

The Role of The Drug and Food Supervisory Agency (BPOM) on The Difference of Chlorined Vinylers Reviewed From Law Number 8 of 1999 Consumer Protection

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ABSTRACT

The purpose of this is to know about the role of BPOM in consumers for the circulation of chlorinated sanitary napkins which are reviewed from the UUPK and how the role of BPOM is in accordance with the provisions of the applicable legislation. The Indonesian Consumers Foundation (which was later abbreviated as YLKI) has tested the chlorine content in the Charm brand sanitary napkin which is a product of PT. Indonesian Charm Union. The YLKI test results found the highest chlorine content in this brand, namely (54.73 ppm). Based on the provisions of the *Food and Drug Administration* (FDA) the United States has recommended that the maximum chlorine limit in sanitary napkins is 0.1 ppm. Consumers who have used the Charm pads in the long term can cause reproductive health problems, such as vaginal discharge, hives, irritation, and even can cause cancer *cervical*.

Keywords: *Role of BPOM; Chlorine; Health problems.*

1. INTRODUCTION

Nowadays in a society's development by seeing the rapid growth and economic development in the business world, especially in developed countries, it is concerned about the issue of consumer protection. Community consumption of these products tends to continue to increase, along with changes in people's lifestyles including their consumption patterns. Changes in production technology, trading systems and consumer lifestyles in reality increase risk with broad implications on consumer health and safety (Roesli, Heri, & Rahayu, 2017). In the event of a product that does not meet the standards, is damaged or contaminated by hazardous materials, the risks that occur will be large and wide scale and take place very quickly.

The first aspect of consumer protection is the issue of the responsibility of the business actor for losses as a result of the product. Lack of awareness and responsibility as a business actor will have fatal consequences and face risks for the survival and credibility of its business. The low quality of the product or the existence of defects in the marketed products will cause losses for

consumers, in addition to the producers will also face demands for compensation which will ultimately lead to losing competitiveness of these products in capturing market share.

Before business actors enter their products into market share. the product must be registered to carry out the results of the raw material testing carried out by the Food and Drug Supervisory Agency which is then abbreviated (BPOM) so that the ingredients contained in the product do not endanger consumers and are suitable for use by consumers.

BPOM is a government agency tasked with supervising, standardizing, and certifying food and drug products that cover all aspects of the manufacture, sale, use and safety of food, medicines, cosmetics and other products.

Based on the Decree of the Head of the Drug and Food Supervisory Agency Number: 02001 / SK / KBPOM Year 2001 concerning the organization and work procedures of the drug and food supervisory body article 2 determines: "BPOM has the duty to carry out government duties in the field of drug and food supervision in accordance with statutory provisions - invitations apply. "

But at this time many sanitary napkins on the market have not fully been able to provide health insurance for women, the variety of news shows, the addition of chemicals namely chlorine to sanitary napkins that endanger female reproductive organs, this is certainly a dilemma in women , remembering sanitary napkins is the main need of women every month.

According to Zullies Ikawati, stated that chlorine is a variety of compounds containing chlorine (*Cl*). One of the reasons for chlorine is being abandoned, partly because it produces *byproducts* or by-products in the form of dioxin. In various studies, dioxin compounds are toxic. In connection with chlorine pads used to whiten the pulp which is a filler in these products. The process of bleaching with chlorine risks producing dioxin.

The Indonesian Consumers Foundation (which was later abbreviated as YLKI) has tested chlorine levels in sanitary napkins. Sample purchases until testing were conducted in January - March 2015, sample purchases were made in modern retail and testing was carried out using the method *Spectrophotometry*, from the results of testing YLKI found the highest chlorine content (54.73 ppm) in the Charm brand which is a product of PT. Indonesian Charm Union. Based on the provisions of the *Food and Drug Administration* (FDA) the United States has recommended that the maximum chlorine limit in sanitary napkins is 0.1 ppm.

Imposing liability against business actors who represent a product incorrectly, either for reasons of default or for reasons of violating the law, is a means that can provide protection to consumers, because the existence of such accountability can cause business people to be more careful in representing a certain product, so that consumers can get a true picture of a product.

Therefore the government provides protection to the people of Indonesia with the issuance of Law Number 8 of 1999 concerning Consumer Protection (which is then abbreviated as UUPK).

2. RESEARCH METHODS

To answer the problems formulated in this paper, the research method used is normative juridical legal research, which is a study using legal materials to solve legal problems or problems to be discussed.

The approach used in this is to use the *paperStatute Approach* and *Conceptual Approach*. The *statute approach* is the approach taken by examining all laws and regulations relating to the legal issues being examined, namely the Civil Code, UUPK, Decree of the Head of the Drug and Food Supervisory Agency Number: 02001 / SK / KBPOM in 2001, Ministerial Regulation Health of the Republic of Indonesia Number: 472 / Menkes / Per / V / 1996 in 1996.

The approach is *conceptual approach*, which is an approach derived from views and doctrines that develop in law. By studying the views and doctrines in law, researchers will find ideas that give birth to legal notions, legal concepts, and legal principles that are relevant to the issues at hand. Understanding of these views and doctrines is the material for making a legal argument in solving the issues at hand.

In this study using two legal materials namely primary legal material and secondary legal material. Primary Legal Materials are binding legal materials, in the form of applicable laws and regulations that have to do with the issues discussed in this case the Civil Code, UUPK, Decree of the Head of the Drug and Food Supervisory Agency Number: 02001 / SK / KBPOM 2001, Ministerial Regulation Health of the Republic of Indonesia Number: 472 / Menkes / Per / V / 1996 of 1996. Secondary legal material is interpreted as non-binding legal material but describes primary legal material which is the result of the opinions or thoughts of experts or experts who study a particular field specifically, such as the opinions of experts in books, legal journals, seminar materials, legal and internet magazine articles.

Collection of legal materials is done by inventorying legal materials related to the subject matter in writing, classifying legal materials that have been inventoried in accordance with writing needs, and sorting them systematically.

To carry out the analysis, systematic interpretation is used, namely interpretation by examining the case and looking at the role of BPOM in the consumer for the circulation of chlorinated sanitary napkins.

3. STUDY OF THEORY

1. Overview of Consumers

The definition of consumers according to article 1 point 2 of the UUPK is: Consumers are everyone who uses goods and / services available in the community, both for their own interests, their families, other people, and other living things and are not traded. As users of goods / services, consumers have a number of rights and obligations. Knowledge of consumer rights is very important so that people can act as critical and independent consumers. The goal, if there is an unfair action against him, he spontaneously realizes that. Consumers can then go further to fight for their rights.

On the issue of circulation of chlorinated sanitary napkins, consumers have rights that are regulated in Article 4 letter a, letter c, letter d and letter h are as follows:

- a. The right to comfort and safety in consuming goods and / or services
- c. The right to correct, clear and honest information regarding the condition and guarantee of goods and / or services.
- d. The right to hear opinions and complaints about the goods and / or services used.
- h. The right to obtain compensation for compensation and / or reimbursement if the goods and / or services received are not in accordance with the agreement or not as appropriate.

Noting the rights of consumers mentioned above, it can be explained that consumers have the right to get products that are comfortable, safe and provide safety. . Therefore consumers must be protected from all hazards that threaten their health, life and property because of using or consuming products. Every product in terms of material composition, construction and quality must be directed to enhance consumers' sense of comfort, safety and safety. There are no products that can harm and injure consumers.

Consumers also have to obtain compensation for compensation and or replacement, if the goods and or services received are not in accordance with the agreement or not as they should. So if the item purchased does not guarantee safety and security, then the consumer has the right to obtain a new replacement for the product.

2. Understanding of Business Actors Business

actors according to article 1 point 3 of UUPK are: Every individual or business entity that is either a legal entity or not a legal entity established and domiciled or conducting activities within the jurisdiction of the Republic of Indonesia, both individually and jointly through an agreement business activities in various economic fields.

This means that what is meant by business actors is those that produce goods and services that are used by consumers. Goods as a result of production according to article 1 number 4 of

UUPK are: Every object both tangible and intangible, both movable and immovable, can be spent or cannot be spent, which can be traded, used, used or utilized by consumers.

The rights of business actors as stipulated in article 6 determine the following :

- a. The right to receive payments in accordance with the agreement on the conditions and exchange rates of traded goods and / or services
- b. The right to legal protection from the actions of consumers with good intentions
- c. The right to defend themselves appropriately in the settlement of the consumer dispute law
- d. The right to rehabilitate the good name if it is proven legally that the consumer loss is not caused by the goods and / or services traded
- e. The rights are regulated in the provisions of other laws and regulations.
- f. The right of the business actor to obtain payment from the sale of goods and or services has been fulfilled by the consumer, the business actor must fulfill his obligations as stipulated in Article 7 of UUPK.

Among the obligations that must be fulfilled by the business actor, namely compensation and compensation for losses resulting from the use, use and utilization of traded goods and / or services received or utilized are not in accordance with the agreement. And regarding compensation is regulated in article 19 paragraph (1) and paragraph (2) UUPK.

3. Food and Drug Supervisory Agency (BPOM)

Defines BPOM is a government agency tasked with regulating, standardizing and certifying food and drug products covering all aspects of manufacturing, sales, use and safety of food, medicines, cosmetics and other products. BPOM is an institution in Indonesia tasked with overseeing the circulation of drugs and food in Indonesia. The functions and duties of this agency resemble the functions and tasks of food and drug administrators (FDA) in the United States.

The function of BPOM is to carry out control and supervision in the fields of medicine and food. BPOM was made into a non-departmental government institution, hereinafter abbreviated (LPND). In order for oversight by BPOM to be more directed, it will be distinguished between its functions and authorities, BPOM as LPND has functions and authorities in establishing regulations in the field of drug and food supervision and clearly requires human resources who are able to carry out orders in implementing law enforcement from statutory provisions applicable laws.

BPOM was formed based on the Decree of the Head of the Drug and Food Supervisory Agency Number: 02001 / SK / KBPOM of 2001 concerning the organization and work procedures of the BPOM. As a government institution that has the duty to carry out the functions and supervision in the field of medicine and food, all BPOM programs and activities have the aim of protecting the public as consumers for the quality, safety and usefulness of circulating products.

Thus BPOM has a strong legal position in making a policy in the field of medicine in the context of implementing drug and food supervision circulating in the territory of Indonesia.

4. DISCUSSION

As a consumer concept was introduced several decades ago in various countries and until now dozens of countries have laws or special regulations that provide protection to consumers including the provision of judicial facilities. In line with these developments, various countries have also established consumer rights that are used as a basis for regulating protection for consumers. The consumer's term comes from the translation of the words of *consumers* from America, or *consument* from the Netherlands. Literally the meaning of the word *consumer* is everyone who uses goods.

Understanding of Consumers According to UUPK can actually be divided into 3 parts, consisting of:

1. Consumers in the general sense, namely users, users and / or users of goods and / or services for certain purposes
2. between consumers, namely users, users and / or users of goods and / or services to be produced into other goods / services or to trade them for commercial purposes. Consumers are the same as business actors
3. end-consumer, namely users, users and / or users of consumer goods and / or services to meet their own, family or household needs and not to be traded again.

Consumers must be protected from all hazards that threaten their health, soul and property because of using or consuming products. Every product in terms of material composition, construction and quality must be directed to enhance consumers' sense of comfort, safety and safety. There are no products that can harm and injure consumers. Therefore, business actors must include their product labels so that consumers can find out the elements that can endanger their security and safety or explain in full about the product so that consumers can decide whether the product is suitable for them. Included also in this case is that the business actor must inspect the product before it is distributed so that food that has expired and is no longer suitable for consumption does not reach consumers.

Business actors are often interpreted as entrepreneurs who produce goods and services. In this sense, every person or entity participating in the supply of goods and services reaches consumers. PT. Indonesian Charm Union as a business actor, namely any individual or business entity in the form of a legal entity or non-established and domiciled in activities within the

jurisdiction of the Republic of Indonesia, both alone and jointly through agreements to conduct business activities in various economic fields as specified in Article 1 number 3 of UUPK.

The obligation of business actors according to Article 7 of UUPK determines :

- a. To have good intentions in carrying out their business activities.
- b. Provide true, clear and honest information about the conditions and guarantees of goods and / or services and provide explanations of use, repair and maintenance.
- c. Treating or serving consumers correctly and honestly and not discriminatory.
- d. Guarantee the quality of goods and / or services produced and / or traded based on the provisions of the applicable quality standards of goods and / or services.
- e. Give an opportunity to consumers to test, and / or try certain goods and / or services and provide guarantees and / or guarantees for goods made and / or traded.
- f. Giving compensation, compensation and / or reimbursement for losses due to use, use and utilization traded goods and / or services.
- g. Give compensation, compensation and / or replacement if the goods and / or services received or utilized are not in accordance with the agreement.

PT. The Indonesian Charm Union must provide correct, clear and honest information about the condition and guarantee of goods and / or services and provide an explanation of the use, repair and maintenance of Charm sanitary napkins which are the products of their production. However, it turns out that YLKI based on the results of the study found that the chlorine content in Charm pads was 54.73 ppm. It can be said that PT. The Indonesian Charm Union in carrying out its business activities has contravened Article 7 letter b and letter d of the UUPK.

Regarding the provisions of the quality standards of a product. The Indonesian government has established a non-departmental government agency, BPOM. One of the authorities of BPOM is the licensing and supervision of drug distribution and supervision of the pharmaceutical industry. This is based on the interests of consumers.

The drug and food supervision objectives are as follows:

- a. Certainty of protection to the public consumers towards the circulation and use of pharmaceutical and food preparations that do not meet the requirements of quality, safety, and efficacy
- b. Strengthening the national economy by increasing the competitiveness of the pharmaceutical and food industries based on excellence.

Regarding the quality standard provisions of a product. The Indonesian government has established a non-departmental government agency, BPOM. One of the authorities of BPOM is the

licensing and supervision of drug distribution and supervision of the pharmaceutical industry. This is based on the interests of consumers.

If it is associated with the issue of circulating chlorinated sanitary napkins, that until now there has been no stipulation from BSN regarding SNI regarding the limits of chlorine levels that can be used against sanitary napkins and only uses the standard provisions of the FDA, namely the maximum chlorine limit of 0.1 ppm. However, it was found Charm sanitary napkins containing chlorine levels exceeding the standard given, which amounted to 54.73 ppm. So BPOM as a government institution is protecting the health of consumers from the risk of product distribution that has not met the requirements and products that are not suitable for consumption (Susilo & Roesli, 2018). This is in accordance with Article 3 of the Decree of the Head of the Drug and Food Supervisory Agency Number: 02001 / SK / KBPOM of 2001 concerning BPOM's organization and work procedures, namely:

- A. Assessment and formulation of national policies in the field of drug and food supervision.
- B. Coordination of functional activities in the implementation of BPOM's tasks
- C. Monitoring, providing guidance and guidance on the activities of government agencies in the field of drug and food supervision Implementation of guidance and general administrative services in the field of general planning, administration, organization and management, staffing, finance, archives, coding, equipment household.

And Article 4 letter c and d based on the Decree of the Head of the Drug and Food Supervisory Agency Number: 02001 / SK / KBPOM of 2001 concerning BPOM's organization and work procedures, namely:

- a. Determination of information systems in the field of drug and food supervision
- b. Determination of requirements for using additives (additives) certain foods and guidelines for drug and food distribution supervision

BPOM also takes various steps that are deemed necessary to prevent the circulation of chlorine-containing sanitary products. These steps include conducting routine inspections or checks into market share. If chlorine-containing sanitary products are found, BPOM will withdraw the product. In addition to carrying out its duties, BPOM also conducts counseling and provides education to consumers by providing communication, information and education as well as issuing warnings to the public when found sanitary products containing chlorine which can endanger health, especially for women.

In the issue of circulating chlorine-containing sanitary napkins, said that BSN had set SNI, but in the SNI there was no mention of chlorine levels in sanitary napkins.

In this case, the relation with BPOM in providing certainty about the safe standard or tolerance of chlorine content that is permitted to be used is to use the standard provisions of the FDA, namely the maximum chlorine limit in sanitary napkins is 0.1 ppm.

With the existence of these standards, BPOM as a drug and food supervisor continues to protect the public as consumers from the dangers of using chlorine-containing sanitary products, because the safety and comfort of using sanitary napkin products is the right of consumers.

In connection with the circulation of charm pads containing chlorine is a violation of consumer rights. Therefore, the business actor has an obligation to provide compensation for losses to consumers whose rights are not protected as Article 19 paragraph (1) and paragraph (2) UUPK, namely:

1. Business actors are responsible for providing compensation for damage, pollution, and / or consumer losses due to consuming goods and / or services produced or traded.
2. Compensation as referred to in paragraph (1) may be in the form of refunds or replacement of goods and / or services of a similar or equivalent value or health care and / or compensation that is in accordance with the provisions of applicable laws and regulations.

In connection with this, consumers who use chlorinated sanitary napkins that have an impact on reproductive health problems, such as vaginal discharge, hives, irritation, and even can cause cancer *cervical*, have the right to receive compensation in the form of refunds or replacement of goods and / or services of similar or equivalent value, or health care and / or compensation. This is in accordance with the provisions of Article 19 paragraph (2) UUPK.

While in the UUPK the regulation concerning sanctions that can be imposed on business actors who commit consumer violations, namely:

1. Administrative

Sanctions These sanctions are regulated in Article 60 paragraph (2) UUPK stated that administrative sanctions can be imposed is in the form of stipulating compensation of a maximum of Rp. 200,000,000.00 (two hundred million rupiahs)

2. The Basic Criminal

Sanctions These sanctions are regulated in Article 62 paragraph (1) stated that business actors violate the provisions referred to in Article 8, Article 9, Article 10, Article 13 paragraph (2), Article 15, Article 17 paragraph (1) letter a, letter b, letter c, letter e paragraph (2) and Article 18 shall be punished by imprisonment for a maximum of 5 (five) years or a fine of at most Rp. 2,000,000,000.00 (two billion rupiahs)

3. Additional Criminal

Sanctions These sanctions are regulated in Article 63 paragraph (1) stated that there are additional forms of criminal sanctions that can be:

- a. Deprivation of certain goods
- b. Announcement of judges' decisions
- c. Payment of compensation
- d. Orders for terminating certain activities that cause losses consumer
- e. Obligation to withdraw goods from circulation or revocation of business licenses

In connection with this, BPOM can also take administrative measures such as providing written warnings to businesses and may also temporarily issue a ban on circulation of sanitary-containing chlorine products or may issue orders to withdraw sanitary products contains chlorine from circulation. This is done as a preventative measure to protect the lives of consumers from chlorine-containing sanitary products.

The actions that can be taken by BPOM are supervision of chlorine-containing sanitary products circulating in the market share, BPOM can also supervise business actors that distribute chlorine-containing sanitary products, one of which is revocation of production licenses and business licenses and it is hoped that this can lead to the deterrent effect on offenders. This is in accordance with the provisions of article 63 paragraph (1) letter f UUPK.

5. CONCLUSION

Based on the description and discussion as in the previous chapter, it can be concluded that the role and actions of BPOM in the circulation of chlorinated sanitary napkins are very necessary because:

- a. BPOM as a government institution is protecting the health of consumers from the risk of product distribution that does not meet the requirements and products that are not suitable for consumption. So BPOM carried out various steps to prevent the circulation of sanitary products containing chlorine so as not to spread to market share. These steps include conducting regular inspections or checks into market share. If found with chlorine-containing sanitary products, BPOM will withdraw the product. BPOM also conducts counseling and provides education to consumers by providing communication, information and education as well as issuing warnings to the public about the dangers of using chlorine-containing sanitary products. BPOM can also take administrative actions against business actors who have made chlorine-containing sanitary products by providing written warnings to business actors and revoking production licenses and business licenses in

order to cause deterrent effects on violators, which are based on article 63 paragraph (1) UUPK.

- b. Because BSN has set SNI, but in the SNI there is no mention of allowable chlorine levels in sanitary napkins, BPOM in providing certainty about safe standards or tolerance of chlorine content that is allowed to be used for sanitary napkins is to use standard provisions from FDA, namely the maximum chlorine limit on sanitary napkins is 0.1 ppm.

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