of this kind can include the use of hazardous materials or those that have not been officially registered. Consequently, the

offender may be subject to imprisonment, which varies depending on the severity of the offense. In certain cases, offenders may be sentenced to prison terms lasting from a few years to more than a decade. In addition to prison sentences, high fines may also be imposed. The purpose of these large fines is to put pressure on brand owners to comply with applicable regulations and not endanger consumers (Shidarta, 2000).

It should be emphasized that criminal sanctions do not only apply to individuals, but can also target corporations as legal subjects. If the company is proven to have violated the regulation, the business entity may be subject to sanctions, including large fines to restrictions on business activities. The process of enforcing criminal sanctions involves investigations from BPOM and related law enforcement agencies. Once sufficient evidence is found, the case will be processed in court to obtain a valid legal decision. The deterrent effect of criminal sanctions is expected not only to affect direct violators, but also as a warning signal to other business actors not to commit similar violations. Thus, the integrity of the skincare industry can be maintained and public confidence in the product increased. The application of criminal sanctions is also an important part of consumer protection efforts. Consistent law enforcement against dangerous violations helps increase the public's sense of security in skincare products on the market.

In addition to formal sanctions, business actors also face social sanctions that are no less impactful. This sanction is in the form of pressure from the public in the form of criticism or negative influence on brand reputation. Mass media, both print and digital, can quickly disseminate information about violations that occur. A tarnished reputation due to negative publicity can reduce the level of consumer confidence and have a direct impact on business performance. In the digital era, where information spreads very quickly, reputation recovery becomes very difficult.

To prevent recurrence of violations, NA-DFC can also increase supervision of previously violated brands. This can involve periodic inspections, production monitoring, and distribution evaluation. The purpose of this tightened supervision is to ensure that all products meet applicable safety standards and minimize risks to consumers. In addition to supervision, business actors are also required to carry out corrective actions as part of the sanctions. These improvements may include improving production processes, training employees on safety procedures, or improving product labeling. All of these actions must be completed within a certain time limit and reported to BPOM for further evaluation.

These various forms of sanctions will automatically cause financial losses for brand owners. Apart from being fined and having to pay compensation, businesses also need to allocate additional funds to run improvement programs, training, and internal audits. This financial burden can reduce profit margins and even threaten business sustainability if not anticipated from the start. Not only the impact on the company, regulatory violations can also cause damage to the environment. Skincare products that contain dangerous and untested substances can pollute the ecosystem, especially if not managed properly. Therefore, BPOM bears the responsibility to ensure that products in circulation are safe for humans while not harming the surrounding nature.

As part of the prevention strategy, BPOM also has an important role in educating industry players on the importance of compliance with legal provisions. Through training, seminars, and socialization of regulations, it is expected that brand owners can understand the risks arising from violations and the importance of maintaining product quality. This step aims to build legal awareness and business ethics in the skincare industry. With this education, business actors will be more aware of their legal obligations and strive to create safe and compliant products. Understanding the various types of sanctions is expected to

motivate brand owners to be more disciplined in running their business, and committed to consumer safety and industry sustainability. Therefore, compliance with regulations imposed by BPOM allows skincare industry players to avoid various forms of legal sanctions, while playing an active role in building a business environment that is integrity, safe, and oriented towards social responsibility towards consumers and environmental sustainability in a sustainable manner.

## **B. The Law Enforcement Process Against Skincare Brand Owners Who Violate BPOM Regulations**

### **a. BPOM's Crucial Role in Supervising the Skincare Industry**

The Food and Drug Administration (BPOM) plays a central role in supervising the circulation of skincare products in Indonesia, a task that is very important to protect the health and safety of consumers. This oversight covers the entire product lifecycle, from the raw materials used, the production process, to the labeling and claims made by manufacturers. The regulations set by BPOM aim to ensure that every skincare product on the market meets the established safety, quality, and efficacy standards. Violations of these regulations not only harm consumers financially, but can also endanger their health, causing skin irritation, allergic reactions, and even more serious long-term effects. Therefore, BPOM has the authority to take enforcement action against brand owners who violate the regulations, ranging from warnings to criminal action. The effectiveness of BPOM's supervision relies heavily on cooperation between the government, industry players, and consumers. Smart and proactive consumers can report products that are suspicious or cause adverse side effects, thus helping BPOM to identify and take action against violations. In addition, continuous education to the public about the importance of choosing safe and registered skincare products is also an important part of consumer protection efforts (Law Number 36 of 2009 concerning Health).

### **b. Various Violations of BPOM Regulations in the Skincare Industry**

Violations of BPOM regulations in the skincare industry can vary, ranging from minor violations to serious violations that have the potential to endanger public health. One of the most frequent violations is the use of hazardous ingredients prohibited by BPOM, such as mercury, hydroquinone, and retinoic acid in inappropriate levels. These ingredients are often used illegally because they provide quick whitening or acne clearing effects, but have very dangerous side effects, including kidney damage, nerve disorders, and skin cancer. Another common violation is the production and sale of skincare products without a distribution permit from BPOM. A distribution permit is proof that the product has been evaluated and meets established safety and quality standards. Products that do not have a distribution permit are often not guaranteed to be safe and may contain undetectable hazardous ingredients. In addition, product claims that do not match scientific evidence are also a frequent violation (Law No. 8/1999 on Consumer Protection). Manufacturers often make exaggerated or misleading claims about the benefits of their products, unsupported by valid scientific data. This can mislead consumers and lead them to purchase ineffective or even harmful products. Incomplete or misleading labeling is also a violation to watch out for.

### **c. Law Enforcement Mechanism by BPOM against Violators**

The law enforcement process by BPOM against skincare brand owners who violate regulations involves a series of systematic and structured stages. The first stage is supervision and inspection, which can be carried out routinely or based on reports from the public. BPOM has a team of inspectors who are trained to conduct inspections of

production facilities, warehouses, and points of sale of skincare products. During the inspection, BPOM officers will check the completeness of documents, production processes, quality of raw materials, and product labeling. If there are indications of violations, BPOM will conduct further investigations to gather strong evidence. This investigation may involve taking product samples for laboratory testing, interviewing witnesses, and examining the company's financial records. Once the investigation is complete, NA-DFC will evaluate the evidence collected and determine the action to be taken. This may include written warnings, corrective orders, suspension of distribution licenses, withdrawal of products from circulation, or even criminal action. In cases involving serious or repeated violations, NA-DFC may take the case to court for a stronger legal ruling. This law enforcement process aims to provide a deterrent effect to violators and protect consumers from dangerous skincare products (Food and Drug Administration Regulation on Cosmetics).

#### **d. Administrative and Criminal Sanctions for Illegal Skincare Brand Owners**

Skincare brand owners who are proven to violate BPOM regulations will face serious legal consequences, both in the form of administrative sanctions and criminal sanctions. Administrative sanctions are actions taken by BPOM to stop illegal activities and recover losses incurred. These sanctions may include fines of varying amounts, depending on the severity of the violation and the impact caused. In addition, BPOM can also revoke the distribution license of skincare products that are proven to violate regulations, so that these products can no longer be sold legally in Indonesia. An order to withdraw the product from circulation is also a common administrative sanction given to violators. This sanction aims to prevent dangerous products from continuing to circulate in the market and endangering consumers. In more serious cases, BPOM can bring the case to the realm of criminal law. Criminal sanctions can include imprisonment and/or fines that are much larger than administrative sanctions. Prison sentences can vary from a few months to several years, depending on the severity of the offense and its impact on public health. Criminal fines can also reach hundreds of millions to billions of rupiah. These criminal sanctions aim to provide a stronger deterrent effect to violators and prevent them from committing similar acts in the future.

#### **e. Active Role of Consumers in Skincare Product Supervision**

Consumers have a very important role in monitoring skincare products and helping BPOM in eradicating the circulation of illegal and dangerous products. Smart and proactive consumers can report products that are suspicious or cause adverse side effects to BPOM. Reports from consumers can be a valuable source of information for BPOM in identifying and taking action against violations. In addition, consumers also need to be more careful in choosing skincare products, by checking the distribution permit from BPOM, the composition of the ingredients contained in the product, and the expiration date. Products that have a distribution permit from BPOM indicate that the product has been evaluated and meets the established safety and quality standards. The ingredient composition also needs to be considered, especially if consumers have allergies or sensitivities to certain ingredients. The expiration date is also important to check, as expired products may undergo chemical changes that are harmful to health. Consumers also need to be aware of exaggerated or misleading product claims (Rambe et al., 2023 ; Rambe., 2024 ; Suhendar & Rambe., 2023 ). If a product claims to provide instant or extraordinary results, consumers need to be more cautious and seek additional information from reliable sources. By being smart and proactive consumers, we can help protect ourselves and others from harmful skincare products.

### **C. Legal and Non-Legal Impacts Experienced by Skincare Brand Owners Who Violate BOPM Regulations**

Skincare brand owners who violate BOPM (Food and Drug Administration) regulations can face a variety of serious legal impacts. One of the main consequences of these violations is the administrative sanctions that can be imposed by the authorities. Based on the Law of the Republic of Indonesia Number 36 Year 2009 on Health, every cosmetic product must obtain a distribution license before being marketed. If brand owners do not comply with this provision, they may be subject to significant fines, business closure, or even criminal prosecution. This law enforcement aims to protect consumers from unsafe and untested products. In many cases, products that violate regulations can be confiscated, which can result in substantial financial losses for brand owners (Suharto., 2020; Rizky F et al., 2024). These sanctions are designed to ensure that all products circulating in the market meet the quality and safety standards set by the government. Therefore, it is important for brand owners to understand and fulfill all legal obligations in order to avoid negative consequences that could harm their business (Rambe et al., 2024; Harahap et al., 2024).

Aside from administrative sanctions, skincare brand owners also have significant legal responsibilities towards consumers. If the products they sell prove to be harmful or cause adverse side effects, consumers have the right to file lawsuits. This is regulated in Article 1365 of the Civil Code (KUHPerduta), which states that every person who commits an unlawful act is obliged to compensate for the losses arising from his actions. (Budiarto (2019) notes that this liability may include financial compensation, a public apology, or withdrawal of the product from the market. In other words, if a product causes harm to consumers, the brand owner will not only face lawsuits, but will also have to bear potentially high costs to compensate for the harm. In this case, compliance with BOPM regulations is not only a legal obligation, but also a strategic move to protect oneself from potential problems in the future, as well as ensuring that the products offered are safe for consumers.

From a non-legal perspective, violations of BOPM regulations can have a significant impact on brand reputation. When consumers find out that a product is not registered or does not meet the set standards, they tend to lose trust. (Ramadhani & Sari., 2021; Rambe et al., 2024) show that brand reputation is highly dependent on consumers' perception of product safety and quality. If brand reputation is poor, this can result in a decrease in sales and customer loyalty. In today's digital era, information about regulatory violations can spread quickly through social media and other online platforms, increasing the negative impact on brands. Consumers today are more likely to do research before buying a product, so a good reputation is very important. Therefore, brand owners must realize that maintaining reputation is an important aspect of business sustainability. Complying with BOPM regulations not only protects consumers but also protects the brand image from potential damage caused by violations. In this context, transparency and commitment to quality are key to building strong trust among consumers.

Furthermore, violations of BOPM regulations can also result in the loss of valuable market opportunities. In an increasingly competitive skincare industry, consumers now prefer products that have clear certification and distribution permits. Yusuf (2022) argues that consumers' awareness of product safety is increasing, which makes them more selective in choosing products. If a brand is involved in a violation, consumers will prefer products from competitors that have a better reputation and meet all legal requirements. This can lead to a significant decrease in market share for the brand owner that violates

the regulations. In addition, non-compliance may hinder access to wider distribution channels, including large retail stores that prefer to sell verified products. In this context, compliance with BOPM regulations not only provides legal protection but also serves as an effective marketing strategy to attract more customers and improve market position (Rambe & Sihombing., 2024; Rambe et al., 2023).

While violating BOPM regulations can have serious consequences, there are also opportunities for improvement for skincare brand owners. By taking steps to comply with all regulations, brand owners can improve their reputation and rebuild consumer trust. According to (Kusumawati (2020)), brand owners who proactively follow the procedures and regulations set by BOPM can improve their brand image in the eyes of consumers. This compliance not only makes products safer, but also opens up opportunities for cooperation with larger distributors and retailers. In a business world that increasingly emphasizes transparency and social responsibility, demonstrating a commitment to regulatory compliance is a significant plus. In this way, brand owners should not only see compliance as an obligation, but also as an opportunity to develop and strengthen their position in a competitive market.

Overall, the legal and non-legal impacts of violating BOPM regulations are significant. Skincare brand owners need to understand the risks associated with non-compliance and strive to comply with all regulations. By doing so, they not only protect themselves from legal sanctions, but also ensure the brand's sustainability and positive reputation in the market. Compliance with BOPM regulations is a strategic move that is not only beneficial from a legal perspective but also from a marketing and consumer relations perspective. In this context, brand owners should invest in understanding and implementing applicable regulations to create safe and quality products for consumers. This will create a healthier and more sustainable ecosystem for the skincare industry in Indonesia.

## CONCLUSION

Skincare brand owners who violate BPOM regulations may be subject to various legal sanctions including administrative, civil, and criminal sanctions. Administrative sanctions such as revocation of distribution licenses, fines, and written warnings, aim to stop violations and encourage improvement. Civil sanctions require manufacturers to compensate consumers for unsafe products, while criminal sanctions are imposed for serious violations, such as the use of hazardous materials and distribution without a distribution license, with the threat of imprisonment and large fines.

In addition, violations of BPOM regulations can impact business reputation, consumer confidence, and business continuity. Non-legal impacts such as social pressure, loss of market share, and financial losses also worsen the brand's position in the industry. Therefore, compliance with BPOM regulations is not only a legal obligation, but also an important strategy to maintain the integrity, public trust, and sustainability of the skincare industry in Indonesia.

The results showed that violations of BPOM regulations by skincare brand owners can lead to various legal consequences that are comprehensive in nature. Business owners who violate can be subject to sanctions in the form of administrative, civil, or criminal sanctions, depending on the level of error and the impact on consumers. Administrative sanctions include revocation of distribution licenses, administrative fines, and official



warnings from BPOM. Meanwhile, in the civil realm, business actors can be sued by aggrieved consumers to provide compensation or return defective or dangerous products.

Meanwhile, criminal sanctions are applied for more serious violations, such as producing and distributing products without official authorization, or using prohibited ingredients that endanger public health. Criminal penalties may include imprisonment and/or large fines. These measures are intended to serve as a deterrent and to protect consumers from health risks.

In addition to formal legal sanctions, violations of BPOM regulations also cause non-legal impacts, such as damage to the brand image in the eyes of the public, decreased consumer confidence, and reduced market opportunities. In the digital era, information about violations can spread quickly and widely, which can worsen a company's reputation. This has a direct impact on sales and consumer loyalty.

This research also confirms that compliance with BPOM regulations has significant strategic value. Not only as a fulfillment of legal obligations, but also as a foundation for maintaining business sustainability, strengthening public trust, and creating a safe and quality skincare market. By complying with applicable legal provisions, business actors can avoid legal risks and at the same time increase the competitiveness of their products amid increasing consumer awareness of the safety and legality of cosmetic products

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