Legal Certainty of P-IRT Through the BPOM Post Market in View of Law Number 8 of 1999 Concerning Consumer Protection

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Abstract  
The current circulation of processed products from home industries makes product standardization certification important as an effort to protect the public. This study aims to explain the legal certainty of P-IRT and post market BPOM as an effort to protect consumers. The method used in this research is the normative juridical method which is carried out with a statutory approach and with an analytical approach. The specification used is conceptual descriptive. The data that will be used is secondary data including legislation and literature relevant to P-IRT and Post Market BPOM. From the research conducted, the results showed that the implementation of P-IRT based on BPOM Regulation Number 22 of 2018 can be a protection for the public from harmful products. As a responsibility for the supervision of products that have given P-IRT certificates, the implementation of post market supervision by BPOM on the basis of implementation of BPOM Regulation Number 9 of 2020 as a form of protecting consumer rights as stipulated in Law Number 8 of 1999 concerning Consumer Protection. In their application, both show clear legal certainty for consumers.

Keyword: Legal Protection, P-IRT, Post Market, Consumer Protection

Abstrak  
Beredarnya produk olahan dari industri rumah tangga saat ini menjadikan sertifikasi standardisasi produk penting sebagai upaya perlindungan masyarakat. Kajian ini bertujuan untuk menjelaskan kepastian hukum P-IRT dan pos pasar BPOM sebagai upaya perlindungan konsumen. Metode yang digunakan dalam penelitian ini adalah metode yuridis normatif yang dilakukan dengan pendekatan perundang-undangan dan dengan pendekatan analitis. Spesifikasi yang digunakan adalah deskriptif konseptual. Data yang akan digunakan adalah data sekunder termasuk perundang-undangan dan literatur yang relevan dengan P-IRT dan Post Market BPOM. Dari penelitian yang dilakukan diperoleh hasil bahwa penerapan P-IRT berdasarkan Peraturan BPOM Nomor 22 Tahun 2018
Introduction

Food is a basic need for humans, therefore, fulfillment of needs is a human right that everyone has and stated in Article 27 of the 1945 Constitution which states that food is a basic need for humans to be able to maintain their lives. Adequacy of food is a human right that must be fulfilled). Activities to fulfill food needs in the current era of development are developing very well, with various kinds of breakthroughs and various kinds of experiments to attract people’s interest in trying and buying unique processed food and beverage products. In this day and age, people are expected to be more careful in buying and consuming processed food and beverage products in order to improve public health.

The large number of processed food and beverage products in circulation today may allow the circulation of food and beverage products that do not meet standards, which can be detrimental to consumers who buy or consume them. (Government Regulation Number 28 of 2004 Concerning Food Safety, Quality and Nutrition, 2004) explains that standardization of food and beverage products is important in maintaining the safety and health of consumers by paying attention to the quality and nutrition of food and protecting it from possible hazards, both biological and chemical, which may interfere with, harm, or endanger human health.

The responsibility of the state in the context of realizing the health and welfare of the people is important, because the interests of the state are to guarantee that the people have the right to health and welfare as stipulated in the 1945 Constitution, Article 28 H, Paragraph 1. (Basuki U, 2020) states that health services are rights Human rights, namely a set of rights whose protection, promotion, enforcement and fulfillment are the responsibility of the government. As a good citizen, the government is expected to be able to participate in the prevention, protection, security and fulfillment of the right to public welfare and health for the sake of life continuity. responsibility for health insurance by imposing several laws and regulations, including the 1945 Constitution of the Republic of Indonesia, Law Number 36 of 2009 concerning Health, Law Number 39 of 1999 concerning Human Rights, Law Number 40 of 2004 concerning the National Insurance System and Law Number 24 of 2011 concerning the Health Insurance Organizing Agency. This is a manifestation of the basic needs of the people which are fulfilled by the state for the welfare of its people (Ardinata, 2020).

As a fulfillment of public protection from health hazards that are very likely to occur and in the context of protecting the health and safety of Indonesian
citizens, it is necessary to provide legal protection to protect consumers from obtaining rights to food and beverage products purchased for consumption as stipulated in Law Number 8 1999 concerning Consumer Protection. SSP-IRT is a household scale food and beverage industry permit, generally the P-IRT is stated on the label on the product packaging in the form of a series of numbers registered with the local health office (Dwi Kurniati, Dwi Kurniati & Ali Alladiyah, 2021). In relation to P-IRT, theoretically in this context it relates to fulfilling legal certainty in the field of consumer protection and/or guaranteeing the safety of processed food products in circulation.

According to Utrecht in (Nasriyan, 2019), there are two definitions of legal certainty, namely, first, there are general rules that inform individuals about what actions may or may not be carried out, and second, there are legal guarantees for individuals from the arbitrariness of the government because of general rules mean that individuals can find out what the state may impose or do on them. In relation to P-IRT, theoretically in this context it relates to fulfilling legal certainty in the field of consumer protection and/or guaranteeing the safety of processed food products in circulation. According to Utrecht, there are two definitions of legal certainty, namely, first, there are general rules that make individuals know what actions may or may not be taken, and second, legal guarantees for individuals from government arbitrariness because with general rules, individuals can know what may be imposed or carried out by the state against them (Riduan Syahrani, 1999).

P-IRT can be a step taken in an effort to protect consumers from various food and beverage products that are currently mushrooming in society. Quoted from (School of UMKM, 2022), it was explained that P-IRT can sort various processed food and beverage products on a home scale with standards and considerations for the production process starting from the preparation of raw materials to packaging according to the health standards in force. obtaining a license certificate for wide circulation. Issuance of a P-IRT certificate for a processed food and beverage product is expected to guarantee public health and safety in meeting their food needs.

It doesn’t stop there, the circulation of processed food and beverage products must also be controlled in order to create stable quality of processed food and beverage products circulating in the community and to ensure that products that have received a P-IRT certificate are distributed in accordance with the permits that have been granted. Efforts to protect the public from the dangers of processed food and beverage products that do not meet standards and have been widely circulated by carrying out surveillance after circulation (post market control) carried out by BPOM, the Food and Drug Supervisory Agency as quoted from the Food and Drug Supervisory Agency. (BPOM Indonesia, 2022) namely to see the consistency of product quality, safety, and product information by taking samples of products in circulation, as well as inspection of production and distribution facilities.

Society from various hazards that may occur as a result of processed food and beverage products that have been circulating. This effort is carried out by BPOM as a form of concern for public health and as a form of protecting the rights of the community in fulfilling their needs for healthy and safe food. However, as reported by kompas.com (Ahmad Naufal Dzulfaroh, 2022), the Food and Drug
Monitoring Agency (BPOM) recently discovered coffee containing the chemicals paracetamol and sildenafil, which can be found in the field. Head of BPOM Penny K. Lukito said the use of food ingredients containing medicinal chemicals can cause heart and liver problems, even death. It is undeniable that the prevention and protection system allows for errors, both intentional and unintentional, which harm and worry consumers about food and beverage products that are dangerous to public health and safety.

As a form of protection, responsibility, and guarantees for consumers or the public to obtain their rights to meet their needs for healthy and good food Efforts that can be made by the government in carrying out its responsibilities to prevent, protect, and guarantee all forms of action that can be physical or physically detrimental to consumers or society materially, namely by providing strong legal certainty, which can protect and minimize physical and material losses from the community as consumers who buy and consume food and beverage products that have been widely circulated in society in order to fulfill the right to food and beverage products.

Based on the description above, this study will analyze the legal certainty of P-IRT through the BPOM Post Market in terms of Law Number 8 of 1999 concerning consumer protection. From past research, which focuses more on the legal responsibility of sellers to consumers in terms of Law Number 8 of 1999 concerning consumer protection, In this study, it will be more complex to discuss legal certainty for consumers with the BPOM program, namely the P-IRT post market, in terms of existing regulations, namely Law Number 8 of 1999 concerning consumer protection, with the formulation of the problem to be solved, namely: (1) How does the P-IRT post market create legal certainty to protect consumers?; and (2) How does the BPOM post market create legal certainty to protect consumers?

This research will use a normative juridical method which is carried out with a statutory approach and with an analytical approach. The specifications used are conceptual descriptive. The data to be used is secondary data, including laws and regulations and literature relevant to P-IRT and the BPOM Postal Market. The data will be processed in a comprehensive, thorough and systematic manner with qualitative normative analysis. This research will use a normative juridical method which is carried out with a statutory approach and with an analytical approach. The specifications used are conceptual descriptive. The data to be used is secondary data including laws and regulations and literature relevant to P-IRT and the BPOM Postal Market. The data will be processed in a comprehensive, thorough and systematic manner with qualitative normative analysis.

**Consumer Protection through P-IRT**

In buying and selling activities there must be 2 parties involved in their activities, namely business actors and consumers, in Law Number 8 of 1999 concerning Consumer Protection, consumers are defined as "Every person who uses goods and/or services available in society, both for their own interests themselves, family, other people or other living things and not for trading", while business actors in Law Number 8 of 1999 concerning Consumer Protection mean "every individual or business entity, whether in the form of a legal entity or not a
legal entity established and domiciled or carry out activities within the jurisdiction of the Republic of Indonesia, either individually or jointly through agreements to carry out business activities in various economic fields.

Products are required to include information in the form of a label on the packaging of the food products they produce. According to Article 1 Paragraph 8 of Government Regulation Number 69 of 1999 concerning Food Labels and Advertisements, what is meant by food packaging is material used to contain and/or wrap food, whether in direct contact with food or not. In this article, it can be explained if P-IRT requires business actors who produce P-IRT products to include labels that can provide information about the contents and ingredients in the product and become a right for consumers as written in Article 4 letter c of the Law -Law Number 8 of 1999 concerning Consumer Protection which states that: "Consumer rights are the right to correct, clear and honest information regarding the conditions and guarantees of goods and/or services". The right to obtain clear and correct information is intended so that consumers obtain a correct picture of a product. With this information, consumers can choose the product they want and avoid losses due to errors in product use.

In the activity of buying and selling food or drink, it is of course important to ensure that the object being traded, namely food and drink, is safe and does not endanger one party, namely the consumer and the elements of violation are fulfilled. So that business actors who produce and trade P-IRT With the existence of labels and information regarding products from business actors which are the obligations of business actors contained in Article 4 letter c of Law Number 8 of 1999, in Article 7 letter b of Law Number 8 of 1999 it is also stated that: business actors namely providing correct, clear and honest information regarding the conditions and warranties of goods and/or services as well as providing explanations for use, repair and maintenance". And the obligation of business actors to include labels is to provide protection for consumers from food and beverages that endanger their health and life in activities to fulfill food needs.

**P-IRT: Legal Certainty To Protect Consumers**

As a step in fulfilling the government’s responsibility to protect the public from the hazards of food and beverage products, P-IRT is implemented as an effort to ensure that food and beverage products for home industries that have passed tests are safe and fit for distribution. and consumption by the public. The implementation of P-IRT was marked by the issuance of a distribution permit for home-produced food and beverage products (Sudewi et al., 2020) Number 22 of 2018, in Article 1 Paragraph 7 it is explained that the distribution of permits is an approval of the results of an assessment of processed food issued by the Head of the Agency in Processed food distribution framework.

From this understanding it can be seen that a distribution permit for a processed food and beverage product will be issued if the food and beverage product has been approved after an assessment has been carried out. The assessment carried out in fulfillment of the distribution permit will be carried out by BPOM with the criteria stipulated in the Regulation of the Head of the Food and Drug Supervisory Agency of the Republic of Indonesia Number 03.1.23.04.12.2207.
of 2012, regarding procedures for inspecting home industry food production facilities from (Wahyuningsih & Sulistiyorini, 2022).

Points or scope of assessment in the inspection, including: feasibility and cleanliness of Production Location and Environment, Buildings and Facilities used to carry out production activities, feasibility and safety of Equipment for production, Water Supply or Water Supply Facilities, Hygiene and Sanitation Facilities and Activities, Health and Employee Hygiene that produces, Maintenance and Sanitation Hygiene Programs, Storage of materials and production results, Control of the production process, Food Labeling to provide information for consumers, Supervision by the Person in Charge, Product Withdrawal, Recording and Documentation, Employee Training;

Assessment of inspection results will be based on the results of inspection of the elements listed on the inspection form for home industry food production facilities, taking into account the number of discrepancies found. After going through the assessment process, a Certificate of Home Industry Food Production (SPP-IRT) is issued by the Regent/Mayor c.q. District/City Health Office if IRTP is level I or II. This level will be obtained from the results of an examination of several elements covering the scope previously mentioned. In practice, P-IRT certificates are given to home-processed food and beverage products that have passed the BPOM evaluation stage.

In its implementation, P-IRT can sort out home-processed food and beverage products that will be distributed and can evaluate products that do not meet them to improve quality and infrastructure so that they comply with the standards that have been imposed. Products that have been P-IRT certified and widely distributed can have their distribution permit or P-IRT revoked if they are proven to endanger the general public or violate the violations listed in BPOM Regulation Number 22 of 2018 Article 5 paragraphs 1 and 2.

1) SPP-IRT can be revoked by the Regent or Mayor c.q. One-Stop Integrated Service Unit if it meets the following conditions:
   a. The owner and/or person in charge of the company commits a violation of regulations in the food sector;
   b. Food production in IRTP is proven to be a source of unusual food poisoning (KLB);
   c. IRTP food is proven to contain hazardous materials and/or medicinal chemicals (BKO);
   d. Claims of Food Production IRTP include other than its designation as Food Production IRTP;
   e. Location of IRTP Production of Food Production Facility is different from the location listed in the registration document when obtaining the SPP-IRT and/or the documents selected at the time of granting the SPP-IRT; and
   f. Processed Food Facilities and/or products produced are not in accordance with the SPP-IRT.

2) Revocation of SPP-IRT as referred to in paragraph (1) can also be carried out based on a recommendation issued by the Food and Drug Supervisory Agency. (Dwi Kurniati & Ali Alladiyah, 2021).
From the description of the revocation of P-IRT, it can be seen that the P-IRT will be revoked and its product distribution permit will be terminated as an action against violations that harm consumers and so that consumer losses do not spread. Indirectly, P-IRT can protect the public from products that are harmful to health and guarantee food and beverage products that are P-IRT certified safe for distribution and consumption by the wider community.

Post-Market BPOM Creates Legal Certainty to Protect Consumers

The large number of home-processed food and beverage products that have been circulating in the community and have been certified by P-IRT does not rule out the possibility that there are products that are harmful to the community, both unintentional and unintentional, in circulation and in the field. or on purpose. According to kompas.com (Ahmad Naufal Dzulfaroh, 2022), the Food and Drug Supervisory Agency (BPOM) recently discovered coffee containing the chemicals paracetamol and sildenafil. Head of BPOM Penny K. Lukito said the use of food ingredients containing medicinal chemicals can cause heart and liver problems, even death. If there is no action or control carried out by the apparatus as an effort to protect the public who are buyers and consumers, then it will be very dangerous. In Law Number 8 of 1999 concerning Consumer Protection it is clearly stated that consumer rights include:

The right to comfort, security and safety in consuming goods and/or services purchased and consumed by consumers, secondly the right to choose goods and/or services and obtain said goods and/or services in accordance with the exchange rate and the conditions and guarantees promised, the right to correct, clear and honest information regarding the conditions and guarantees of goods and/or services, the right to have opinions and complaints heard about the goods and/or services used, the right to obtain advocacy, protection and efforts to resolve consumer protection disputes in an independent manner appropriate, the right to receive consumer guidance and education, the right to be treated or served properly and honestly and not discriminatory, the right to receive compensation, compensation and/or reimbursement, if the goods and/or services received are not in accordance with the agreement or not as should, the rights regulated in the provisions of other laws and regulations.

From the consumer rights that have been mentioned, it can be concluded that if consumers are given rights that cannot be taken or violated by sellers, these rights are protected by relevant laws, namely Law Number 8 of 1999, in order to protect consumers from products that are harmful to them. consumption; besides that, consumers are also given the right to obtain good and non-discriminatory information and services; if consumer rights are reduced or violated, consumers are also entitled to obtain legal protection in dispute resolution; and they are entitled to compensation for losses caused by products that have been consumed.

As an effort by the government to fulfill these consumer rights, the government through BPOM conducts inspections of home-processed food and beverage products after they have been circulated, which are called "post markets." Described in BPOM Regulation Number 9 of 2020, market posts are activities to monitor drug and food products while they are in circulation. The regulation also states that one of BPOM's functions and duties is to carry out
supervision before distribution and supervision after distribution. In its circulation, it can be said that BPOM has the responsibility to protect the public from the risk of consuming dangerous food and beverage products circulating in the market. As an effort to protect the public for home-processed products, in practice BPOM will check packaging, check expiration dates, check product safety labels, and take samples of products that are indicated to be unsafe and can harm the community (Arrahman, 2018).

By carrying out routine and direct supervision and checking, it is expected to be able to protect the public from the dangers of processed food and beverage products that have been widely circulated and ensure that products that have been widely circulated are safe and healthy for health. public consumption. Not only in the implementation of supervision, BPOM Regulation Number 9 of 2020 also states that BPOM has the function and duty to take action against violations of statutory provisions in the field of drug and food control, and BPOM places more emphasis on its functions and authority in the administrative field.

Sanctions in accordance with the provisions of the legislation. With its functions and duties based on BPOM Regulation Number 9 of 2020, BPOM has the authority to take action to impose sanctions, which can be in the form of product withdrawal from circulation or revocation of distribution permits, as in BPOM Regulation Number 22 of 2018, processing criminal law against product manufacturers that harm the community. Not only that, in an effort to protect and guarantee the health and welfare of the community, society and the fulfillment of consumer rights are protected by Law Number 8 of 1999 concerning Consumer Protection (Suchatiningsih, 2022). Protection is a legal instrument created to protect and fulfill consumer rights, as stipulated in the Consumer Protection Act Number 8 of 1999 is to increase awareness, ability and independence of consumers to protect themselves, elevate consumer dignity by prevent them from the negative excesses of using the product.

With legal guarantees that if there are activities that reduce or eliminate consumer rights, sanctions will be given according to Law Number 8 of 1999 Article 45, that is, if there is a violation that harms consumers, every consumer can sue the business actor through the authorized institution in resolving disputes between business actors and consumers through the courts or amicable relations. The law explains that even though dispute resolution is carried out outside of court, sellers who violate consumer rights must still be criminally responsible (Sri & Poernomo, n.d. 2020). If efforts to resolve consumer disputes outside the court have been chosen, a lawsuit through the court can only be taken if the effort is declared unsuccessful by one of the parties or by the parties to the dispute (Faiqoh, 2022).

With its functions and duties based on BPOM Regulation No. 9 of 2020, BPOM has the authority to take action to impose sanctions. As in BPOM Regulation No. 9 of 2020, sanctions can be in the form of withdrawing products from circulation, canceling permits, or being given administrative sanctions. According to Article 102 of Law Number 18 of 2012 concerning Food, it is stated that: "Administrative sanctions as referred to in paragraph (1) are in the form of: written warnings and warnings, temporary suspension of product production and
distribution, freezing or cancellation of approval letters, product withdrawals from the market and destruction, and revocation of permits" (Hermanu, 2014).

Meanwhile, according to Article 47 Paragraph 2 Government Regulation Number 28 of 2004 concerning Food Safety, Quality and Nutrition states that: "administrative measures in the form of, written warning, temporary ban on distribution and/or orders to withdraw food products from distribution, food destruction, if proven to be harmful to human health and life, temporary stoppage of production, the imposition of a maximum fine of Rp. 50,000,000.00 (fifty million rupiah), and/or revocation of production permits, business licenses, registration approvals or certificates for home industry food production."

And as in BPOM Regulation No. 22 of 2018 to process criminal laws against product manufacturers that can harm society, namely criminal sanctions contained in Article 62 Paragraph 1 of Law Number 8 of 1999 concerning Consumer Protection which states that: "Business actors who 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 with imprisonment for a maximum of 5 (five ) years or a maximum fine of Rp. 2,000,000,000.00 (two billion rupiah).

Not only there, in an effort to protect and guarantee the health and welfare of the community, the community as well as the fulfillment of consumer rights are protected by Law no. 8 of 1999 concerning Consumer Protection, with legal guarantees that if there are activities that reduce or take away consumer rights, (Rahman Hakim, 2020) sanctions will be given according to Law no. 8 of 1999 article 45, includes:

(1) Every consumer who has been harmed can sue business actors through an institution tasked with resolving disputes between consumers and business actors or through a court within the realm of general courts.

(2) Settlement of consumer disputes can be reached through court or out of court based on the voluntary choice of the disputing parties.

(3) Settlement of disputes outside the court as referred to in paragraph (2) does not eliminate criminal responsibility as regulated in the Law.

(4) If an out-of-court effort to settle consumer disputes has been chosen, a lawsuit through a court can only be pursued if said attempt is declared unsuccessful by one of the parties or by the parties to the dispute.

With that in mind, if producer practices occur that can harm consumers physically or materially, consumers can file disputes in an effort to get legal protection, claim losses, and get justice.

**Conclusion**

Post market supervision carried out by BPOM is carried out as the government’s responsibility in fulfilling consumer rights. The post market provides legal certainty to consumers by checking directly in the field on home industry products that have been circulating on the market with the aim of ensuring the suitability of licensed products circulating on the market in accordance with the permits granted or not violating the relevant regulations.
harm consumers and can minimize behaviors that can harm consumers in meeting food needs.

With the implementation of a certification system for granting licenses to processed food and beverage products for the home industry, it is possible to sort out products that will be widely distributed in order to guarantee and protect consumers from the dangers of processed food and beverage products that are detrimental to consumers. And if violations that harm consumers are found, regulations related to consumer protection clearly explain that consumers are entitled to legal protection and advocacy from authorized institutions and are entitled to compensation, and violators can be punished by withdrawing products from the market, revoking permits, or by criminal law with threats of punishment. 5 years in prison and a maximum fine of 2 billion rupiah.

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