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Foreword



We want to express our gratitude to the Almighty God for His grace and guidance, enabling the publication of this journal, “Eruditio: Indonesia Journal of Food and Drug Safety.” This journal is part of the Indonesian Food and Drug Authority’s (BPOM) responsibility as the institution that oversees the development of the Pharmaceutical and Food Supervisory (PFM) functional position, providing a platform for BPOM employees to develop their profession in the scope of drug and food surveillance.

Research results and findings in Indonesia’s drug and food surveillance field are crucial in making decisions and policies to address challenges and issues in this sector. Therefore, Eruditio: Indonesia Journal of Food and Drug Safety, Volume 5, No. 2, June 2025 Edition, presents seven articles to address these challenges.

These seven articles include: (1) Consumer Perceptions and Behavior in Jakarta towards the “Healthier Choice” Logo on Processed Food by Siti Maemunah, Tety Herawaty; (2) Tonry-Farrington Typological Approach to Preventing the Circulation of Illegal Processed Food in Indonesia’s Border Areas by Yovia Rizki Arrahman, Andi Wibowo; (3) Stability Study for Determining the Shelf Life of Glucosamine Hydrochloride Laboratory Reference Standard by Neni Isnaeni; (4) Analysis of Trends in Cosmetics Supervision Cases in Indonesia in 2021-2024 by Mohamad Kashuri, Taruna Ikrar, Gunawan Indrayanto; (5) Profile of Herbal Medicine Registration Documents Compliance in 2021–2023 for Stunting Prevention by Rima Dwi Pratiwi, Erna Rahmawati; (6) Analytical Hierarchy Process Approach in Determining the Weight of Crime Vulnerability Information in Food and Drug Control by Pepi Fauziah, Andi Wibowo, Yulian Dwi Anggraeni Puspa Handoko, Indriyana; (7) Development of an Analytical Method for Lidocaine Identification in Magic Tissue Using Gas Chromatography Mass Spectrometry by Ilma Yulianita, Theresia Sepmiarti, Lilik Budiati.

We want to thank all the authors, reviewers, and parties who have contributed to the publication of Eruditio: Indonesia Journal of Food and Drug Safety, Volume 5, No. 2, June 2025 Edition. We welcome all readers to read this journal, and constructive suggestions and criticisms are highly appreciated for improving it in subsequent editions. Hopefully, the articles in this edition of Eruditio: Indonesia Journal of Food and Drug Safety can provide new knowledge and perspectives to contribute to drug and food surveillance.

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Eruditio

Consumer Perceptions and Behavior in Jakarta towards the "Healthier Choice" Logo on Processed Food

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ABSTRACT / ABSTRAK

Non-communicable diseases pose a major global mortality threat, with an estimated 15 million people aged 30–70 dying annually due to these conditions. One contributing factor is the excessive consumption of processed foods high in sugar and salt. Nutritional information on processed foods serves as an alternative to help consumers make dietary choices aligned with their nutritional needs. The “Healthier Choice” logo is a government initiative designed to protect consumers. However, research on the “Healthier Choice” logo has not been conducted in Indonesia. This study aimed to examine consumer perceptions and behaviors regarding the use of the “Healthier Choice” logo on processed foods. A survey was conducted with 63 subjects in Jakarta, predominantly aged 24–54 years (85.7%) and holding higher education degrees (84.1%). The results indicated that 54% of respondents had positive perceptions and 68.3% exhibited favorable behaviors toward the logo. Correlation analysis by residential area in Jakarta showed that only North Jakarta had a negative perception below 50% (33.3%), whereas 71.4% of respondents in East Jakarta reported positive perceptions. Regarding behavior, at least 50% of respondents in all Jakarta regions demonstrated good practices in response to the logo. Bivariate analysis by age revealed that most respondents aged 25–54 had positive perceptions (74.1%) and positive behaviors (59.3%) toward the logo. These findings suggest that consumers support the implementation of the “Healthier Choice” logo. Further research is needed to explore consumer perceptions and behaviors regarding the logo with more diverse respondent characteristics, including residential area and educational background.

Penyakit tidak menular menjadi ancaman kematian global, 15 juta orang usia 30–70 tahun akan meninggal setiap tahun akibat penyakit tidak menular. Penyakit ini disebabkan antara lain karena konsumsi pangan yang mengandung gula garam berlebih. Informasi nilai gizi pangan olahan menjadi alternatif membantu konsumen mengonsumsi pangan olahan sesuai kebutuhan gizi. Logo “pilihan lebih sehat” menjadi inovasi pemerintah dalam melindungi konsumen. Penelitian logo “pilihan lebih sehat” belum pernah dilakukan di Indonesia. Tujuan penelitian untuk mengetahui persepsi dan perilaku konsumen terhadap logo “pilihan lebih sehat” pangan olahan. Metode penelitian survei pada subjek 63 orang di Jakarta, mayoritas usia 24–54 tahun (85,7%) dan pendidikan perguruan tinggi (84,1%). Hasil penelitian menunjukkan responden memiliki persepsi positif 54% dan perilaku baik 68,3% terhadap penerapan logo. Korelasi antara tempat tinggal di Jakarta dengan persepsi responden terhadap penerapan logo yaitu hanya Jakarta Utara yang memiliki persepsi negatif dibawah 50,0% (33,3%) sedangkan Jakarta Timur 71,4% responden berpersepsi positif. Korelasi antara tempat tinggal di Jakarta dengan perilaku responden terhadap penerapan logo yaitu $\geq 50,0\%$ responden di semua wilayah Jakarta memiliki perilaku yang baik terhadap penerapan logo. Hasil bivariat antara usia dengan persepsi responden, terlihat

sebagian besar responden usia 25–54 tahun memiliki persepsi baik (74,1%) terhadap penerapan logo. Analisis bivariat antara usia dengan perilaku responden terlihat responden usia 25–54 tahun berperilaku positif (59,3%). Hal ini menandakan ada dukungan konsumen terhadap penerapan pencantuman logo. Penelitian lebih lanjut diperlukan untuk mengetahui persepsi dan perilaku konsumen terhadap penerapan logo “pilihan lebih sehat” dengan karakteristik tempat tinggal serta pendidikan terakhir responden yang lebih beragam.

Keywords: healthier choices logo, processed food, non-communicable disease
Kata Kunci: logo pilihan lebih sehat, pangan olahan, penyakit tidak menular

1. Introduction

According to the 2018 WHO Report on Non-Communicable Diseases Country Profiles, non-communicable diseases (NCDs) have become one of the major health challenges of the 21st century and the leading cause of global deaths, accounting for 71% (41 million) of the 57 million deaths in 2016, based on WHO data. NCDs are responsible for deaths caused by cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes. An estimated 15 million people aged 30–70 years die annually due to NCDs. In Indonesia, in 2016, approximately 73% of NCDs contributed to mortality, with 35% due to cardiovascular diseases, 12% to cancer, 6% to chronic respiratory diseases, 6% to diabetes, and 15% to other NCDs. Risk factors for NCDs include insufficient physical activity, high salt/sodium intake, tobacco use, increased blood pressure, and obesity. Consuming foods high in salt contributes to the risk of hypertension, heart disease, and stroke, while obesity is often linked to an increased risk of hypertension and other NCDs (WHO, 2018). NCDs are multifactorial diseases influenced not only by individual lifestyle choices but also by environmental factors. Therefore, multisectoral NCD prevention efforts are essential, considering NCD risk factors extend beyond the health sector. Prevention can be achieved through policies considering their adverse impact on society (Ndubuisi, 2021).

One strategy to reduce NCD risk factors is promoting a healthy diet. To mitigate NCD risk factors, WHO recommends policies for a 30% reduction in salt/sodium intake, halting the rise of diabetes and obesity, and a 25% reduction in hypertension prevalence through the promotion of nutrition labeling (WHO, 2013).

In line with WHO's policy options, the Indonesian government has responded to WHO's recommendations by issuing regulations related to food labelings, such as Law No. 18 of 2012 on Food, Government Regulation No. 69 of 1999 on Food Labels and Advertising, and The Indonesian FDA Regulation No. 26 of 2021 on Nutrition Information on Processed Food Labels. The nutrition information policy allows consumers to understand and choose processed foods according to their nutritional needs. The Indonesian FDA's regulation on nutrition labeling mandates that all individuals producing and/or distributing processed foods must include nutrition information. The mandatory dietary components include sugar, salt, and fat. Additionally, The Indonesian FDA has introduced a nutrition labeling innovation to facilitate consumer understanding, including a monochrome-designed guide highlighting key nutritional information and the "Healthier Choice" logo. This innovation provides supplementary nutrition information to enhance consumer comprehension of food choices and does not replace standard nutrition information (Engelhardt *et al.*, 2023).

The inclusion of the "Healthier Choice" logo is regulated under The Indonesian FDA Regulation No. 22 of 2019, which was later revised by The Indonesian FDA Regulation No.

26 of 2021 (The Indonesian FDA, 2019, 2021). This regulation stipulates those businesses, including nutrition information tables, may also feature the "Healthier Choice" logo. The inclusion of this logo is voluntary. Businesses must meet the nutritional requirements of their products following the criteria outlined in The Indonesian FDA's Regulation No. 26 of 2021. Currently, the regulation defines 20 nutritional profiles of processed foods, including instant noodles and ready-to-drink beverages, as eligible for the "Healthier Choice" logo if they meet the criteria. The "Healthier Choice" logo is illustrated in Figure 1. The logo includes the phrase "Compared to Similar Products When Consumed in Reasonable Amounts" at the bottom, outside the circle, signifying that products with this logo have a healthier composition than similar products when consumed in reasonable quantities (The Indonesian FDA, 2021).



Figure 1. Healthier Choice Logo

Source: The Indonesian FDA Regulation No. 26 of 2021 (The Indonesian FDA RI, 2021)

The inclusion of the "Healthier Choice" logo aims to assist consumers in making initial decisions about processed food selection based on their dietary needs. It is also expected to encourage food businesses to innovate processed food products that align with WHO's program to reduce NCD rates so that NCD prevention and reduction through nutrition labeling can ultimately be realized.

The "Healthier Choice" logo also serves as a standard communication tool for healthy food labeling to consumers. This logo indicates that the product meets the recommended nutritional profile criteria for sugar, salt, and fat for specific food categories (Muangsri *et al.*, 2021). However, there are still limitations in public understanding of nutrition labels, especially in developing countries. Additionally, previous studies, such as Hapsari *et al.* (2019), have highlighted the influence of labels like the halal logo on consumer purchasing decisions. This study indicated that the visual symbol of the halal logo positively influences purchasing decisions and that awareness of the importance of halal labeling correlates positively with consumer purchase decisions.

Food labels, including specific logos on processed food products, can influence consumer choices and ultimately affect health. Several studies have reinforced this. A study by Fadlillah *et al.* (2015) on consumer awareness of food labels and food additives in Bogor found that 67% of respondents aged >24 read labels, and 73% were familiar with the term "food additives."

Perception theory states that perception is how individuals organize and interpret sensory impressions to give meaning to their environment. When consumers see or hear about a product/service through their senses, it leaves an impression on them, allowing them to perceive the product/service. This definition also states that perception arises and occurs through a process influenced by three factors: the characteristics of the perceiver, the object being perceived, and the environmental elements surrounding the perceiver (Putri, 2018).

In marketing management, when consumers form a negative impression of a product/service, they tend to reject it. Conversely, consumers are more likely to accept, consume, and use the product/service when they form a positive impression. Such actions constitute consumer behavior. Consumer behavior involves actions directly related to acquiring, consuming, and disposing of products and services, including the decisions leading up to these actions. Consumer behavior is influenced by cultural (culture, social class), social (family, roles, and status), personal (age, occupation, economic status), and psychological factors (beliefs, motivation, learning, attitudes, and perception) (Putri, 2018).

Despite the extensive research on nutrition labeling, studies on consumer perception and behavior toward the "Healthier Choice" logo in Indonesia remain limited. This study aims to identify consumer perceptions and behaviors regarding implementing the "Healthier Choice" logo on processed food products, particularly instant noodles and ready-to-drink beverages. The selection of these processed food products is based on literature considerations. The September 2017 National Socioeconomic Survey (SUSENAS) showed that instant noodles were among the 25 essential food commodities consumed nationwide. Meanwhile, in September 2017, the average consumption of instant noodles per capita in Indonesia for urban and rural areas was 308 grams and 269.6 grams, equivalent to 3 packs assuming that one pack of instant noodles weighs 80 grams (BPS-Statistics Indonesia, 2017). Additionally, Indonesia ranks as the second-highest consumer of instant noodles after China and Hong Kong, with 13.27 billion servings consumed in 2021 (World Instant Noodles Association, 2021). Regarding beverages, Indonesia ranks third in sugary drink consumption in Southeast Asia (Fanda *et al.*, 2020).

This study examines consumer perceptions and behaviors toward implementing the "Healthier Choice" logo and consumer characteristics related to these perceptions and behaviors. The findings are expected to contribute to developing more effective nutrition labeling policies and increasing public awareness of healthy eating habits. Furthermore, the study can serve as an evaluation tool for implementing policies related to Indonesia's "Healthier Choice" logo.

2. Methodology

This study employs a quantitative research method using an online questionnaire distributed via Google Forms, a component of Google Docs for conducting online surveys. The study was conducted from July 10 to 12, 2022, targeting consumers residing in Jakarta. Jakarta was chosen as the study location because it is the capital city of Indonesia and one of the most densely populated provinces. According to Statistics Indonesia (BPS), in 2021, the population of Jakarta reached 10,609,681 people (BPS DKI Jakarta, 2021). Several studies emphasize the government's role in increasing health awareness and protecting public health, particularly in urban areas. Urban environments are believed to positively and negatively impact health (Jiang *et al.*, 2021; Pinchoff *et al.*, 2020).

The consumption levels of instant noodles and sugary beverages in Jakarta show high per capita weekly consumption rates. In 2021, assuming an instant noodle weight of 80 grams per serving, the weekly per capita consumption in Jakarta's regions was as follows: South Jakarta 1,087 grams, East Jakarta 1,069 grams, Central Jakarta 1,211 grams, West Jakarta 1,250 grams, and North Jakarta 1,116 grams. The 2018 Basic Health Research (Riskesdas) survey indicated that 60.3% of Jakarta residents aged ≥ 3 years consumed instant/processed foods 1–6 times per week (Ministry of Health, 2018).

The percentage of Jakarta residents aged ≥ 3 years who consumed sugary beverages ≥ 1 time per day and 1–6 times per week was 61.72% and 28.58%, respectively (Ministry of Health, 2018). Excessive sugar consumption from sugary beverages can cause health disorders, including the onset of NCDs. Research by Malik and Hu (2022) found a relationship between high sugary beverage consumption and increased body weight and cardiometabolic diseases. High consumption levels have also been linked to financial burdens. In Brazil, reducing sugary beverage consumption was projected to save medical costs associated with diseases caused by excessive sugar intake (Leal *et al.*, 2022).

This study also considers respondents' income levels, as there is a correlation between income and health status. Higher-income individuals tend to allocate resources toward healthier lifestyles (Rakasiwi, 2021).

The questionnaire consists of demographic data, perception (6 statements), and behavior (7 statements) related to the implementation of the "Healthier Choice" logo. Respondents' perception and behavior toward the "Healthier Choice" logo are assessed using a Likert scale from 1 to 5. The mean value (23.57) is a cutoff point due to the normal data distribution (0.276) to determine respondents' perception scores. Perception scores are classified into positive perception ($\geq$ mean) and negative perception ($<$ mean). Bloom's cutoff point classification applied for behavior scores: good behavior (80–100%), moderate behavior (60–79%), and poor behavior ($<60\%$) (Swarjana, 2022).

Chi-square analysis is used to examine correlations between respondent characteristics and perception, respondent characteristics and behavior, and perception and behavior. Univariate analysis is conducted to obtain frequency distributions of each variable. The chi-square test analyzes relationships between age, place of residence, gender, education level, occupation, average monthly income, primary household food purchaser, and perception and behavior. The study sample consists of respondents who meet the inclusion criteria: aged at least 15 years, residing in Jakarta, and having consumed instant noodles and ready-to-drink beverages. Respondents who have never consumed these products or do not reside in Jakarta are classified under exclusion criteria.

Data collection is conducted through the distribution of an online questionnaire to consumers. The questionnaire collects respondents' demographic characteristics, perceptions, and behavior. Quantitative data from the questionnaire is processed using SPSS 16.0 software. Additionally, researchers review related literature for supporting information.

3. Results and Discussion

3.1 Consumer Characteristics

Based on the questionnaire results, 83 respondents participated in the survey. However, after data cleaning, only 63 met the inclusion criteria. Twenty respondents were excluded due to unwillingness to complete the survey, residence outside Jakarta, or lack of consumption of instant noodles and ready-to-drink beverages.

The characteristics of respondents in this study include age, gender, marital status, place of residence, educational background, occupation, average monthly income, primary household food purchaser, and whether they are following a special diet. These characteristics are detailed in Table 1.

Table 1. Frequency Distribution of Respondents' Characteristics

No	Characteristics	Percentage (%)
1	Age	
	15-24 years	6
	25-54 years	85,7
	≥ 55 years	4,8
2	Gender	
	Male	20,6
	Female	79,4
3	Marital Status	
	Married	68,3
	Single	28,6
	Divorce	3,2
4	Residence	
	Central Jakarta	49,2
	East Jakarta	22,2
	South Jakarta	12,7
	West Jakarta	6,3
	North Jakarta	9,5
5	Education Level	
	Primary School	1,6
	Junior High School	4,8
	Senior High School	9,5
	Higher Education	84,1
6	Occupation	
	Student	1,6
	Housewifw	17,5
	Worker	41,3
	Merchant	6,3
	Civil Servant	31,7
	Retired	1,6
7	Average Monthly Income	
	a. < Rp.1.000.000	11,1
	b. Rp.1.000.000 - Rp.3.000.000	12,7
	c. Rp. 3.000.001 – Rp.6.000.000	33,3
	d. >Rp.6.000.000	42,9
8	Primary Household Food Purchaser	
	Yes	71,4
	No	28,6
9	Following a Special Diet	
	Yes	11,1
	No	87,3

3.2. Consumer Perception and Behavior Toward the "Healthier Choice" Logo

For the perception variable regarding the implementation of the "Healthier Choice" logo, 54% of respondents had a positive perception, while 46% had a negative perception. In terms of behavior, 68.3% of respondents exhibited good behavior, 30.2% exhibited moderate behavior, and 1.6% exhibited poor behavior toward the implementation of the "Healthier Choice" logo.

Table 2. Relationship Between Age and Consumer Perception and Behavior Toward the "Healthier Choice" Logo

Variabel	Age (years)		
	15 – 24	25 – 54	≥55
Perception			
Positive	33,3%	74,1%	33,3%
Moderate	50,0%	25,9%	66,7%
Poor	16,7%	0%	0%
Behavior			
Positive	16,7%	59,3%	33,3%
Negative	83,3%	40,7%	66,7%

Table 2 shows the chi-square results for the correlation between age and perception and age and respondent behavior regarding the application of the "healthier choice" logo.

The frequency distribution analysis shows variations in perception and behavior among different age groups regarding the "Healthier Choice" logo. Among respondents aged 15–24, 33.3% had a positive perception, 50.0% had a moderate perception, and 16.7% had a poor perception. In the 25–54 age group, 74.1% had a positive perception, 25.9% had a moderate perception, and none had a poor perception. In the ≥55 age group, 33.3% had a positive perception, and 66.7% had a moderate perception, with no respondents having a poor perception.

For behavior, 16.7% of respondents aged 15–24 exhibited positive behavior, while 83.3% showed negative behavior. Among respondents aged 25–54, 59.3% exhibited positive behavior, while 40.7% exhibited negative behavior. In the ≥55 age group, 33.3% exhibited positive behavior, while 66.7% exhibited negative behavior.

These results indicate that the 25–54 age group demonstrates the highest level of positive perception and behavior toward the "Healthier Choice" logo compared to the other age groups. This finding suggests that the working-age population is more responsive to nutritional information provided through the logo than younger (15–24 years) and older (≥55 years) groups. This aligns with the study by Sulong et al. (2023), which found that younger consumers are less interested in labels and tend to purchase products without considering or understanding the nutritional information provided. These differences in perceptions and behavior between age groups indicate a need for tailored communication and education strategies. Education based on digital technology, such as social media and interactive applications, can be an effective approach to increase understanding and awareness of the young age group regarding the importance of choosing healthy food products. This approach can also be integrated with promoting healthy lifestyles that are relevant to the preferences and habits of the younger generation.

3.3. Relationship Between Income and Consumer Perception and Behavior Toward the "Healthier Choice" Logo

Table 3 presents the correlation between respondents' average monthly income and perception of the "Healthier Choice" logo implementation.

Table 3. Distribution of Respondents Based on Average Monthly Income and Perception Toward the "Healthier Choice" Logo

Income	Perception (%)	
	Positive	Negative
<Rp. 1.000.000	57,1	42,9
Rp. 1.000.000 – Rp. 3.000.000	50,0	50,0
Rp. 3.000.001 – Rp. 6.000.000	57,1	42,9
>Rp. 6.000.000	51,9	48,1

The analysis indicates variations in positive and negative perceptions of the "Healthier Choice" logo based on respondents' income levels. In the income group of < Rp. 1,000,000, the majority (57.1%) had a positive perception, while 42.9% had a negative perception. A similar trend was observed in the Rp. 3,000,001 – Rp. 6,000,000 income group, where 57.1% had a positive perception. Meanwhile, in the Rp. 1,000,000 – Rp. 3,000,000 and > Rp. 6,000,000 income groups, the perception distribution was relatively balanced. For the income group Rp. 1,000,000 – Rp. 3,000,000 positive and negative perceptions were recorded at 50.0% each. Meanwhile, in the income group > Rp. 6,000,000, positive perceptions are slightly higher (51.9%) than negative perceptions (48.1%). This finding aligns with Kumarga et al. (2024), which suggests that income level does not significantly influence consumer perception of the "Healthier Choice" logo.

Table 4 shows the correlation between respondents' average monthly income and behavior toward the "Healthier Choice" logo.

Table 4. Distribution of Respondents Based on Average Monthly Income and Behavior Toward the "Healthier Choice" Logo

Income	Behavior (%)		
	Good	Moderate	Poor
<Rp. 1.000.000	71,4	28,6	0
Rp. 1.000.000 – Rp. 3.000.000	75,0	25,0	0
Rp. 3.000.001 – Rp. 6.000.000	76,2	23,8	0
>Rp. 6.000.000	59,3	37,0	1

Bivariate analysis shows that respondents with incomes ranging from < Rp. 1,000,000 to > Rp. 6,000,000 positively perceived the "Healthier Choice" logo, with at least 50% in each category. This study is consistent with the *Science for Policy report by the Joint Research Centre (JRC)*, which states that higher income levels are generally correlated with greater interest in front-of-pack nutrition labeling (FOPNL) (European Commission, 2022).

3.4. Correlation Between Perception and Behavior Toward the "Healthier Choice" Logo

Table 5 shows the chi-square analysis results for the correlation between respondents' perceptions and behaviors toward the "Healthier Choice" logo.

Table 5. Distribution of Respondents Based on Perception and Behavior Toward the "Healthier Choice" Logo

Perception	Behavior (%)		
	Good	Cukup	Good
Positive	88,2	11,81	0
Negative	44,8	51,7	3,4

The bivariate analysis between consumer perception and behavior toward the "Healthier Choice" logo shows a strong correlation, with 88.2% of respondents who had a positive perception also exhibiting good behavior. This indicates that consumers who perceive the logo positively are more likely to accept and choose processed food products displaying the "Healthier Choice" logo. These findings align with Puspita et al. (2024), which state that nutrition label perception influences communication behavior in disseminating nutrition information and promoting healthy eating habits.

3.5. Correlation Between Residence in Jakarta and Perception Toward the "Healthier Choice" Logo

Table 6 shows the correlation between respondents' residence in Jakarta and their perception of the "Healthier Choice" logo.

Tabel 6. Distribution of Respondents based on residence in Jakarta and Respondents' perceptions of the application of the "healthier choice" Logo

Residence	Perception (%)	
	Positive	Negative
Central Jakarta	51,6	48,4
East Jakarta	71,4	28,6
South Jakarta	50,0	50,0
West Jakarta	50,0	50,0
North Jakarta	33,3	66,7

The results indicate that only North Jakarta had a negative perception rate exceeding 50.0% (66.7%), while East Jakarta had the highest positive perception rate (71.4%). Although research on the "Healthier Choice" logo in different Jakarta regions is limited, a study by Retno & Fatmah (2019) found increased nutrition label comprehension among respondents in East Jakarta.

3.6. Correlation Between Place of Residence in Jakarta and Behavior Toward the "Healthier Choice" Logo

Table 7 presents the correlation between respondents' place of residence in Jakarta and their behavior toward the "Healthier Choice" logo.

The findings indicate that $\geq 50.0\%$ of respondents in all Jakarta regions exhibited good behavior toward the "Healthier Choice" logo. This suggests a positive consumer response to the implementation of the logo on processed food products. This aligns with the study by Fatimah & Ruhaya (2019), where 80% of respondents supported the implementation of the Healthier Choice Logo (HCL) as it helps consumers choose food products. Similarly,

Feunekes et al. (2008) found that the Healthier Choice Tick may effectively assist consumers in selecting food products. Hawley et al. (2013) noted that the logo did not increase consumption of "less healthy" products, indicating that consumers can differentiate between healthy and unhealthy products (Vargas-Meza *et al.*, 2019).

Table 7. Distribution of Respondents Based on Residence in Jakarta and Behavior Toward the "Healthier Choice" Logo

Residence	Behavior (%)		
	<i>Good</i>	<i>Moderate</i>	<i>Poor</i>
Central Jakarta	74,2	22,6	3,2
East Jakarta	71,4	28,6	0
South Jakarta	62,5	37,5	0
West Jakarta	50,0	50,0	0
North Jakarta	50,0	50,0	0

The "Healthier Choice" logo aims to facilitate consumer identification of healthier food options within the same food category and encourage manufacturers to reformulate products to meet the criteria. In addition to consumers, food manufacturers in Malaysia have also shown higher acceptance of the "Healthier Choice" logo. The logo has encouraged food manufacturers to reformulate their products (Nguyen Ngoc *et al.*, 2023; Sulong *et al.*, 2023).

This study has some limitations, including the focus on respondents residing in Jakarta and most respondents have a higher education background. Further research is needed with a broader geographic scope and more diverse educational backgrounds.

4. Conclusion

This study demonstrates that 54% of consumers, with the majority having higher education, have a positive perception of the implementation of the "Healthier Choice" logo on processed foods. The study also reveals that 68.3% of respondents behave well toward the logo. The correlation between the place of residence in Jakarta and respondents' behavior toward the logo shows that $\geq 50.0\%$ of respondents in all Jakarta regions display good behavior regarding the "Healthier Choice" logo. This indicates a positive response and consumer support for the logo's implementation. The study also finds a correlation between consumer perception and behavior toward the "Healthier Choice" logo, showing that consumers with a positive perception are likely to adopt positive behavior toward products displaying the logo. Further research with a wider geographical scope and more diverse respondent characteristics is recommended to provide greater benefits to consumers and contribute to more effective nutrition labeling policies.

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Tonry-Farrington Typological Approach to Preventing the Circulation of Illegal Processed Food in Indonesia's Border Areas

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The circulation of processed food, particularly imported unregistered products (TIE), is a significant contributor to crime vulnerability in border areas, accounting for 71% of total findings. This has become a complex issue due to its close links with the socio-economic conditions of local communities. A purely repressive approach has proven insufficient for comprehensive mitigation of this phenomenon. This study employed a mixed-methods approach, combining quantitative and qualitative methods, to examine and explain community and institutional participation, including law enforcement agencies, in addressing crime vulnerability related to processed food commodities in Indonesia's border regions, based on the Tonry-Farrington typology. The study area covers North Kalimantan, West Kalimantan, Riau, Riau Islands, and East Nusa Tenggara provinces. The findings indicate that crime prevention using the Tonry-Farrington typology can be implemented through: (1) Developmental and Social Prevention, emphasizing crime prevention functions by engaging local key opinion leaders and traditional authorities with reputable standing to support BPOM's efforts; (2) Community-Based Prevention, promoting collaborative approaches and resource-sharing to enhance value creation; (3) Situational Prevention, involving joint supervision and collaboration with well-informed stakeholders; and (4) Law Enforcement, advocating collaborative measures with the criminal justice system to establish strong legitimacy and a deterrent effect on offenders. The Tonry-Farrington typology can be adapted by BPOM as a novel approach to address the circulation of TIE food products in Indonesia's border regions, enabling holistic and integrated management of crime vulnerability in these areas.

Peredaran pangan olahan khususnya asal impor Tanpa Izin Edar (TIE) mendominasi kerawanan kejahatan di wilayah perbatasan dengan persentase sebesar 71% dari total temuan. Hal tersebut telah menjadi permasalahan kompleks karena kaitan yang erat dengan sosial ekonomi masyarakat setempat. Pendekatan represif saja terbukti tidak cukup dalam upaya komprehensif penanggulangan fenomena tersebut. Penelitian disusun dengan menggunakan metode mix method yakni kuantitatif dan kualitatif dengan tujuan untuk mengetahui dan menjelaskan bagaimana partisipasi masyarakat dan instansi terkait termasuk aparat penegak hukum dalam upaya penanggulangan kerawanan kejahatan khususnya untuk komoditi Pangan Olahan di wilayah perbatasan Negara Indonesia berdasarkan pendekatan tipologi Tonry-Farrington. Cakupan wilayah perbatasan yang dibahas adalah Provinsi Kalimantan Utara, Kalimantan Barat, Riau, Kepulauan Riau, dan Nusa Tenggara Timur. Hasil penelitian menunjukkan bahwa pendekatan pencegahan kejahatan dengan tipologi Tonry-Farrington, dapat diperoleh melalui konsep: (1) Developmental and Social Prevention terkait fungsi pencegahan kejahatan, perlu dilakukan penggalangan kepada key-opinion leader setempat termasuk tokoh masyarakat dan adat setempat yang memiliki reputasi baik serta mendukung upaya Badan POM; (2) Community Based terkait pendekatan kolaborasi dan berbagi sumber daya diperlukan dalam rangka meningkatkan nilai tambah; (3) Situational Prevention terkait kolaborasi yang dapat dilakukan dengan melakukan pengawasan bersama dan menggandeng pemangku kepentingan yang sudah teredukasi dengan baik; dan sebagai upaya terakhir (4) Law Enforcement yaitu upaya kolaboratif dengan Criminal Justice System sebagai upaya untuk memberikan legitimasi yang kuat untuk mewujudkan efek gentar kepada pelaku kejahatan. Teori tipologi Tonry-Farrington dapat diadaptasi oleh BPOM sebagai pendekatan baru dalam

penanggulangan permasalahan peredaran produk pangan TIE di wilayah Perbatasan Indonesia sehingga mampu ditangani secara holistik.

Keywords : Border Area, Processed Food, Tonry-Farrington, Unregistered Products
Kata Kunci : Wilayah Perbatasan, Pangan Olahan, Tonry-Farrington, Tanpa Izin Edar

1. Introduction

The development and advancement of Indonesia's border regions have consistently been the subject of scholarly discussion, particularly among those advocating for substantial transformation to improve the welfare of border communities. The continuity of national development priorities is evident in the transition from President Joko Widodo's *Nawacita* program to President Prabowo Subianto's *Asta Cita*. While *Nawacita* emphasized "building Indonesia from the periphery and strengthening regions and villages within the framework of the unitary state," *Asta Cita* continues this spirit by focusing on "building from villages and the grassroots to achieve equitable economic distribution and poverty eradication." This underscores the government's strong commitment to supporting underdeveloped regions, especially border areas and outer islands, with particular attention to revitalizing socio-economic policies in these regions (Badan Pusat Statistik, 2017). The strategic position of border regions, coupled with their dynamic complexities, often exposes them to various criminal activities. Yunardhani (2012) noted that border vulnerabilities are closely linked to transnational crimes, including illegal fishing, illegal logging, human trafficking, narcotics distribution, terrorism entry points, illegal migrant labor, and diverse socio-economic and cultural challenges—among which food-related crimes are also included.

Border regions could potentially serve as competitive advantages if the goods and services consumed therein were sourced domestically. However, population growth and the lack of adequate transport infrastructure for supply chains have increased demand for food and beverages, which are often fulfilled through cross-border trade. The growing spatial inequality across districts and municipalities, as identified by Akita & Miyata (2017), reflects the limited effectiveness of decentralization in addressing logistics and economic needs in peripheral regions. Deficiencies in infrastructure and household expenditures in rural areas, including border zones, have weakened domestic supply chains and fostered reliance on imports. Such dependence on neighboring countries, particularly Malaysia, poses an anomaly to state sovereignty, as local communities increasingly prefer imported products due to inadequate local economic and logistical infrastructure (Nugroho et al., 2023). The resulting domino effect is the illegal circulation of processed food products from abroad within Indonesia's frontlines. Thus, the inability of domestic supply chains in border regions to achieve economies of scale across the food and drug sectors has become a significant impediment to socio-economic development in these communities.

These challenges inevitably contribute to heightened risks of crime. Cross-ministerial and inter-agency efforts have been undertaken to reduce such risks, including initiatives led by the Ministry of Agriculture (Sulaiman et al., 2017), which envision food security management in border regions through three simultaneous approaches: security, prosperity, and environment. This vision is operationalized via the concept of *Lumbung Pangan Berbasis Ekspor di Wilayah Perbatasan* (LPBE-WP, Export-Oriented Food Barns in Border Regions). The program aims to promote self-sufficiency in basic food supplies, reducing dependency on foreign countries and thereby mitigating associated criminal activities (Marwasta, 2016). However, food-related issues in border regions are not limited to staple commodities; derivative products such as processed foods exhibit similar vulnerabilities (Angriawan & Mutiarin, 2019). To implement the LPBE-WP plan, Sulaiman et al. (2017) identified several policy supports: (1) designation of special investment zones for food in border areas, (2)

accelerated infrastructure development, (3) assurance of business sustainability, including investment guarantees, and (4) the availability of technological and institutional innovations. Importantly, such efforts require not only government initiatives but also reciprocal policies aligned with community empowerment.

Moreover, shifts in food and drug supervision have been accelerated by the COVID-19 pandemic, which reshaped consumer behavior toward greater reliance on digital platforms (Barr & Ozturk, 2021), although physical transactions remain prevalent. This transformation compels regulatory authorities to revitalize law enforcement strategies, transitioning from reactive to preventive approaches. In this regard, the Indonesian FDA regularly analyzes crime vulnerability data, particularly for processed food commodities, using inputs collected by its technical units (*Unit Pelaksana Teknis/UPT*) in border regions. The 2022 vulnerability analysis covered North Kalimantan, West Kalimantan, Riau, the Riau Islands, and East Nusa Tenggara. Findings indicated that processed food vulnerabilities predominantly involve unregistered products (TIE), accounting for 71% of cases, followed by expired food products (27%) and food contaminated with hazardous substances (2%).

The issue of illegal imports, such as unregistered processed foods, is highly complex and cannot be effectively addressed through repressive measures alone (Angriawan & Mutiarin, 2019; Meutia, 2016). By adapting the Tonry-Farrington typology, organizations can adopt a more holistic approach to combating the circulation of unregistered processed foods in border regions. Achieving this requires synergizing law enforcement with community empowerment, communication, information, and education for vulnerable groups, as well as robust inspection and monitoring to support situational prevention strategies (Tonry et al., 2012).

In light of these challenges, this study seeks to examine crime vulnerabilities in the processed food sector, formulate recommendations for community participation in monitoring and enforcement, and strengthen local empowerment as part of crime prevention strategies in Indonesia's border regions. It is expected that this research will provide relevant recommendations to ensure that community-based prevention efforts targeting processed food commodities can be implemented effectively.

2. Methodology

The analysis of the Tonry-Farrington typology approach in preventing the circulation of illegal processed food in Indonesia's border regions was conducted using a mixed-methods design, combining both quantitative and qualitative approaches. As the initial stage, the researchers carried out quantitative data processing and analysis based on primary data collected by Indonesian FDA technical units (*Unit Pelaksana Teknis/UPT*) through the Enforcement Dashboard Application (*Aplikasi Dashboard Penindakan/ADP*)—specifically the *Modul Rawan Kasus* (Crime Vulnerability Module), accessible at <https://penindakan.pom.go.id/>. The dataset employed covered vulnerabilities in food and drug crimes during 2022. Quantitative analysis was conducted using Microsoft Excel's PivotTable function, enabling the researchers to calculate, summarize, and analyze the data, thereby illustrating comparisons, patterns, and trends. The processed data were further visualized in the form of charts and tables.

Subsequently, a qualitative descriptive analysis was undertaken to interpret the phenomena emerging from the quantitative findings, providing a basis for recommending solutions to the circulation of unregistered processed food products in Indonesia's border regions, in alignment with the Tonry-Farrington typology of crime prevention.

With regard to violations identified as crime vulnerabilities in the processed food sector, three main parameters were highlighted: (1) circulation of unregistered products (*Tanpa Izin Edar/TIE*), (2) distribution of expired food products, and (3) distribution of food products contaminated with hazardous substances (e.g., formalin, borax, and prohibited coloring agents). While expired and contaminated products are considered high-risk violations that are typically subject to strict

administrative and criminal sanctions, this study primarily focuses on addressing the circulation of unregistered processed food products (TIE) in Indonesia's border areas. The geographical scope of this study encompasses the provinces of North Kalimantan, West Kalimantan, Riau, the Riau Islands, and East Nusa Tenggara. Among these, North Kalimantan serves as the focal point, given its status as the youngest Indonesian province and the region with the lowest population density compared to other provinces.

3. Results and Discussion

3.1. Processed Food Crime Vulnerabilities in Indonesia, 2022

The proportion of processed food-related crimes in 2022 was recorded at 11% of the total food and drug commodity violations. Observing the trend from 2018 to 2022, processed food crimes have shown an increase both in terms of quantity and the diversity of information sources. Figure 1 illustrates the number of processed food crime cases reported on the *Dashboard Peta Rawan Kasus* (Crime Vulnerability Map Dashboard) from 2018 to 2022.

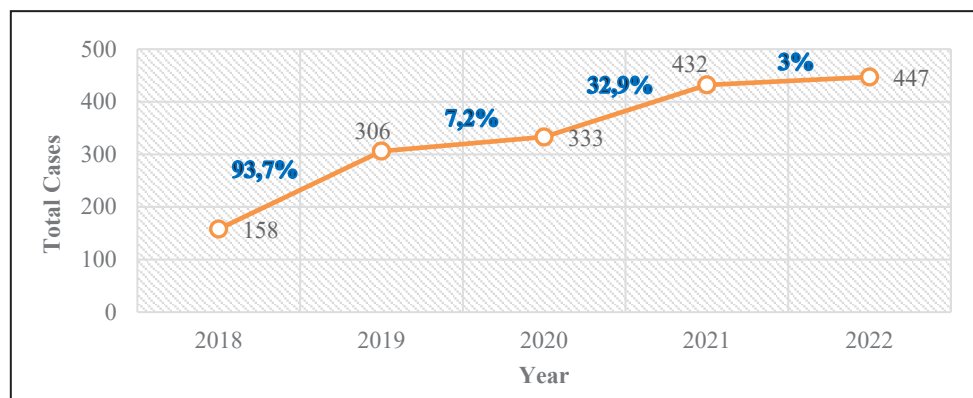


Figure 1. Trend of Processed Food Crime Cases in Indonesia, 2018–2022
(Source: Analysis of Processed Food Crime Vulnerabilities, 2022)

Analysis of the data indicates that there was a 93.7% increase in processed food crime cases in 2019, followed by 7.2% in 2020, 32.9% in 2021, and 3% in 2022, compared to the previous years. Further, based on the types of violations recorded in 2022, the majority of cases involved unregistered processed food products (*Tanpa Izin Edar/TIE*), with 294 cases (66%). This was followed by expired processed food products (*Expired Date/ED*), with 91 cases (20%), and processed foods containing hazardous substances (*Bahan Berbahaya/BB*), with 62 cases (14%) (Directorate of Prevention and Protection, 2022).

According to the 2022 Vulnerability Analysis of Processed Food Crimes, the main categories most frequently associated with violations under Indonesian FDA Regulation No. 34 of 2019 on Food Categories were:

- 14.1.5 Coffee, coffee substitutes, tea, herbal infusions, and hot cereal- or grain-based beverages (excluding chocolate).
- 07.2.1 Cakes, cookies, and pies (fruit-filled or custard/cream-based).
- 05.1.1 Cocoa powder, cocoa cakes, and cocoa mass.
- 15.1 Snack foods made from potatoes, tubers, cereals, flour, or starch (including legumes).
- 14.2.6 Spirit-based beverages with more than 15% ethanol content.

3.2. Processed Food Crime Vulnerabilities in Border Areas, 2022

Based on the distribution data of processed food crime vulnerabilities in border regions in 2022, socio-cultural factors were identified as the most critical drivers of crime vulnerability (see Figure 2). The amplification of information technology use and the rise of the sharing economy, which simplifies business and promotional activities (Baur, 2017), suggest that uncovering future crimes will become increasingly challenging, requiring the adoption of advanced investigative techniques supported by sophisticated technologies.

Socio-cultural dynamics must therefore be closely monitored, as they intersect with technological advancements and demographic shifts—factors that have been recognized as key drivers in reshaping law enforcement strategies (Gelles et al., 2019). Nevertheless, the circulation of illegal products, particularly unregistered food, must be addressed with careful consideration. Persistent disparities in economic growth, where financial inclusion remains concentrated in major urban centers, combined with distribution challenges that increase consumer prices in underdeveloped regions (*daerah 3T*), further exacerbate vulnerabilities. While acknowledging the criminal potential of cross-border trade in unregistered products, enforcement measures should be implemented prudently to avoid counterproductive impacts on food and drug regulatory policies.

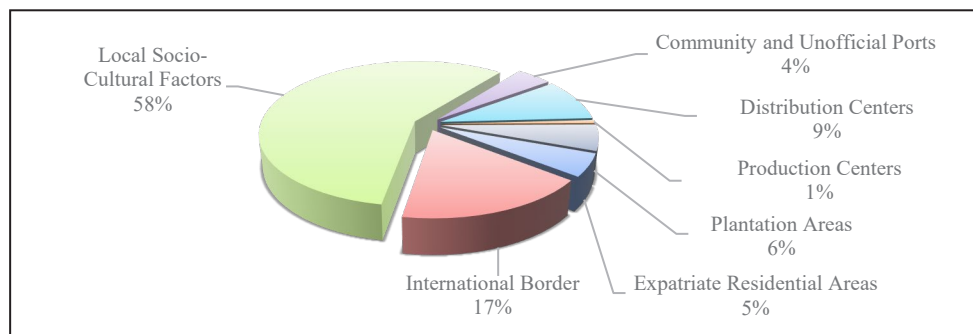


Figure 2. Distribution of Criteria for Determining Processed Food Crime Vulnerabilities in Border Regions, 2022

(Source: Enforcement Dashboard Application, 2022)

Reports from regional FDA offices (*Balai Besar/Balai/Loka POM*) that share direct borders with neighboring countries, as compiled in the 2022 Vulnerability Analysis of Processed Food Crimes—including BBPOM Pontianak, BBPOM Riau, BPOM Batam, BPOM Tarakan, BPOM Kupang, and Loka POM in various border areas—reveal that category 14.0 beverages (both ready-to-drink and powdered forms) dominated reported findings in the *Crime Vulnerability Map Dashboard*. Within this category, 14.1.5 Coffee, coffee substitutes, tea, herbal infusions, and hot cereal- or grain-based beverages (excluding chocolate) was the most frequent subcategory. This was followed by bakery products under 07.2.1 Cakes, cookies, and pies (fruit-filled or custard/cream-based), and confectionery products under 05.0 candies and chocolate, specifically 05.1.1 Cocoa powder, cocoa cakes, and cocoa mass. These findings indicate that the illegal circulation of unregistered food products in border areas typically targets consumers purchasing for personal consumption or as souvenirs, as the categories involved are generally not staple food items.

In the beverage category (14.0), alcoholic beverages without distribution permits present a particularly high criminal risk, whether promoted online or sold directly in retail outlets. According to Presidential Regulation No. 74 of 2013 on the control and supervision of alcoholic beverages, such products are prohibited from being advertised in any mass media. Furthermore, the regulation stipulates strict conditions for alcohol sales—limited to hotels, restaurants, and cafés with the proper licenses, or in duty-free shops for outbound travelers. As such, risk-based enforcement should be prioritized to ensure positive economic impacts while mitigating vulnerabilities.

Currently, the determination of crime vulnerability levels in border regions relies heavily on inputs provided by technical units, particularly BBPOM and Loka POM. Increasing the diversity of information sources would be valuable for mapping connections across datasets and is expected to enhance predictive enforcement measures, ensuring that risk-based interventions in the future become more targeted and effective.

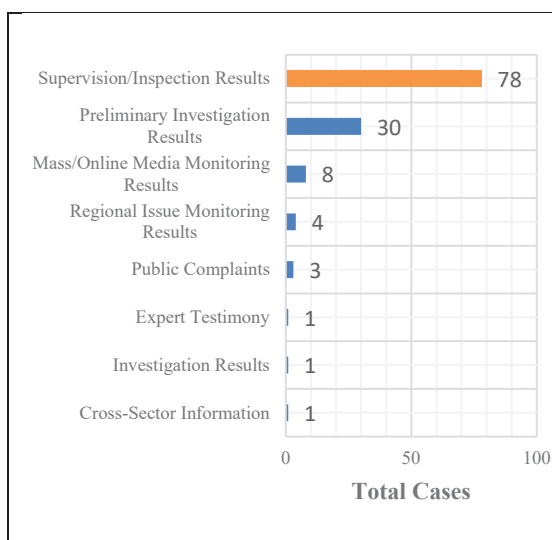


Figure 3. Distribution of Information Sources on Processed Food Crime Vulnerabilities in Border Regions, 2022

(Source: Enforcement Dashboard Application, 2022)

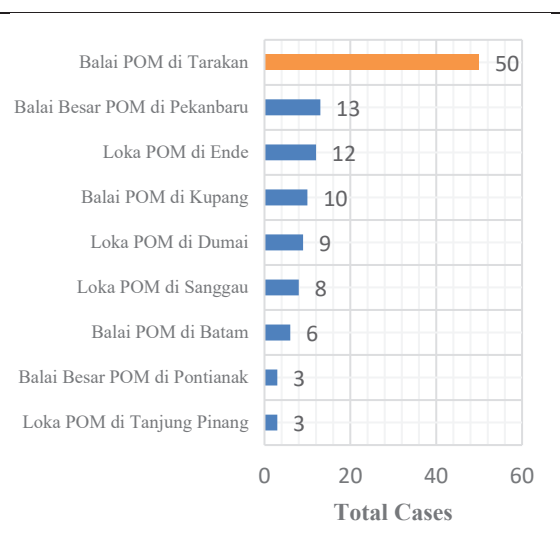


Figure 4. Distribution of Processed Food Crime Vulnerabilities by Technical Units in Border Regions, 2022

(Source: Enforcement Dashboard Application, 2022)

Evaluation of 2022 input data on processed food crime vulnerabilities (see Figure 3) shows that case reporting remains dominated by primary business processes such as supervision/inspections and preliminary investigations. Given the socio-cultural shifts in society—particularly in relation to digital literacy—greater intensification of cyber monitoring is required. Meanwhile, Figure 4 illustrates that BPOM Tarakan reported the highest level of vulnerabilities, likely due to North Kalimantan's extensive borders with neighboring countries, followed by BBPOM Pekanbaru and Loka POM Ende. Risk-based analysis and diversification of information sources are essential to obtaining comprehensive data on crime vulnerabilities. Proactive engagement with emerging data sources is expected to strengthen crime prevention in the food and drug sector through accurate, evidence-based decision-making.

Further analysis of food crime vulnerabilities in border regions revealed that unregistered food products (TIE) dominate at 71%, followed by expired products - ED (27%) and those contaminated with hazardous substances - BB (2%), such as formalin, borax, and banned colorants (Directorate of Prevention and Protection, 2022)

In addition to licensing violations, another noteworthy trend is the promotion and sale of non-compliant food products via social media (6%), although direct sales in physical retail outlets in border regions remain dominant (82%) (see Figure 6). This phenomenon demands greater vigilance in food and drug crime prevention. Information technology has proven capable of transcending national borders, decentralizing food and drug crimes into smaller units driven by the sharing economy (Dharma Negara & Sri Soesilowati, 2021). Under this system, enterprises need not control complete supply chains before starting operations; rather, they can share economic value by leveraging the competitive advantages of other entities in production, transport, storage, logistics, or digital marketing. Consequently, products can be produced and distributed on a *just-in-time* basis, in stark contrast to the traditional supply chain model that is capital-intensive and lengthy.

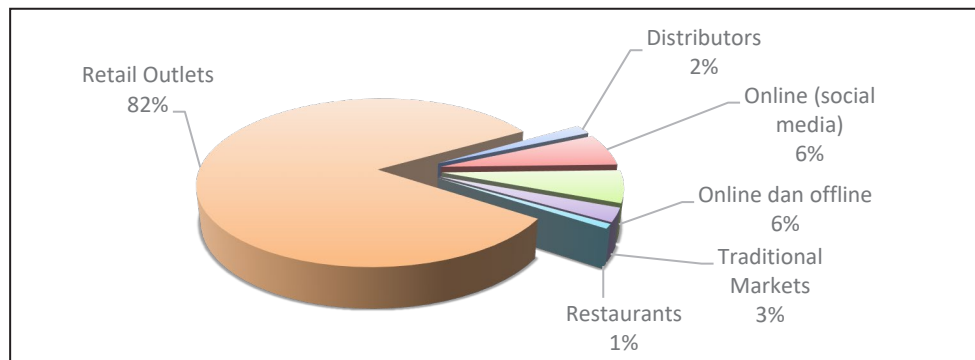


Figure 5. Modes of Illegal Processed Food Circulation, 2022
(Source: Enforcement Dashboard Application, 2022)

3.3. Crime Prevention Approach Using the Tonry-Farrington Typology

Various typologies have been proposed to distinguish crime prevention strategies, particularly between situational and social contexts. Situational prevention focuses on “reducing opportunities” for crime (such as through surveillance technologies in public spaces), whereas social prevention emphasizes transforming social environments and individual motivations (Hughes et al., 2002). The term *social crime* is associated with economic, social, and cultural conditions that discourage potential offenders from engaging in future violations. Situational prevention, including crime prevention through environmental design, seeks to minimize opportunities for crimes to occur.

Another way to classify prevention strategies is by levels of intervention: primary, which reduces opportunities for crime by deterring potential offenders; secondary, which targets individuals before they engage in criminal behavior; and tertiary, which seeks to prevent recidivism among known offenders (Brisman & South, 2015; Weber et al., 2014). In this framework, primary prevention is linked to criminal law enforcement (rather than offender motivation), secondary prevention addresses pre-criminal interventions, and tertiary prevention focuses on deterring repeat offenses.

Tonry and Farrington (1995), however, rejected this secondary/tertiary classification and instead proposed four principal strategies of crime prevention, now known as the Tonry-Farrington Typology: 1) Law Enforcement – strategies involving the enforcement of criminal law aimed at prevention, incapacitation, and rehabilitation; 2) Developmental Preventive Interventions – interventions intended to disrupt the development of criminal potential in at-risk individuals; 3) Community Prevention – strategies designed to alter community conditions that influence the likelihood of crime; 4) Situational Prevention Interventions – strategies aimed at reducing crime by minimizing opportunities and increasing risks for offenders.

Socio-cultural challenges in Indonesia’s border regions, as highlighted by Bakce et al. (2019), center on two key issues: inadequate population registration due to cross-border kinship ties, and the strong social bonds among border communities. These socio-cultural factors exacerbate economic challenges, including the ineffectiveness of cross-border trade cooperation and the dependence of border residents on neighboring countries. One of the most prominent examples of cross-border trade is the circulation of processed food products between Malaysia and Indonesia (Angriawan & Mutiarin, 2019). Illegal circulation of unregistered imported processed food products (TIE) remains a persistent issue, hindered by limited human resources and inadequate infrastructure for supervision (Angriawan & Mutiarin, 2019). In this context, food distribution licensing requirements are anchored in Law No. 18 of 2012 on Food, which, under Article 91(1), stipulates that for the purpose of ensuring food safety, quality, and nutrition, all processed food products produced domestically or imported for retail sale must have a distribution permit.

Supported by national policies promoting border region development, new economic hubs have begun to emerge, enhancing the competitiveness of local products (Marwasta, 2016). To address TIE

issues, the Indonesian FDA (Badan POM) has established exemptions for certain categories of processed foods from licensing requirements through Badan POM Regulation No. 27 of 2017 on Processed Food Registration. Exemptions apply to products used exclusively as raw materials (not sold directly to end consumers), foods sold and packaged in small quantities directly in front of consumers, and ready-to-eat foods. These exemptions were further clarified in Badan POM Regulation No. 7 of 2021, which refined technical and procedural provisions without altering the core exemption categories. Additionally, the enactment of Law No. 6 of 2023, which ratified the Government Regulation in Lieu of Law No. 2 of 2022 on Job Creation, introduced risk-based supervision principles. This allows low- and medium-risk food businesses to be exempt from criminal sanctions, shifting oversight toward administrative and supervisory measures.

From the perspective of enhancing competitiveness and creating added value for local products—while also preventing counterproductive conflicts with border communities—these exemptions offer opportunities to channel imported processed foods into legitimate uses rather than direct consumer sales. For instance, imported products could be processed within local culinary industries, thereby creating new economic opportunities (Siregar et al., 2020).

Given the high complexity of unregistered processed food circulation in border regions, addressing this issue requires a multiperspective strategy that reduces reliance on repressive enforcement (Angriawan & Mutiarin, 2019; Meutia, 2016). Adopting the Tonry-Farrington typology provides a holistic framework: integrating law enforcement, community empowerment, communication and education for vulnerable groups (developmental interventions), and robust inspection and monitoring (situational prevention) (Tonry et al., 2012).

Based on the background description of the problems raised in this paper, the following discussion will focus on processed food products without distribution permits (TIE) circulating in the Indonesian border areas with Malaysia, Singapore, and Timor Leste. This is evident from the recapitulation of the 2021 data input results conducted by the Enforcement Dashboard (ADP) officers in the case-prone module, which found that 71% of processed food crime problems in the border area were related to the circulation of imported food without distribution permits. In general, efforts to address the problem of TIE imported food by the Food and Drug Monitoring Agency (BPOM)'s UPT, which covers the country's borders, are still being implemented partially between functions, in addition to the constraints of limited human resources and infrastructure (Angriawan & Mutiarin, 2019).

As the youngest province in Indonesia, North Kalimantan has interesting socio-cultural dynamics for further discussion, particularly in the context of the distribution of food without a distribution permit (TIE). Referring to the study conducted (Marwasta, 2016), in the context of crime prevention, it is certainly necessary to involve cross-functional and focus on the context of collaboration in striving for added value for parties involved in the process. By adapting the Tonry-Farrington typology in the concept of crime prevention (Tonry & Farrington, 1995), which focuses on the synergy of law enforcement functions, strengthening social norms (Developmental), Community Empowerment (Community-Based), and a situational approach through surveillance efforts (Situational Prevention), the approach to preventing the crime of the distribution of processed food without a distribution permit (TIE), especially in the North Kalimantan region, can be elaborated as follows:

3.3.1 Law Enforcement Dimension

Based on a compilation of court rulings published on the Supreme Court (Mahkamah Agung/MA) website under the food category (last accessed June 12, 2022), it was recorded that between 2012 and 2022 there were 120 rulings related to violations of Law No. 18 of 2012 on Food. Of these, 37.5% (45 rulings) were associated with violations involving unregistered processed food products (*Tanpa Izin Edar/TIE*). The heaviest sentence handed down was 1 year and 6 months of imprisonment in cases concerning the circulation of alcoholic beverages in Papua (2020) and West Kalimantan (2018), which were investigated by the Indonesian National Police. Another case

involved bottled drinking water (AMDK) investigated by BPOM in Kendari in 2016 (Supreme Court Ruling No. 1741 K/PID.SUS/2016).

Cases in border regions can also be reflected in rulings investigated by BPOM investigators (PPNS Badan POM), including BBPOM Pontianak (Supreme Court Ruling No. 2048 K/PID.SUS/2014) – imprisonment of 3 months and a fine of IDR 25 million. BBPOM Samarinda (District Court Ruling No. 258/Pid.B/2016/PN.Tnr) – imprisonment of 10 months and a fine of IDR 15 million (or 5 months in lieu of payment). Loka POM Dumai (District Court Ruling No. 253/Pid.Sus/2019/PNDum) – a fine of IDR 5 million (or 2 months imprisonment in lieu of payment).

The evidence seized in these border-related cases consisted largely of imported food products from Malaysia. For example, in Samarinda (North Kalimantan), the evidence comprised 150 cartons (2,484 packs) of Milo chocolate powder. Under Article 91(1) of Law No. 18 of 2012 on Food, violations of TIE provisions are punishable under Article 142, with a maximum sentence of 2 years imprisonment or a fine of up to IDR 4 billion. Yet, rulings on TIE cases in border regions were generally lighter, with the heaviest sentence being 10 months imprisonment (41.67% of the statutory maximum). This is considerably lower than similar cases outside border regions, such as the bottled water case in Kendari, where the court imposed 18 months imprisonment (75% of the statutory maximum).

The variability in sentencing outcomes may be influenced by differences in judicial panels. In Indonesia, cases are typically adjudicated by at least three judges—one presiding judge and two members—allowing for the possibility of dissenting opinions (Firmansyah, 2018). Consequently, a more structured approach is needed to strengthen the role of judges in adjudicating TIE cases. This requires improving the quality of case dossiers, expert testimonies, and arguments supported by factual data to ensure that rulings create both deterrent and preventive effects.

3.3.2 Developmental and Social Prevention

At this stage, crime prevention interventions are focused on addressing the formation of individual character and criminal potential at an early stage. Tonry et al. (2012) illustrate that social crime prevention may begin as early as childhood. For example, introducing schoolchildren to programs that reshape their understanding of “environment,” “fish,” and “fishing.” Such initiatives could involve strategies such as “catch and release” practices in recreational fishing, framed within broader issues like the impact of climate change on fish species. These approaches encourage children to participate in programs designed to shift attitudes and behaviors.

In applying this social prevention concept to the circulation of unregistered imported processed food (*TIE*) in border regions, one may consider the following example: According to Statistics Indonesia (Badan Pusat Statistik, 2021), the population structure in North Kalimantan is dominated by the millennial generation, aged 25–39 years. Data also show that 24.43% of the population aged five years and above had completed senior high school or its equivalent, indicating relatively high educational attainment among productive-age groups in the province.

Based on the Distribution of Communities in East and North Kalimantan Provinces (Ministry of Youth and Sports, 2014), communities in these provinces are significantly involved in religious organizations (44%), with Islam as the dominant faith. Given this demographic profile, communication, information, and education (CIE) programs, as well as character-building initiatives, can be effectively directed through religious leaders (ulama) and community figures, ensuring strong cultural and moral resonance.

In addition, nationalistic and student organizations contribute significantly to youth engagement. Mobilizing these groups may involve collaboration with stakeholders such as the Department of Education, the Scout Movement, and local community organizations led by key opinion leaders. Activities must also align with the interests of younger generations. Traditional one-way activities, such as lectures, open discussions, and seminars, may not be sufficient. Instead, collaborative,

interactive, and value-adding initiatives are needed to foster a *learning-by-doing* approach to social crime prevention. Role-play, science projects, participation in food and drug regulatory student corps (*Saka POM*), cultural festivals, and creative product competitions can serve as effective tools to integrate crime prevention into social life while instilling pride in local products (*local pride*).

Such efforts require long-term commitment and continuous nurturing to achieve sustainable outcomes. Collaboration across sectors must also be mapped comprehensively. Organizations may implement *Creating Shared Value (CSV)* programs, proactively engaging students to identify opportunities for enhancing the value of local food products. This approach fosters entrepreneurial thinking while emphasizing food safety, quality, and nutrition. With early exposure to such knowledge, students can be expected to become agents of change, capable of transforming both local and imported food products into value-added commodities, thereby strengthening domestic economic potential.

3.3.3 Community-Based Crime Prevention

In implementing community-based crime prevention, two key factors must be considered: the socio-economic conditions of the community and the demographic composition of the population. These factors are crucial because each community is highly context-specific; approaches suitable for communities in western Indonesia may differ significantly from those required in the east. Within this framework, communities should not be perceived merely as objects of supervision, but rather as stakeholders who share responsibility for addressing the circulation of unregistered processed foods (*TIE*). As such, communities can contribute their voices and collaborate in building synergistic common values. By utilizing socio-economic data, organizations can identify community conditions requiring improvement, integrate these needs into operational processes, and implement empowerment programs with mutually agreed goals. Establishing an equal partnership between authorities and communities will facilitate consensus-building and ultimately foster a mutually beneficial ecosystem.

Table 1. Population Distribution in North Kalimantan

No	District/City	2018	2019	2020	2021
1	Bulungan	136,619	140,527	142,967	153,558
2	Malinau	79,903	80,822	81,243	81,925
3	Nunukan	178,975	182,028	188,246	194,119
4	Tana Tidung	24,19	24,145	25,352	26,508
5	Tarakan	228,723	241,893	237,601	241,893

(Source: kaltara.bps.go.id, accessed June 29, 2022)

Table 2. Average Monthly Per Capita Food Expenditure in North Kalimantan

District/City	Average Monthly Per Capita Food Expenditure in North Kalimantan (in Rupiah)		
	2019	2020	2021
Bulungan	755.385,86	820.903,87	787.950,35
Malinau	684.153,73	789.991,81	661.294,49
Nunukan	658.495,31	643.647,08	673.082,87
Tana Tidung	812.949,80	810.954,51	806.682,11
Tarakan	744.925,87	759.186,54	794.562,94

(Source: kaltara.bps.go.id, accessed June 29, 2022)

For example, data from Statistics Indonesia (BPS) show that the accommodation and food service industry contributed significantly to North Kalimantan's Gross Regional Domestic Product (GRDP), increasing from IDR 396.4 billion in Q1 2021 to IDR 457.2 billion in Q1 2022. However, there are stark disparities in per capita food expenditures. Although Nunukan District has the second-largest population in the province, its per capita food expenditure is lower than other regions. In contrast, Tana Tidung, with the smallest population, shows the highest per capita food expenditure. Such disparities may lead to the diversion of imported food products beyond border areas, undermining localized consumption.

A strong hypothesis is that ensuring imported products are fully absorbed within border communities—rather than leaking into other areas—requires efforts to increase local food consumption. This should not rely solely on household consumption but also extend to the industrial sector, such as hotels, restaurants, and catering (HOREKA). This aligns with local government initiatives to improve community welfare. For example, the Ministry of Public Works and Public Housing (PUPR), in partnership with the Nunukan District Government, implemented the *Kota Tanpa Kumuh* (KOTAKU, “City Without Slums”) program to enhance sustainable livelihoods and housing quality. The program included the construction of culinary tourism houses in Nunukan Utara. By expanding culinary tourism, imported processed food products can be transformed into diverse local culinary offerings, thereby increasing economic value while absorbing cross-border supplies.

In this community-based prevention model, culinary tourism managers can be empowered to integrate cross-border processed food products into local culinary industries, household food enterprises, or start-ups. Because these products are used as raw materials rather than sold directly to consumers, they are exempt from licensing requirements. This approach not only generates added economic value for communities but also mitigates the risk of diversion of unregistered products into broader distribution networks.

3.3.4 Situational Prevention

Situational prevention focuses on reducing crime incidents by increasing risks for offenders, thereby limiting opportunities for criminal acts. In the context of unregistered processed food (*TIE*) circulation in border regions, this strategy emphasizes the mobilization of local resources through coordinated activities. One such initiative is SABER (Sapu Bersih / Clean Sweep), aimed at blocking and clustering diverted products to prevent their distribution beyond border areas. Mobilization can be achieved by engaging local stakeholders, such as municipal police (*Satpol PP*), youth organizations, and religious groups, while also aligning with regional government performance indicators—such as enhancing the competitiveness of local SMEs (small and medium enterprises). This ensures that collaboration is mutually beneficial, with all parties gaining advantages from the joint effort.

Another critical step is the implementation of **uniformed patrols** to intensify the “clean sweep” of diverted cross-border TIE products. Uniformed patrols are vital in situational prevention, which is grounded in rational choice theory: individuals engage in crime based on rational calculations of risks and benefits. If offenders perceive an environment as unfavorable due to heightened risks, they are more likely to refrain from criminal activity. Thus, visible and consistent patrols—both physical and digital—play an essential role in creating deterrence.

3.4. Conceptual Implementation of the Tonry-Farrington Typology in Preventing the Circulation of Unregistered Processed Foods in Border Regions

A purely repressive approach has proven insufficient to comprehensively address the circulation of unregistered processed foods (*TIE*) in Indonesia's border regions. Thus, a collaborative approach is required, integrating the roles and functions of both internal and external stakeholders of the

Indonesian FDA (Badan POM). By applying the Tonry-Farrington crime prevention typology, a comprehensive prevention framework can be developed, as illustrated in Figure 7.

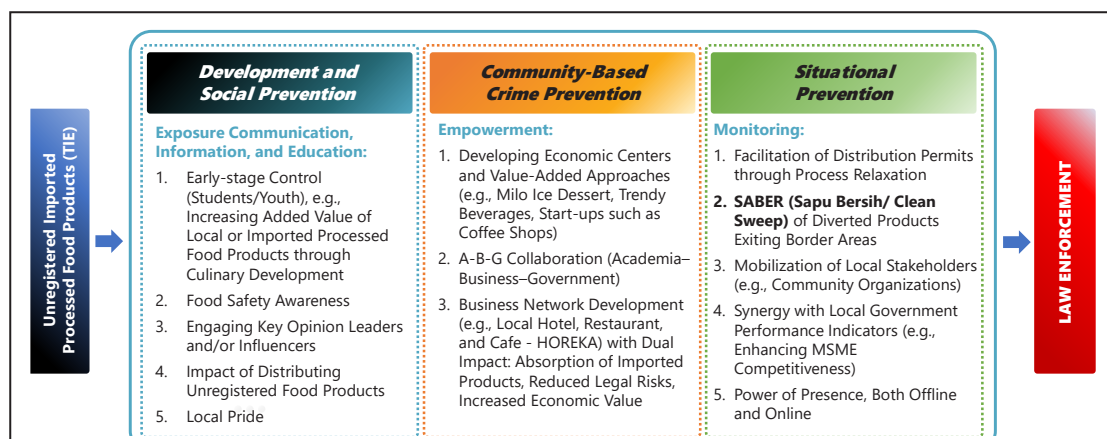


Figure 6. Application of the Tonry-Farrington Typology in Combating TIE Products in Indonesia's Border Regions

(Source: Tonry, M., & Farrington, D. P. (1995))

In the context of Social Development and Prevention, Crime prevention requires engaging local key opinion leaders, including respected community and traditional figures, to support the FDA's efforts in combating TIE imports. Social and cultural proximity enables more effective penetration of communication, information, and education (CIE) programs, reaching deep into grassroots communities—such as youth, students, and entrepreneurs—thus discouraging them from engaging in food-related crimes.

In the context of community-based crime prevention, a collaborative and resource-sharing approach is needed to increase added value, particularly in terms of the economy and competitiveness of local products. Considering the issue of imported products that are most widely circulated are from category 14. Beverages and category 07. Bakery Products, a culinary development approach can be a solution to increase added value compared to selling imported products directly to consumers who are required to have a distribution permit. The Food and Drug Monitoring Agency (BPOM), through its Technical Implementation Unit (UPT), can facilitate these frequently imported products to enter through official channels by fulfilling food safety requirements, for example through SKI requirements, where if used for Hotel, Restaurant or Catering needs, it is one of the exceptions to the requirement to have a distribution permit. For example, the product investigated by BBPOM Samarinda is chocolate powder (Milo Powder) from Malaysia which can be reconstituted into the Es Kepal Milo product which was once a favorite in Indonesia. This added value can certainly have a significant impact on economic progress in border areas. This needs to be supported by local stakeholders, for example the Regional Government, to share resources, especially budgets, to encourage the growth of new, innovative culinary centers without violating regulations and laws.

In the context of situational prevention, collaboration can be achieved through joint supervision and engagement with well-educated stakeholders. Furthermore, the intensification of supervision conducted by the Food and Drug Monitoring Agency (BPOM) through its Technical Implementation Units (UPT) must be continuously improved, not only physically but also virtually. The presence of BPOM in processed food business centers can encourage behavioral change, especially if more economically promising business alternatives are already available and supported by the regulatory ecosystem in border areas.

As a last resort, in the context of law enforcement, strong legitimacy is needed to create a deterrent effect manifested in the form of quality decisions. This needs to be supported by a strong Criminal Justice System (CJS), where the role of the POM Agency is crucial in supporting it in accordance

with its duties and functions, for example in terms of the quality of the files by investigators, expert opinions, and arguments supported by factual data related to the consequences of the case. Cooperation with other law enforcement agencies is also essential, so that good orchestration by law enforcement officers can be assessed by potential criminals as a manifestation or logical consequence of committing a crime.

In addition, the Enforcement Dashboard Application (ADP) marks an important institutional step in risk-based enforcement strategies. By serving as a collaborative data lake, ADP strengthens FDA's position as a data-driven organization. The analysis generated from ADP is expected to further improve targeted, evidence-based approaches to preventing the circulation of unregistered imported processed foods.

4. Conclusion

The circulation of processed food, especially imported food without a distribution permit (TIE), dominates the crime risk in border areas. This has been going on for a long time and has become a complex problem because the problem is closely related to the social culture of the community. A repressive approach alone is not enough in a comprehensive effort to overcome this case, so another approach is needed which is a collaboration between elements of duties and functions, especially within the POM Agency. The research concentrates on overcoming the problem of the circulation of TIE food in Indonesia's border areas. Among the provinces discussed are North Kalimantan, West Kalimantan, Riau, Riau Islands, and East Nusa Tenggara. This discussion will focus on North Kalimantan as the youngest province in Indonesia. Through a crime prevention approach with the Tonry-Farrington typology, a concept can be obtained for handling the circulation of processed food without a distribution permit in border areas, namely (1) Developmental and Social Prevention; (2) Community Based; (3) Situational Prevention; and as a last resort (4) Law Enforcement, namely collaboration can be carried out by conducting joint supervision and involving stakeholders who have been well educated. The Tonry-Farrington typology theory can be adapted by the Food and Drug Monitoring Agency (BPOM) as a new approach to addressing the problem of the circulation of TIE food products in Indonesia's border regions, enabling holistic management. Further research can focus on pilot projects implementing the Tonry-Farrington typology crime prevention in border regions for further evaluation.

5. Recommendations

Based on the foregoing analysis, crime prevention strategies in border regions should emphasize socio-cultural approaches and economic value creation. Short-term strategic measures rooted in local wisdom can serve as catalysts to absorb cross-border food products within border areas, preventing their diversion into other regions. Community mobilization thus becomes a key factor in addressing these challenges. The following recommendations are proposed:

5.1 Community Empowerment and Processed Food Business Development

Community-based crime prevention should involve collaboration with local leadership forums (*FORKOMPIMDA*) and culinary communities in border regions. These groups can support the empowerment of culinary hubs and promote local processed food products, particularly in Category 14 (Beverages, excluding dairy) and Category 07 (Bakery products). Culinary entrepreneurs already organized in local associations should be nurtured as role models for utilizing cross-border food products as raw materials, thereby strengthening community-based economic resilience. The ultimate goal is to ensure that cross-border processed foods are fully absorbed within border regions, minimizing the risk of diversion.

5.2 Social Engineering and Public Communication

Prevention efforts should identify demographic characteristics and cultural contexts in border regions, engaging key opinion leaders and influencers who resonate with target audiences. Tailored communication strategies will ensure that food safety messages reach specific groups—such as youth and students—while simultaneously fostering **local pride** in domestic production. Communication must be adapted to the unique characteristics of each community to ensure effectiveness and sustainability.

5.3 Pre- and Post-Market Supervision

Collective engagement with local government agencies (*SKPD*) is needed to ensure shared perspectives and coordinated action, particularly in implementing risk-based “clean sweep” (*sapu bersih*) measures against diverted products. Strengthening both physical and digital uniformed patrols will reinforce the visible presence of regulatory institutions, affirming their authority in safeguarding food safety and public health.

5.4 Law Enforcement as *Ultimum Remedium*

As a final step, enforcement against TIE products in border regions must focus on offenders with clear criminal intent (*mens rea*). This requires specific regional analyses targeting supply chains that frequently divert cross-border TIE products into domestic markets. By concentrating enforcement on deliberate offenders, authorities can maximize deterrence and ensure proportionality in the application of criminal sanctions.

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Stability Study for Determining the Shelf Life of Glucosamine Hydrochloride Laboratory Reference Standard

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ABSTRACT / ABSTRAK

Reference standards are essential in drug and food control to ensure the quality and validity of test results. According to ISO 17034:2016, the Center for National Quality Control Laboratory of Drugs and Food (PPOMN), as a producer of reference materials, must evaluate and monitor the stability of the standards it produces. Stability testing is critical to maintain product quality during storage and use. However, PPOMN-developed reference standards had not undergone stability testing to determine shelf life. This study therefore conducted a stability assessment of the Glucosamine hydrochloride reference standard to ensure stability during transportation, distribution, and storage. Long-term stability tests were conducted at 4–8°C at 0 months (control), 72 months, and 144 months. Short-term stability tests were performed at 25°C and 60°C for 72, 120, 168, and 240 hours, with 0 hours as the control. Stability analysis was performed using validated High-Performance Liquid Chromatography (HPLC), and analyte stability was assessed using a t-test. Results indicated that the Glucosamine hydrochloride secondary reference standard remained stable under recommended storage conditions for 144 months and at distribution temperatures up to 60°C for 240 hours (t-count = 0.976). These findings demonstrate that the reference standard maintains its quality under specified conditions, ensuring the reliability and validity of pharmaceutical testing. The study concludes that the glucosamine hydrochloride reference standard has guaranteed quality and can be used as long as it is stored under the recommended conditions and shelf life. Information regarding storage conditions and shelf life can be included on the reference standard label.

Baku pembanding sangat penting dalam pengawasan obat dan makanan untuk menjamin kualitas dan validitas hasil pengujian. Sesuai dengan ISO 17034:2016, PPPOMN sebagai produsen bahan acuan harus mengevaluasi dan memonitor stabilitas baku pembanding sekunder yang diproduksi. Uji stabilitas merupakan langkah krusial untuk memastikan bahwa kualitas produk tetap terjaga selama penyimpanan dan penggunaan. Namun, baku pembanding yang dikembangkan oleh PPPOMN belum dilakukan uji stabilitas untuk menentukan masa simpan baku pembanding tersebut. Oleh karena itu, pada penelitian ini dilakukan studi stabilitas baku pembanding glukosamin hidroklorida untuk memastikan kestabilannya selama proses transportasi, distribusi, dan penyimpanan. Studi stabilitas jangka panjang dilakukan pada suhu penyimpanan 4-8°C pada 0 bulan sebagai kontrol dan selama 72 dan 144 bulan, studi stabilitas jangka pendek dilakukan pada suhu 25°C dan 60°C pada 0 jam dan selama 72, 120, 168, dan 240 jam. Metode analisis stabilitas dengan KCKT yang tervalidasi. Stabilitas analit dianalisis dengan uji t. Hasil analisis menunjukkan baku pembanding glukosamin hidroklorida stabil pada suhu penyimpanan yang direkomendasikan selama 144 bulan stabil selama distribusi dengan maksimal suhu 60°C selama 240 jam (t hitung = 0,976). Studi membuktikan

bahwa baku pembanding Glukosamin hidroklorida stabil pada kondisi penyimpanan tersebut. Dengan demikian, kualitas dan validitas hasil pengujian sediaan farmasi yang menggunakan baku pembanding tersebut dapat terjamin. Dari penelitian ini dapat disimpulkan bahwa baku pembanding Glukosamin hidroklorida memiliki kualitas yang terjamin dan dapat digunakan sepanjang disimpan pada kondisi penyimpanan dan umur simpan yang direkomendasikan. Informasi terkait kondisi penyimpanan dan umur simpan dapat dicantumkan pada label baku pembanding tersebut.

:Keywords: stability study, Glucosamine hydrochloride, reference standard, ISO 17034:2016

Kata Kunci: studi stabilitas, Glukosamin hidroklorida, baku pembanding, ISO 17034:2016

1. Introduction

Reference standards are uniform and authentic materials used in the testing of physical and chemical properties, whose characteristics are compared with substances of high purity according to their intended use (WHO, 2007). Secondary reference standards are compounds whose characteristics are established through comparison with primary reference standards. Primary reference standards are recognized as having appropriate quality within a specific context, where their values are accepted without comparison to other chemical substances. The traceability of both must be well documented (WHO, 2007).

Secondary reference standards must share the same properties as the relevant primary standards in relation to the designated tests. The requirements for reference standards include clearly defined characteristics, stability, homogeneity, and appropriate labeling on the packaging or certificate of analysis that provides transparent information. The values specified in pharmacopeial reference standards are considered valid for their intended use (ISO, 2009; WHO, 2007).

The development of reference standards is crucial for strengthening testing capacity and capability to enhance drug and food regulatory control in Indonesia. Reference standards are used to ensure the quality and validity of drug and food testing. The Reference Standard Laboratory at the Center for National Quality Control Laboratory of Drugs and Food (PPPOMN), as an ISO 17034-accredited producer of reference materials, is responsible for guaranteeing the quality of both Indonesian Pharmacopeia Reference Standards (BPFI) and Laboratory Reference Standards (BPL). Quality assurance of reference standards is conducted through the evaluation and monitoring of the stability of the standards produced.

Stability testing is a key step in pharmaceutical product development to ensure that quality is maintained throughout storage and use. According to the WHO, environmental factors such as temperature, humidity, and light, as well as product-related factors such as the chemical and physical properties of the active ingredients and excipients, dosage form and composition, manufacturing process, container-closure system, and packaging materials, can all affect the stability of pharmaceutical products (Ashutosh Kumar Yadav et al., 2023). The primary purpose of long-term stability studies is to determine the shelf life of drug products. The term "stability" refers to the length of time a dosage form remains within its specifications before degradation occurs. The shelf life (expiry date) of a product is calculated based on this duration. Stability testing aims to demonstrate how the quality of a drug substance changes over time (Ashutosh Kumar Yadav et al., 2023). Accordingly, this study carried out both long-term and short-term stability testing of the glucosamine

hydrochloride reference standard to verify its stability during transportation, distribution, and storage. The distinction between long-term stability and short-term stability lies primarily in the objectives, observation period, and storage conditions. Long-term stability testing is used to establish expiry dates and recommended storage conditions, typically lasting from six months to several years, depending on the desired shelf life. In contrast, short-term stability testing assesses the stability of a substance when short-term deviations from recommended storage conditions occur, for example, during distribution or temporary removal from storage. The observation period generally ranges from one day to several weeks, depending on the deviation scenario (WHO, 2018).

Glucosamine hydrochloride (CAS 66-84-2), chemically named D-Glucose, 2-amino-2-deoxy-, hydrochloride, is a white or nearly white crystalline powder with the chemical formula $C_6H_{13}NO_5 \cdot HCl$ and a molecular weight of 215.63 g/mol (United States Pharmacopeia, 2023). Its chemical structure is presented in Figure 1.

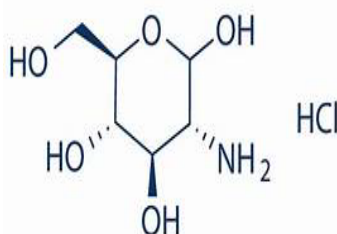


Figure 1. Chemical structure of glucosamine hydrochloride

Glucosamine is an amino sugar naturally produced by the body and serves as a precursor in the biochemical synthesis of glycosylated proteins and lipids. It is a component of polysaccharides, chitosan, and chitin, and is one of the most abundant monosaccharides. Commercially, glucosamine is produced by hydrolyzing the exoskeletons of crustaceans (Nam Xuan Vo, Ngan Nguyen Hoang Le, Trinh Dang Phuong Chu & Khang Xuan An Dinh, Uyen Thi Thuc Che, Thanh Thi Thanh Ngo, 2023). Deficiency in glucosamine can lead to health issues, particularly in joints, increasing the risk of osteoarthritis. Osteoarthritis is a degenerative disease caused by insufficient cartilage regeneration in joints, leading to stiffness, pain, and swelling. Several studies suggest that glucosamine may aid in cartilage regeneration, reduce inflammation, and decrease collagen degradation, thus helping to treat osteoarthritis, although its exact mechanism remains unclear. Glucosamine is most commonly available in supplement form and is widely used as a dietary supplement to promote joint health and manage osteoarthritis.

Several studies have reported methods for analyzing glucosamine hydrochloride using infrared spectrophotometry and high-performance liquid chromatography (HPLC) (Alberto-Silva et al., 2020; Asthana et al., 2019; Choezom et al., 2021). However, no studies have reported stability testing of PPPOMN-produced glucosamine hydrochloride secondary reference standard for shelf-life determination. Therefore, this study conducted stability testing of the glucosamine hydrochloride reference standard to ensure that its quality remains intact during storage and use. The material was characterized using infrared spectrophotometry and HPLC, followed by method validation and stability testing using HPLC. Validation parameters included selectivity, accuracy, linearity, range, detection, and quantification limits, as well as precision (repeatability and intermediate precision).

Consequently, the developed reference standard can be reliably applied in both qualitative and quantitative testing of pharmaceutical and cosmetic products.

2. Methodology

2.1. Time and Place of Study

The study was conducted at the Reference Standard Laboratory, the Center for National Quality Control Laboratory of Drugs and Food (PPPOMN), Indonesian FDA (BPOM).

2.2. Materials and Instruments

The materials used in this study included: Glucosamine hydrochloride USPRS Lot No. F0C363 obtained from USP (Rockville, USA), glucosamine hydrochloride BPL produced by PPPOMN (BPOM, Indonesia) as the sample, potassium bromide, reagents such as sodium pentane sulfonate, HPLC-grade acetonitrile, perchloric acid, potassium hydroxide (Merck, Germany), and demineralized water obtained from a Milli-Q purifier water system (18.2 MΩcm). The instruments used were: a Mettler Toledo XS3DU microbalance, Shimadzu IR-Prestige 21 infrared spectrophotometer (Shimadzu, Japan), Labline oven, Nuve deep freezer, desiccator, and an HPLC system (Shimadzu LC-20AD Prominence) equipped with an autosampler, diode array detector (Shimadzu, Japan), and a C18 Lichrospher® 100 endcapped column (250 × 4.0 mm i.d., 5 μm).

2.3. Sample Characterization

Characterization was conducted to confirm the identity of the tested samples using two methods: infrared spectrophotometry and high-performance liquid chromatography (HPLC).

2.3.1. Infrared Spectrophotometry Characterization

Glucosamine hydrochloride USPRS and glucosamine hydrochloride BPL were separately dispersed into 200 mg of potassium bromide, and absorption was measured using a Shimadzu IR-Prestige 21 spectrophotometer. Glucosamine hydrochloride USPRS and glucosamine hydrochloride BPL were separately dispersed into 200 mg of potassium bromide, and absorption was measured using a Shimadzu IR-Prestige 21 spectrophotometer.

2.3.2. High-Performance Liquid Chromatography (HPLC) Characterization

Standard and test solutions were prepared as follows. Standard solution: Glucosamine hydrochloride USPRS at a concentration of 1 mg/mL in the mobile phase. Test solution: Glucosamine hydrochloride BPL at a concentration of 1 mg/mL in the mobile phase.

Both test and standard solutions were injected into the HPLC system under the following conditions: C18 Lichrospher® 100 endcapped column (250 × 4.0 mm i.d., 5 μm); mobile phase consisting of 0.5 g sodium pentane sulfonate dissolved in 800 mL water, with 4 mL of 1M potassium hydroxide added, diluted to 1000 mL with water, followed by 430 μL perchloric acid and 50 mL acetonitrile. The flow rate was 0.5 mL/min, and detection was carried out at 195 nm using a diode array detector (DAD).

2.4. Method Validation and Stability Testing by HPLC

The validation parameters established included selectivity/specificity, accuracy, linearity, range, detection and quantification limits, and precision (repeatability and intermediate precision).

2.4.1. Selectivity/Specificity

Standard and test solutions (1 mg/mL each) were prepared as described in Section 2.3.2. The blank (mobile phase), standard, and test solutions were injected into the HPLC system under the same conditions.

2.4.2. Accuracy

The standard solution was prepared as described in the selectivity test. Two solutions of the same concentration were prepared and injected six times each into the HPLC system under the conditions described in the HPLC identification test. Accuracy was expressed as % bias.

The accuracy calculation is determined using the following formula:

$$\text{Calculated content (\%)} = \frac{r_2}{r_1} \times \frac{C_1}{C_2} \times \text{Reference content (\%)} \quad (\text{Eq. 1})$$

Accuracy is expressed as % bias, calculated using the following formula:

$$\% \text{ Accuracy (\% bias)} = \left| \frac{\text{Calculated content} - \text{Reference content}}{\text{Reference content}} \right| \times 100\% \quad (\text{Eq. 2})$$

Notes:

r_1	=	Mean peak response of standard solution 1
r_2	=	Mean peak response of standard solution 2
C_1	=	Concentration of standard solution 1 (%)
C_2	=	Concentration of standard solution 2 (%)
Reference content	=	Reference standard content on the label/certificate of analysis

2.4.3. Linearity and Range

Linearity solutions were prepared at five concentration levels: 0.50, 0.75, 1.0, 1.25, and 1.50 mg/mL. Each solution was injected and the area under the curve (AUC) was recorded. A calibration curve was plotted between concentration and AUC, and regression analysis was performed. Linearity was established based on the regression correlation coefficient (r).

2.4.4. Limit of Detection (LOD) and Limit of Quantification (LOQ)

LOD and LOQ were calculated statistically from the linear regression of the calibration curve in the linearity test.

$$LOD = \frac{3.3 \times SD}{\text{slope (b)}} \quad (\text{Eq. 3})$$

$$LOQ = \frac{10 \times SD}{\text{slope (b)}} \quad (\text{Eq. 4})$$

2.4.5. Precision

Standard and test solutions were prepared as described in the selectivity test. Solutions were injected into the HPLC system under identical conditions. Repeatability was assessed by injecting the test solution 10 times in a single day, while intermediate precision was

determined by conducting measurements on two different days. The relative standard deviation (RSD) of these measurements was calculated.

2.4.6. Short-Term Stability Testing

Ten vials of glucosamine hydrochloride BPL (200 mg each) were used. Samples were stored at -70°C (freezer) as a control, in duplicate. Short-term stability testing was performed at two different temperatures: 25°C and 60°C (three vials each). Samples were taken on days 3, 5, 7, and 10. After each sampling, vials were transferred to -70°C until further analysis. Stability testing was conducted using HPLC under the same conditions described in Section 2.3.2, with test solutions prepared at 1 mg/mL in duplicate.

2.4.7. Long-Term Stability Testing

Samples of glucosamine hydrochloride BPL were stored at $4-8^{\circ}\text{C}$ and analyzed at 0 month (control), 72 months, and 144 months. Three vials were analyzed at each interval, in duplicate, using HPLC under the conditions described in Section 2.3.2.

2.4.8. Data Analysis

Stability test results were analyzed using the t-test. If $t\text{-count} < t\text{-table}$, the reference standard was considered stable. If $t\text{-count} > t\text{-table}$, the reference standard was considered unstable.

The stability evaluation is calculated using Equations (5–7) as follows:

$$t_{count} = \frac{b_i}{s_{bi}} \quad (\text{Eq. 5})$$

$$b_i = \frac{\sum_{i=1}^n (x_i - \bar{x})(y_i - \bar{y})}{\sum_{i=1}^n (x_i - \bar{x})^2} \quad (\text{Eq. 6})$$

$$s_{bi} = \frac{s}{\sqrt{\sum_{i=1}^n (x_i - \bar{x})^2}} \quad (\text{Eq. 7})$$

Notes:

x_i = time (months for LTS, hours for STS)

y_i = concentration (%)

3. Results and Discussion

3.1. Infrared Spectrophotometry Characterization

The infrared absorption spectrum of glucosamine hydrochloride showed characteristic absorption bands at 1617, 1584, 1539, 1420, 1249, 1094, 1033, and 912 cm^{-1} . The infrared spectrophotometric identification produced identical profiles and fingerprint spectra between glucosamine hydrochloride BPL and glucosamine hydrochloride USPRS, as presented in Figure 2.

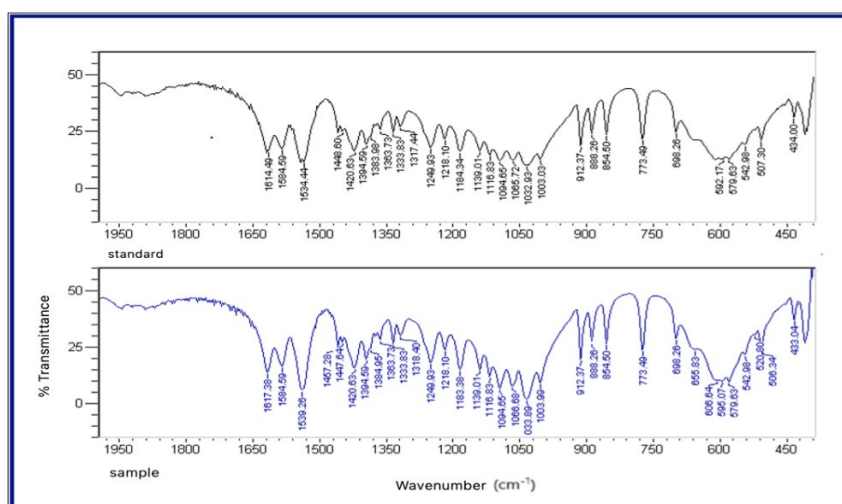


Figure 2. Infrared spectra of glucosamine hydrochloride USPRS (top) and glucosamine hydrochloride BPL (bottom)

The O–H stretching frequency overlapped with the C–H stretching frequency. Wavenumbers at 1384 cm^{-1} and 912 cm^{-1} indicated the presence of C–H bonds; wavenumbers between $1500\text{--}1700\text{ cm}^{-1}$ showed the presence of an amine group; wavenumbers at $1318\text{--}1249\text{ cm}^{-1}$, 1183 cm^{-1} , and 1139 cm^{-1} indicated the presence of C–OH bonds. The wavenumber at 1617 cm^{-1} corresponded to C–C stretching vibrations and N–H bending. The wavenumber at 1094 cm^{-1} indicated the presence of secondary alcohol –OH. Peaks at 854 cm^{-1} and 773 cm^{-1} were due to meta-substituted ring groups. Based on these results, the compound was confirmed to be glucosamine hydrochloride.

3.2. High-Performance Liquid Chromatography (HPLC) Characterization

HPLC-DAD characterization aimed to determine analyte retention time and peak spectrum. The results (Figure 3) showed that the retention time of the major peak in the glucosamine hydrochloride test solution chromatogram matched the main peak in the standard solution chromatogram at 3.33 minutes, confirming the identity of the test sample as glucosamine hydrochloride.

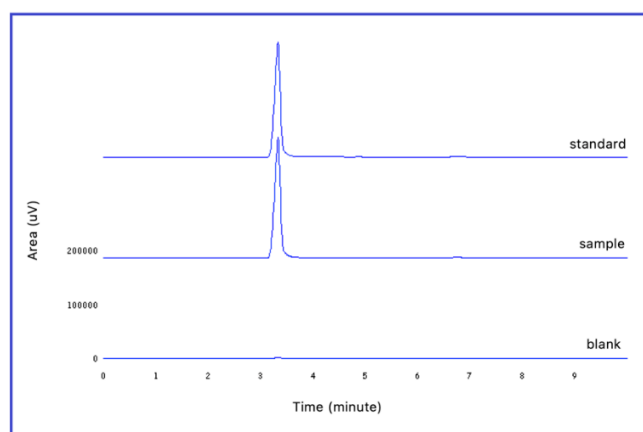


Figure 3. HPLC chromatogram of glucosamine hydrochloride (C18 Lichrospher® 100 endcapped, $250 \times 4.0\text{ mm i.d.}$, $5\text{ }\mu\text{m}$; mobile phase: 0.5 g sodium pentane sulfonate dissolved in 800 mL water + 4 mL 1M potassium

hydroxide, diluted to 1000 mL with water, 430 µL perchloric acid, and 50 mL acetonitrile; flow rate: 0.5 mL/min; detection: 195 nm with DAD).

3.3. Method Validation

System suitability testing included chromatographic parameters such as tailing factor, theoretical plates, and injection repeatability. The glucosamine hydrochloride peak had a tailing factor of 0.96 with 3,621.25 theoretical plates. Injection repeatability yielded relative standard deviations (RSD) of 0.18% for peak area and 0.07% for retention time. These results confirmed that the HPLC system met analytical validation requirements and demonstrated good precision.

Table 1. System suitability test for glucosamine hydrochloride

Parameter	Result	Criteria (USP, 2020)
Tailing factor	0,96	$\leq 1,5$
Theoretical plates	3621,25	≥ 2000
RSD area (%)	0,18	$\leq 2,0 \%$
RSD retention time (%)	0,07	$\leq 1,0 \%$

The blank chromatogram showed no peaks with retention times identical to the major peak in the standard chromatogram (Figure 3). The main peak in the test chromatogram matched the main peak in the standard chromatogram. Thus, the method was confirmed to be selective and specific for glucosamine hydrochloride analysis by HPLC.

Accuracy was determined by calculating the % bias between measured concentrations and the certified concentration stated in the CoA (certificate of analysis). The mean accuracy obtained was 0.43%, meeting the acceptance criterion of % bias $\leq 2.0\%$ (Ahuja, 2005). This demonstrated that the method was accurate and valid for quantifying the glucosamine hydrochloride BPL reference standard.

Linearity was assessed using calibration curves for glucosamine hydrochloride (Figure 4). The curve was linear across 0.48–1.45 mg/mL, with the regression equation $y = 1,575,103.591x + 87,841.200$ and correlation coefficient (R) of 1.000, satisfying the requirement of $R \geq 0.995$ (AOAC, 2002). The limit of detection (LOD) and limit of quantification (LOQ) were 0.014 µg/mL and 0.047 µg/mL, respectively.

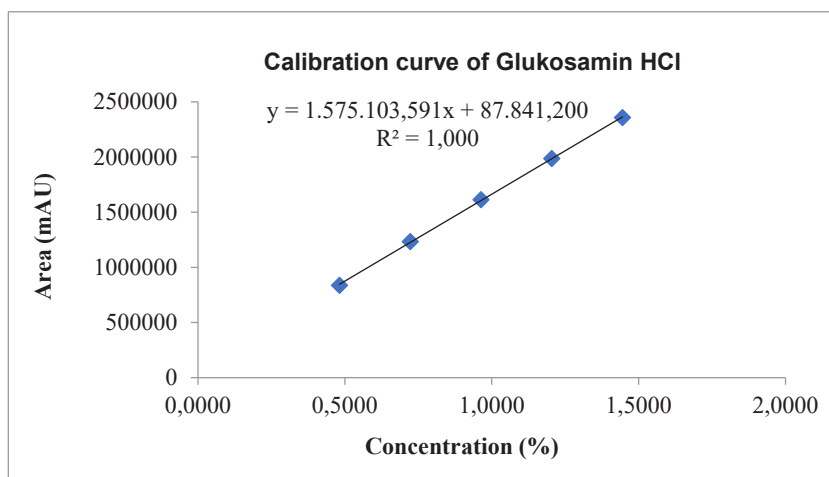


Figure 4. Calibration curve of glucosamine hydrochloride

Precision is a measure that indicates the degree of agreement among individual test results, assessed through the distribution of individual values around the mean when the procedure is applied to replicate samples taken from a homogeneous mixture. Precision can yield repeatability values that are close together, with standard deviation (SD) or relative standard deviation (RSD) used as parameters (ICH, 2005). The precision parameters evaluated in this study included system precision, method precision, and intermediate precision conducted on two different days. System precision, obtained from repeated injections of the standard solution, showed RSD values of less than 2.0%. Method precision on two different days in this study was 0.60% and 0.36%, while intermediate precision was 0.48%. An RSD value of less than 2% indicates that the precision parameters provided acceptable repeatability.

3.4. Stability Testing

This study conducted both short-term and long-term stability testing of glucosamine hydrochloride BPL to ensure its stability during transport, distribution, and storage.

Short-Term Stability at 25°C and 60°C, samples were tested over 0, 72, 120, 168, and 240 hours (Figures 5 and 6). Both curves showed slopes close to zero. Statistical analysis using the t-test showed $t\text{-count} < t\text{-table}$. At 25°C, $t\text{-count} = -2.738 < 2.306$, and at 60°C, $t\text{-count} = 0.976 < 2.306$. These results confirmed that glucosamine hydrochloride BPL remained stable for up to 10 days under these conditions, indicating its quality was preserved during short-term transport and distribution at 25°C and 60°C.

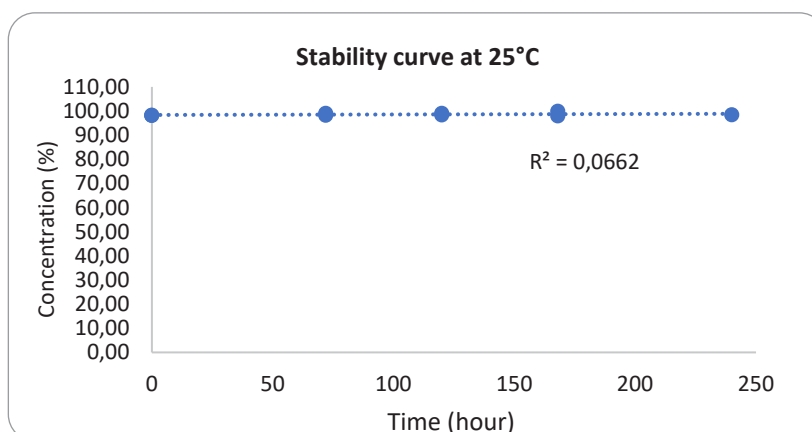


Figure 5. Short-term stability curve of glucosamine hydrochloride at 25°C

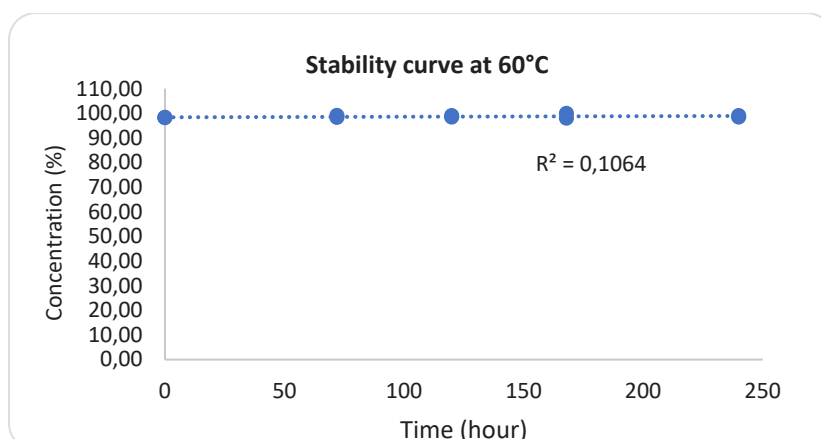


Figure 6. Short-term stability curve of glucosamine hydrochloride at 60°C

Long-term stability testing, also serving as quality monitoring of the produced reference standard, demonstrated that glucosamine hydrochloride BPL was stable at the recommended storage temperature (4–8°C) for up to 144 months. The slope of the curve was close to zero (Figure 7), and statistical analysis showed $t\text{-count} = -8.793 < 2.032$, meeting stability criteria. This proved that glucosamine hydrochloride BPL is stable under recommended storage and distribution conditions, ensuring product reliability in the pharmaceutical industry.

Based on its physicochemical properties, glucosamine hydrochloride is relatively stable at room temperature. However, prolonged exposure to high temperatures can cause degradation, potentially damaging its glucosamine ring or cleaving the hydrochloride component, leading to impurities. Decomposition may occur above 150°C. Furthermore, glucosamine hydrochloride is hygroscopic, absorbing moisture from the environment, which can accelerate degradation, form unwanted byproducts, and shorten shelf life. It must therefore be stored in tightly sealed, moisture-resistant containers under dry conditions. It is stable when kept away from direct sunlight, as prolonged light exposure, particularly UV radiation, can cause degradation, discoloration, and reduced effectiveness. Thus, storage in light-resistant containers is essential (Kompantsev, 2012; Pan et al., 2023).

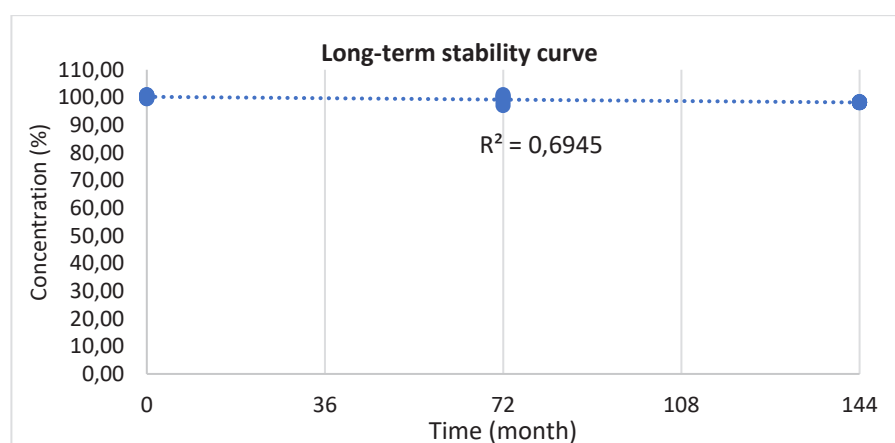


Figure 7. Long-term stability curve of glucosamine hydrochloride at storage temperature

Over time, glucosamine hydrochloride may form impurities due to environmental factors or improper storage. These include hydrolysis and thermal degradation byproducts, which can compromise its quality. Therefore, the reference standard should be stored in tightly closed containers, in cool, dry places, protected from light and excessive heat (Chauhan & Choudhari, 2018).

When compared with Glucosamine hydrochloride USPRS, which has an expiry period of 72–84 months (United State Pharmacopoeia, 2024), glucosamine hydrochloride BPL produced by PPPOMN demonstrated twice the stability. This highlights the superior quality of glucosamine hydrochloride BPL, making it a reliable reference standard for pharmaceutical testing.

4. Conclusion

Glucosamine hydrochloride BPL was shown to be stable at the recommended storage temperature of 4–8°C for up to 144 months (12 years) and under transport or distribution conditions at 25°C and 60°C for up to 10 days. However, further studies with longer storage durations at 25°C and 60°C are necessary to confirm extended stability under these conditions. Overall, glucosamine hydrochloride BPL demonstrated assured quality and can be used as long as it is stored under the recommended storage conditions and shelf life. Information regarding storage conditions and shelf life should be clearly stated on the reference standard label.

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Analysis of Trends in Cosmetics Supervision Cases in Indonesia in 2021-2024

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ABSTRACT

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This study offers a comprehensive analysis of cosmetic product regulation in Indonesia from 2021 to 2024, examining enforcement trends, patterns of regulatory non-compliance, and the evolving oversight role of the Indonesian Food and Drug Authority (BPOM). Data were obtained from BPOM's annual inspection and enforcement reports and analyzed descriptively to identify changes in regulatory compliance over time. The results reveal that the majority of violations originated from Small and Medium-Sized Enterprises (SMEs), accounting for 1–2% of total cases, while larger industries reported slightly higher rates (2.7–6.9%). A significant 165% surge in products without distribution permits was recorded from 2021 to 2022, followed by substantial reductions in 2023 (85%) and 2024 (32%). Adherence to Good Cosmetic Manufacturing Practices (GCMF) showed a consistent improvement from 2022 onwards. Violations involving labeling, advertising, and product claims also declined, though more than 1,500 cases are still reported annually. Public education campaigns have played a crucial role in enhancing consumer awareness and minimizing exposure to unsafe products. Enforcement data further demonstrate a reduction in formal sanctions and warnings, reflecting BPOM's strategic pivot toward a more preventive and facilitative regulatory approach. Looking ahead, BPOM needs to strengthen industry compliance by expanding its technical assistance initiatives through both direct consultations and digital platforms, supporting a more risk-based and innovation-friendly regulatory environment.

Penelitian ini memberikan analisis komprehensif mengenai regulasi produk kosmetik di Indonesia pada periode 2021–2024, dengan menelaah tren penegakan hukum, pola ketidakpatuhan regulasi, serta peran pengawasan Badan Pengawas Obat dan Makanan (BPOM) yang terus berkembang. Data diperoleh dari laporan tahunan inspeksi dan penindakan BPOM, kemudian dianalisis secara deskriptif untuk mengidentifikasi perubahan kepatuhan regulasi dari waktu ke waktu. Hasil penelitian menunjukkan bahwa sebagian besar pelanggaran berasal dari Usaha Mikro, Kecil, dan Menengah (UMKM), dengan kontribusi sebesar 1–2% dari total kasus, sementara industri besar menunjukkan tingkat pelanggaran sedikit lebih tinggi (2,7–6,9%). Peningkatan signifikan sebesar 165% dalam jumlah produk tanpa izin edar tercatat dari 2021 ke 2022, diikuti penurunan substansial pada 2023 (85%) dan 2024 (32%). Kepatuhan terhadap Cara Pembuatan Kosmetika yang Baik (CPKB) menunjukkan peningkatan konsisten sejak 2022. Pelanggaran terkait penandaan, iklan, dan klaim produk juga menurun, meskipun lebih dari 1.500 kasus masih dilaporkan setiap tahunnya. Kampanye edukasi publik memainkan peran penting dalam meningkatkan kesadaran konsumen dan meminimalkan paparan terhadap produk berisiko. Data penegakan juga menunjukkan penurunan jumlah sanksi formal dan peringatan, mencerminkan

pergeseran strategi BPOM menuju pendekatan regulasi yang lebih preventif dan fasilitatif. Pada masa mendatang, direkomendasikan agar BPOM memperluas inisiatif bantuan teknis melalui konsultasi langsung dan pemanfaatan platform digital sebagai strategi untuk meningkatkan kepatuhan industri serta membangun sistem regulasi yang berbasis risiko dan mendukung inovasi.

Keywords: Cosmetics, compliant, cosmetic non-compliant, supervision regulations
Kata Kunci: Kosmetik, kepatuhan, ketidakpatuhan kosmetik, regulasi pengawasan

1. Introduction

Cosmetics are defined as substances or preparations intended to be applied to the external parts of the human body, including the skin, hair, nails, lips, external genital organs, teeth, and oral mucosa with the purpose of cleaning, perfuming, changing appearance, correcting body odors, or protecting and maintaining these areas in good condition (Badan Pengawas Obat dan Makanan, 2020). However, regulatory definitions and categorizations of cosmetics vary considerably across jurisdictions, creating inconsistencies in international supervision and enforcement mechanisms (Su et al., 2020). Such divergence poses challenges for global harmonization, particularly in ensuring consumer safety and enabling effective cross-border regulatory coordination.

Globally, the cosmetics industry has witnessed robust growth. According to the Indonesian French Chamber of Commerce and Industry (IFCCI), the Indonesian cosmetics market was projected to grow at a compound annual growth rate (CAGR) of 7.5% from 2021 to 2027, making it the fastest-growing market in Asia and positioning it among the top five global markets within the next 5–10 years (EIBN, 2019). In 2023, the industry's revenue reached USD 8.09 billion and was projected to increase to USD 9.17 billion in 2024 (Mileneo, 2024). This expansion has been driven by consumer demand, digital marketing penetration, and regulatory reforms, such as the streamlined cosmetic notification process introduced by the Indonesian Food and Drug Authority (BPOM). As of 2024, over 90,000 new cosmetic distribution permits had been issued, reflecting both regulatory facilitation and market responsiveness (Kashuri, 2024b).

However, the rapid market expansion has also brought significant regulatory challenges. BPOM reported that illegal cosmetics accounted for 144 out of 335 regulatory violations, representing 43% of all food and drug violations in Indonesia (Marchelin, 2020). These violations include the use of hazardous ingredients, mislabeling, and the distribution of unregistered products. BPOM's publicly accessible database (Direktorat Standardisasi Obat Tradisional, 2024) identifies 947 cosmetic products containing banned substances and highlights 16 products that, although registered as cosmetics, were marketed and used as medicines.

Underlying these violations are various systemic and behavioral factors. Yunianto and Anggoro (2021) identified several causes of illegal cosmetic marketing, including limited consumer awareness, the difficulty of verifying legality, opportunistic behavior by sellers, and weak marketplace surveillance. Wijanarko and Anggoro (2021) further revealed that compliance with Good Manufacturing Practices (GMP) imposes substantial operational costs, particularly in building maintenance, sanitation, and quality control, which may discourage small manufacturers from full adherence. Similarly, Othman et al. (2020) observed that prohibited substances are still prevalent in Malaysian cosmetics, leading to

adverse consumer outcomes and highlighting the need for strict legal enforcement against violators.

Globally, other regulatory authorities have also faced similar issues. For instance, Teixeira et al. (2019) documented safety issues in Brazil based on retrospective analyses from 2006 to 2018, while Ribet et al. (2021) emphasized the importance of cosmetovigilance in improving dermo-cosmetic product safety. Mercader-García et al. (2024) identified allergic reactions associated with phenylethyl resorcinol in Spain, and Vieira et al. (2024) reported the recall of non-compliant products in Portugal due to health risks. Pratiwi et al. (2022) reviewed analytical techniques to detect restricted substances in cosmetics under FDA and EU law. Meanwhile, Barthe et al. (2021) presented advances in alternative testing models to assess genotoxicity and skin irritation without animal testing. In the context of emerging technologies, Yustina et al. (2024) emphasized the need for nano-analysis instruments to monitor nano-cosmetic safety in Indonesia.

Despite extensive efforts by BPOM to safeguard public health, including controlling harmful substances and monitoring dangerous foods (Najemi et al., 2019; Indradewi & Muliati, 2022; Sutriyono et al., 2024), challenges remain. These include limitations in human resources and technology, as well as low public awareness regarding the importance of purchasing safe and authorized cosmetics (Kashuri, 2024a).

Regionally, Indonesia aligns its cosmetic regulation with the ASEAN Cosmetic Directive (ACD), which aims to harmonize safety and technical standards across Southeast Asia. The ACD adopted in 2003 and implemented in 2008 includes eight technical documents covering product definitions, labeling, GMP, safety assessment, and limits of contaminants (Health Sciences Authority (HSA), 2002; Oindrila Ghosal, 2025). At the international level, the Scientific Committee on Consumer Safety (SCCS) of the EU has published the 12th revision of its safety evaluation guidance (Scientific Committee on Consumer Safety of European Union, 2023). Morel et al. (2023) compared regulatory regimes across 17 countries, including ASEAN members, revealing diverse approaches to ingredient restrictions and product approval. Similarly, Ferreira et al. (2022) analyzed regulatory variations between the EU, US, Canada, Japan, China, and Brazil, providing a comparative perspective for policy development. Table 1 summarizes Indonesia's regulatory structure based on these international and national standards.

In addition to aligning with international frameworks, Indonesia requires halal certification for all cosmetic products by October 17, 2026, as mandated by Law No. 33 of 2014, Article 33 (LPPOM MUI, 2024). A comprehensive overview of the registration process is available in Investinasia (Mulya, 2023).

This study aims to analyze trends in BPOM's cosmetic surveillance activities between 2021 and 2024, with a focus on the typology, frequency, and implications of regulatory violations. It also evaluates the contributing factors behind non-compliance and the effectiveness of existing regulatory responses. By offering empirical insights into industry behavior and policy implementation, the findings are expected to support evidence-based decision-making among regulators, industry stakeholders, and consumers.

2. Methods

This research employed a quantitative, descriptive-analytical methodology to examine trends in the supervision of cosmetic products in Indonesia between 2021 and 2024. A retrospective study design was applied, drawing upon primary data extracted from the

official post-marketing surveillance reports published annually by the Indonesian Food and Drug Authority (Hess, 2004). These surveillance reports provided comprehensive and systematic documentation, encompassing metrics such as the number of registered and unregistered cosmetic products, inspection results of manufacturing facilities, identified cases of non-compliant products, violations concerning advertising, labelling, and marketing claims, as well as regulatory enforcement measures implemented during the observation period.

Table 1. Summary of the Regulation for Cosmetics in Indonesia.

Name of the Regulation	Number of the Regulation	Brief description
Cosmetics Production Permit	Minister of Health of the Republic of Indonesia, No. 1175/MENKES/PER/VIII/2010 of 2010 (Kementerian Kesehatan, 2010a)	This regulation outlines the requirements and procedures for obtaining a production permit for cosmetics in Indonesia.
Supervision of Cosmetics Production and Distribution	Peraturan BPOM No 12, 2023 (Badan Pengawas Obat dan Makanan, 2023a)	This regulation outlines the general provisions, procedures for supervision, administrative sanctions, and closing provisions to ensure that cosmetics production and distribution comply with safety, quality, and environmental sustainability standards.
Amendment to the BPOM Regulation Number 23 Year 2019 Concerning Technical Requirements for Cosmetic Ingredients	Peraturan BPOM No 17, 2022 (Badan Pengawas Obat dan Makanan, 2022a)	This Regulation No. 17, 2022, is an amendment to Regulation No. 23, 2019. It updates the technical requirements for cosmetic ingredients to align with advancements in science and technology, ensuring the safety, quality, and efficacy of cosmetic products
Good Manufacturing Practice (GMP) Certification for Cosmetics	Peraturan BPOM No 33, 2021 (Badan Pengawas Obat dan Makanan, 2021)	This Regulation sets forth the requirements for certifying good manufacturing practices in the cosmetics industry. Adhering to specific standards and guidelines aims to ensure that cosmetic products are produced safely, effectively, and consistently.
Amendment to the BPOM Regulation Number 27 Year 2022 Concerning Supervision of the Importation of Drugs and Food into Indonesian Territory	Peraturan BPOM No 28, 2023 (Badan Pengawas Obat dan Makanan, 2023b)	This Regulation is an amendment to BPOM Regulation No. 27, 2022. It updates the regulations concerning the supervision of the importation of drugs and food into Indonesian territory to ensure compliance with legal and safety standards
Technical Requirements for Cosmetics Labeling	Peraturan BPOM No 30, 2020 (Badan Pengawas Obat dan Makanan, 2020)	This regulation specifies the necessary information that must be included on cosmetic product labels to ensure they are clear, accurate, and not misleading for consumers. It aims to protect consumer health and provide transparency about cosmetic products.
Labeling, Promotion, and Advertising of Cosmetics	Peraturan BPOM No 18, 2024 (Badan Pengawas Obat dan Makanan, 2024)	This regulation replaces several previous Regulations and aims to ensure that cosmetic products are labeled accurately, promoted responsibly, and advertised truthfully to protect consumer rights and safety.

Table 1. (Continued).

Name of the Regulation	Number of the Regulation	Brief description
Technical Requirements for Cosmetic Claims	Peraturan BPOM No 3, 2022 (Badan Pengawas Obat dan Makanan, 2022c)	This regulation aims to ensure that claims made about cosmetic products are accurate, not misleading, and supported by scientific evidence to protect consumer rights and safety.
Technical Requirements for Cosmetics	Peraturan BPOM No 19, 2015 (Badan Pengawas Obat dan Makanan, 2015)	This regulation outlines the standards for safety, quality, labeling, and claims of cosmetic products to ensure they meet regulatory requirements and protect consumer health.
Cosmetics Notification	Minister of Health of the Republic of Indonesia, No. 1176/MENKES/PER/VIII/2010 of 2010 (Kementerian Kesehatan, 2010b)	This regulation outlines the requirements for notifying the Ministry of Health about cosmetic products before they are marketed. The aim is to ensure that all cosmetics meet safety, quality, and efficacy standards to protect consumer health.

3. Results and Discussion

Table 2 provides a summary of the laboratory testing results for samples of commercial cosmetics collected in Indonesia between 2021 and September 2024. The ratio of non-compliant to compliant products was relatively low, ranging from approximately 1% to 2%. Most non-compliant products originated from Small and Medium-Sized Enterprises (SMEs). In contrast, large-scale industries accounted for only 2.7% and 6.9% of the non-compliant cosmetics in 2022 and 2021, respectively. These findings underscore the importance of enhancing BPOM's technical assistance programs to support SMEs. Imported non-compliant cosmetics rose from 8.4% in 2021 to 18.0% in 2024, potentially due to an increase in the importation of cosmetics without an Import Certificate (Table 3, violation indicator number 4). Skincare products represented the largest category of non-compliant cosmetics, ranging from 72.7% in 2024 to 84.5% in 2021. The list of hazardous substances found in cosmetics marketed in Indonesia is published in the database of the Direktorat Standardisasi Obat Tradisional BPOM (Direktorat Standardisasi Obat Tradisional, 2024).

Developing more advanced analytical methods to detect hazardous ingredients in cosmetics is essential to improve the effectiveness of regulatory oversight, particularly considering the increasing number of imported products. Although analytical technologies have significantly improved, the complex composition of cosmetic matrices and the presence of various trace-level unauthorized additives continue to pose challenges. Therefore, the application of suitable pre-treatment techniques becomes crucial. Du et al. (2024) offer a comprehensive overview of the development of pre-treatment techniques tailored to different cosmetic types, including emulsified, liquid, powdered, and wax-based matrices.

Table 2. BPOM Surveillance Results from Laboratory Testing

Criteria	Years			
	2021	2022	2023	2024 ^a
1. Laboratory Testing:				
a. Compliant	22,591	25,502	24,941	17,688
b. Non-compliant	259	367	329	300

Table 2. (Continued).

Criteria	Years			
	2021	2022	2023	2024 ^a
2. Non-Compliance Category :				
a. Containing PRC ^{b, d}	46	159	154	126
b. Containing PAT ^{c, d}	213	208	175	174
3. Non-compliant Cosmetic Producer.				
a. Large scale	18	10	12	11
b. SMEs ^e	219	307	271	235
c. Importers	22	50	46	54
4. Type of non-compliant cosmetics:				
a. Skincare	219	298	256	218
b. Decorative	40	69	73	82

Note: ^aData from January to September 2024, ^bCosmetics contain prohibited or restricted pharmaceutical/chemical compound(s), ^cCosmetics contain permitted substance(s) with a concentration above the threshold limit, ^d The list of permitted and prohibited compounds and their concentrations are described by BPOM Regulation No 17, 2022 (Badan Pengawas Obat dan Makanan, 2022a), ^e SMEs: Small and Medium-Sized Enterprises.

Table 3 outlines routine inspection activities conducted in factories, distribution centers, and retail outlets, covering document review, field observation, and stakeholder interviews. Seven violation categories were identified. Products deemed non-compliant during these inspections were subject to sampling and laboratory testing. However, the actual number of non-compliant cosmetics found through lab testing far exceeds those flagged through routine inspections (refer to Table 2, violation category 2; Table 3, violation category 2). This poses a significant concern for consumers who are exposed to potentially harmful products. It highlights the urgency to increase sampling rates in the market. Approximately 1–2% of cosmetics currently available may contain harmful substances that could adversely affect health (Table 2, violation indicator number 1).

Table 3 (violation indicator number 1) shows that the production and distribution of cosmetics without a distribution permit rose by 165% from 2021 to 2022, followed by declines to 85% in 2023 and 32% in 2024. Additionally, the production of cosmetics not adhering to GMP standards declined substantially in 2023 and 2024 (violation indicator number 3). The surge in imported cosmetics without Import Certificates from 2022 to 2024 (violation indicator number 4), driven by e-commerce expansion and illegal trade, reflects the need for BPOM to strengthen digital-based supervision mechanisms. Big data analytics and artificial intelligence have great potential in the early detection of illegal cosmetic products on digital platforms. Kalia et al. (2023) demonstrated that social influences have a significant impact on consumer behavior during online shopping.

Table 3. Summary of the Violations Committed Observed in Factories, Distributors, and Stores

No.	Violation Criteria	Years				Regulation Violated
		2021	2022	2023	2024	
1.	Producing/ distributing cosmetics without a distribution permit	696	1,448	1,230	459	- Regulation of the Minister of Health of the Republic of Indonesia No. 1175/MENKES/PER/VIII/2010 of 2010 on Cosmetic Production Permit. (Kementerian Kesehatan, 2010a) - BPOM Regulation No. 12 of 2023 on the Supervision of Cosmetics Production and Distribution (Badan Pengawas Obat dan Makanan, 2023a)
2.	Producing/ distributing cosmetics containing pharmaceutical/prohibited compounds	9	2	5	30	BPOM Regulation No. 17 of 2022 on Amendments to BPOM Regulation No. 23 of 2019 on Technical Requirements for Cosmetic Ingredients (Badan Pengawas Obat dan Makanan, 2022a)
3.	Producing cosmetics that do not comply with the GMP	87	101	52	33	BPOM Regulation No. 33 of 2021 on Certification of Good Cosmetic Manufacturing Practices (Badan Pengawas Obat dan Makanan, 2021)
4.	Importing cosmetics without an Import Certificate	NA	50	48	181	BPOM Regulation No. 28 of 2023 on Amendments to BPOM Regulation No. 27 of 2022 on the Oversight of Drug and Food Importation into the Territory of Indonesia (Badan Pengawas Obat dan Makanan, 2023b)
5.	Labeling Violations	6,413	3,792	2,599	1,712	- BPOM Regulation No. 30 of 2020 on Technical Requirements of Cosmetics Label (Badan Pengawas Obat dan Makanan, 2020) - BPOM Regulation No. 18 of 2024 on Labelling, Promotion, and Advertising of Cosmetics (Badan Pengawas Obat dan Makanan, 2024)
6.	Violations of Advertising and Claim Practices	5,575	6,165	4,497	1,782	- BPOM Regulation No. 18 of 2024 on Labelling, Promotion, and Advertising of Cosmetics (Badan Pengawas Obat dan Makanan, 2024) - BPOM Regulation No. 3 of 2022 on Technical Requirements for Cosmetic Claims (Badan Pengawas Obat dan Makanan, 2022c) - BPOM Regulation No. 19 of 2015 on Technical Requirements for Cosmetics (Badan Pengawas Obat dan Makanan, 2015)
7.	Injectable products registered as cosmetics	NA	NA	4	15	- Regulation of the Minister of Health of the Republic of Indonesia Number 1176/MENKES/PER/VIII/2010 of 2010 on Cosmetic Notification (Kementerian Kesehatan, 2010b) - BPOM Regulation No. 21 of 2022 on Procedures for Submitting Cosmetic

No.	Violation Criteria	Years				Regulation Violated
		2021	2022	2023	2024	

Notifications (Badan Pengawas Obat dan Makanan, 2022b)

Table 3 (violation indicators 5 and 6) also shows a decline in violations related to labeling, claims, and advertising between 2021 and 2024. However, the total number of such cases remained relatively high, exceeding 1,500 annually. This indicates the importance of public education campaigns to raise awareness of the risks of unsafe cosmetics. Nayak et al. (2023) emphasized the necessity of understanding the potential health risks associated with cosmetics and using them appropriately to reduce adverse effects. Establishing a cosmetovigilance system could help minimize these events.

Table 4. Enforcement Actions of the BPOM Regulatory Violations

No.	Violation Criteria and Sanction	Years			
		2021	2022	2023	2024

1. Producing/ distributing cosmetics without a distribution permit:
 - a. Temporary suspension of activities NA NA NA 3
 - b. Written Warning/ Recall Order/ Destruction 696 1,448 1,230 459
 - c. Notification suspension NA NA 22 NA
2. Producing/ distributing cosmetics containing pharmaceutical/ prohibited compounds:
 - a. Temporary suspension of activities NA NA 1 4
 - b. Revoke the distribution permit 7 2 5 27
 - c. Written Warning/ Recall Order/ Destruction 9 2 3 29
 - d. Closure of notification access NA NA NA 5
 - e. Closure of import certificate access NA NA NA 2
3. Producing cosmetics that do not comply with the GMP:
 - a. Temporary suspension of activities NA NA 1 1
 - b. Written Warning 87 101 52 33
4. Importing cosmetics without an Import Certificate:
 - a. Written warning NA 50 48 NA
 - b. Destruction order NA NA NA 152
 - c. Closure of electronic public services access NA NA NA 29
 - d. Closure of import access
5. Labeling Violations:
 - a. Technical guidance 5,936 3,438 2,238 1,359
 - b. Written warning 477 354 361 353
 - c. Revoke the distribution permit NA NA NA NA
6. Violations of advertising and claim practices:
 - a. Technical guidance 3,260 4,079 728 695
 - b. Written warning 2,315 2,086 3,769 1,083
 - c. Revoke the distribution permit NA NA NA NA
7. Injectable products registered as cosmetics:
 - a. Revoke the distribution permit NA NA 4 15
 - b. Temporary suspension of activities NA NA 1 NA
 - c. Notification suspension NA NA 2 2
 - d. Import certificate access suspension NA NA 1 NA

Note: NA (Not Available) indicates that no violations were found during the respective sampling and inspection activities.

In 2023 and beyond, BPOM identified injectable products that were incorrectly categorized as cosmetics (violation indicator number 7). These findings suggest that every possible method is being used to distribute cosmetics, including deceptive practices. It is therefore critical that BPOM enhances its market monitoring efforts, especially for cosmetics distributed online.

Table 4 summarizes enforcement actions undertaken by BPOM from 2021 to 2024 in response to the violations outlined in Table 3, seventh column. A single violation may lead to multiple sanctions. For example, in 2024, 459 violations involving the unauthorized production or distribution of cosmetics resulted in 459 written warnings and three temporary operational suspensions (violation indicator number 1). The total number of written warnings, recall orders, and destruction notices increased from 2021 to 2022 but declined from 2022 to 2024 for violation number 1. Written warnings for violation indicators 5 and 6 also saw a decreasing trend from 2021 to 2024. Meanwhile, the number of revoked distribution permits and recall/destruction orders for violation indicator number 2 significantly increased in 2024. For violation indicator 3 (labeling), no distribution permits were revoked, although a small number were revoked for violations related to advertising and product claims (violation indicator number 6). As shown in Tables 3 and 4, some years or categories display the notation “NA,” which signifies that no violations were identified during the inspection or sampling period. This may reflect full compliance or a limited scope of surveillance during that time.

Although the number of injectable products falsely registered as cosmetics remains small, it demonstrates attempts to circumvent the classification of medical products. This further underscores the need for clear definitions between medical and cosmetic categories, along with stricter cross-sectoral supervision. All injectable products registered as cosmetics were eventually revoked (violation indicator number 7). A review of BPOM’s enforcement data from 2021 to 2024 reveals a downward trend in technical guidance sanctions and written warnings, suggesting a regulatory shift toward a more supportive and proactive approach. Going forward, BPOM is expected to expand its technical assistance initiatives through direct consultations and **interactive digital platforms such as webinars**.

The declining trend in certain violation types may reflect improved enforcement effectiveness (Tables 2–5). Nevertheless, fluctuation in specific categories signals persistent challenges in cosmetic product oversight. Globally, regulators continue to face difficulties in controlling new cosmetic ingredients, calling for flexible yet robust risk-based regulations. Collaborative approaches with customs and other agencies can strengthen prevention efforts against the entry of illegal substances into Indonesia.

According to Su et al. (2020), regulations must remain adaptive to market dynamics by incorporating modern supervision technologies, fostering innovation, and prioritizing scientific research. Risk-based regulatory models implemented in developed countries (Scientific Committee on Consumer Safety of European Union, 2023) provide valuable frameworks that Indonesia can adopt to enhance its oversight of cosmetics. In line with this, (Kashuri, 2024b) offers concrete steps to safeguard domestic cosmetic products from being overwhelmed by imported alternatives, thereby promoting the growth of local industries.

4. Conclusions

This study reveals that the most prominent regulatory violations in Indonesia's cosmetic sector between 2021 and 2024 were related to unauthorized distribution, non-compliance with ingredient restrictions, deviations from Good Manufacturing Practices (GMP), misleading claims, and improper labeling practices. The findings underscore that despite regulatory modernization and intensified enforcement by BPOM, including risk-based surveillance strategies, significant compliance gaps persist, particularly in online distribution channels and imported products. Factors contributing to these violations include limited industry awareness, challenges in GMP implementation, and regulatory loopholes in ingredient control and advertising claims. The analysis emphasizes the importance of enhancing digital monitoring systems, strengthening cross-border collaboration under the ASEAN Cosmetic Directive, and improving public education to foster a culture of compliance. Insights from this study provide empirical support for risk-based and preventive regulatory approaches, offering valuable input for national policy formulation and future regional harmonization efforts.

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Profile of Herbal Medicine Registration Documents Compliance in 2021–2023 for Stunting Prevention

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Stunting is one of the indicators of social and economic problems in a country. As part of efforts to prevent stunting, one of the strategies that can be implemented is the use of herbal medicines. This study examines the registration process for herbal medicines aimed at preventing stunting, submitted to the Indonesian Food and Drug Authority (Badan POM) between 2021 and 2023. A total of 900 products have been registered with an increasing annual trend, indicating high interest from businesses in producing and registering these products. Although awareness of the importance of product registration to ensure safety and quality has increased, there are still significant issues related to the incompleteness of the necessary documents. This research showed that, on average, 77% of product submissions were still incomplete, particularly from the UKOT group, which accounted for 90%. This analysis found that aspects of quality and labeling often failed to meet the standards set by Badan POM Regulation No. 25 of 2023. The study suggests that simplifying the registration procedures and more targeted interventions, such as the provision of educational materials and more intensive training, can help address these issues. Additionally, the research recommends further surveys to specifically identify the obstacles faced by businesses, which will assist in the design of more effective policies to support the improvement of quality and speed in the product registration process in the future.

Stunting menjadi salah satu indikator dari permasalahan sosial dan ekonomi dalam suatu negara. Dalam rangka melakukan pencegahan stunting, salah satu upaya yang dapat dilakukan adalah pemberian obat tradisional. Pada penelitian ini dilakukan kajian proses registrasi produk obat tradisional untuk pencegahan stunting yang diajukan ke Badan Pengawas Obat dan Makanan (Badan POM) Indonesia selama periode 2021–2023. Sebanyak 900 produk telah didaftarkan dengan tren peningkatan tahunan, menunjukkan tingginya minat pelaku usaha dalam memproduksi dan mendaftarkan produk tersebut. Meskipun kesadaran akan pentingnya registrasi produk untuk memastikan keamanan dan mutu telah meningkat, masih terdapat masalah signifikan terkait dengan ketidaklengkapan dokumen yang diperlukan. Penelitian ini menunjukkan bahwa rata-rata 77% dari pengajuan produk masih belum lengkap dan kelompok usaha yang paling banyak mengajukan adalah Usaha Kecil Obat Tradisional (UKOT). Dari kelompok UKOT, pengajuan yang belum lengkap mencapai 90%. Analisis ini menemukan bahwa aspek mutu dan penandaan sering kali tidak memenuhi Peraturan Kepala BPOM Nomor 25 tahun 2023 tentang Kriteria dan Tata Laksana Registrasi Obat Bahan Alam. Penelitian ini menyarankan bahwa penyederhanaan prosedur registrasi dan intervensi yang lebih ditargetkan, seperti penyediaan materi sosialisasi dan pelatihan lebih intensif, dapat membantu mengatasi masalah ini. Selain itu, penelitian merekomendasikan survei lebih lanjut untuk mengidentifikasi secara spesifik hambatan yang dihadapi pelaku usaha, membantu dalam merancang kebijakan yang lebih efektif untuk mendukung peningkatan kualitas dan kecepatan proses registrasi produk di masa depan.

Keywords: stunting, herbal medicine, traditional medicine, product registration
Kata Kunci: stunting, obat herbal, obat tradisional, registrasi produk

1. Introduction

Stunting is a chronic nutritional disorder caused by prolonged nutrient deficiencies, which impairs children's physical growth, cognitive development, and future generational productivity (J et al., 2022). The prevalence of stunting serves as a critical indicator of a country's social and economic challenges (Nasrun & Rahmania, 2018; Musheiguza et al., 2023). The 2023 Indonesian Nutritional Status Survey, conducted by the Ministry of Health, reported that the prevalence of stunting in Indonesia remains high at 21.6%. (Kementerian Kesehatan RI, 2022). Stunting is also a national priority issue outlined in the 2020–2024 National Medium-Term Development Plan (RPJMN) (Pemerintah Republik Indonesia, 2020). This condition has long-term adverse impacts, including impaired physical growth and cognitive development (Mustakim et al., 2022). Ultimately, this reduces the quality of human resources and, consequently, affects national economic productivity in the long run. To accelerate the reduction of stunting, the utilization of safe and effective traditional medicines has emerged as a crucial solution.

One of the measures to prevent stunting is the use of herbal medicines with efficacy claims that support stunting prevention, such as improving nutritional value, preventing helminth infections (Kusuma et al., 2023), stimulating appetite (Kusuma et al., 2023), and promoting breast milk production (Subandrate et al., 2023). Previous studies, including that of Rahmah and Hassanah (2024), indicated that stunting prevention efforts may involve nutritional supplementation in both synthetic and herbal forms (Rahmah & Hasanah, 2024). Family Household medicinal plants, which are rich in nutrients, such as moringa leaves, have also been identified as alternatives for preventing stunting, particularly among pregnant women (Ifada et al., 2022).

The Directorate of Traditional Medicine, Health Supplements, and Cosmetics Registration (Dit. Reg OTSKK) of the Indonesian Food and Drug Authority (BPOM) conducts premarket registration evaluations for herbal medicinal products in accordance with BPOM's 2020 Strategic Plan. This evaluation covers the criteria of safety, quality, efficacy, and labeling, as stipulated in BPOM Regulation No. 25 of 2023. As a government institution, Dit. Reg OTSKK also supports the national stunting reduction program by expediting the marketing authorization of herbal medicinal products.

The registration process for traditional medicines involves assessing the documents submitted by applicants. These documents are evaluated according to a predetermined timeline. If corrections or additional data are required, applicants must provide the missing information within the specified deadline. Currently, stakeholders often face challenges in the registration process of herbal medicinal products, as evidenced by the frequent issuance of requests for additional registration data. These requests typically include administrative documents, safety, efficacy, quality, and labeling information that have not been fully completed during the registration process. Such challenges constitute obstacles to the issuance of marketing authorizations. This issue is reflected in the 2022 and 2023 Public Satisfaction Survey Reports of Dit. Reg OTSKK (Ditreg OTSKK, 2022, 2023), which

indicated that the service requirement scores were still lower compared to the other nine service components.

The issuance of marketing authorization for herbal medicines follows the provisions of BPOM Regulation No. 25 of 2023 on Criteria and Procedures for Herbal Medicine Registration, which require administrative, safety, efficacy, quality, and labeling documents (Badan POM, 2023). Compliance with these documentation requirements supports faster approval, ensuring the availability of herbal medicines in the market. The availability of herbal medicines for stunting prevention could support efforts to mitigate stunting. Ensuring that herbal medicines make a tangible contribution to reducing stunting prevalence is thus essential.

To date, no studies have analyzed the profile of herbal medicine registration document compliance for stunting prevention during 2021–2023. This research, therefore, aims to examine the completeness of registration documents based on the ASROT database, to determine the compliance profile of herbal medicine registration for stunting prevention at Dit. Reg OTSKK between 2021 and 2023. The profile can be utilized to identify challenges faced by businesses in preparing registration documents, thereby assisting them in compliance. The findings are also expected to provide recommendations for the Directorate to accelerate the issuance of marketing authorizations for herbal medicines aimed at preventing stunting.

2. Methodology

This study employed a descriptive design conducted at the Directorate of Traditional Medicine, Health Supplements, and Cosmetics Registration (Dit. Reg OTSKK) of the Indonesian Food and Drug Authority (BPOM). A total of 900 data entries were collected from the registration database (ASROT). The data included herbal medicinal products intended for stunting prevention, which were classified by business types (IOT, UKOT, UMOT, and importers) during the period from 2021 to 2023. Herbal medicinal products classified under stunting prevention included those with claims such as maintaining health by improving nutritional intake, stimulating appetite, preventing helminth infections, and promoting breast milk production.

The data obtained were analyzed using Microsoft Excel to determine median values. The analysis aimed to identify trends in the number of product submissions, the percentage of incomplete documentation, and document compliance profiles based on business type. Based on this analysis, the business group with the highest frequency of incomplete documents was examined further to assess aspects of registration document completeness, including administration, quality, efficacy/safety, and labeling/packaging.

3. Results and Discussion

3.1. Profile of Product Registration Submissions

Based on Figure 1, the number of herbal medicinal product submissions for stunting prevention registered with BPOM increased year by year from 2021 to 2023. The growing number of products indicates an increasing interest among business actors in producing herbal medicines that are beneficial for stunting prevention. Business actors have also become more aware of the importance of registering their products before market distribution to ensure the safety and quality of the products.

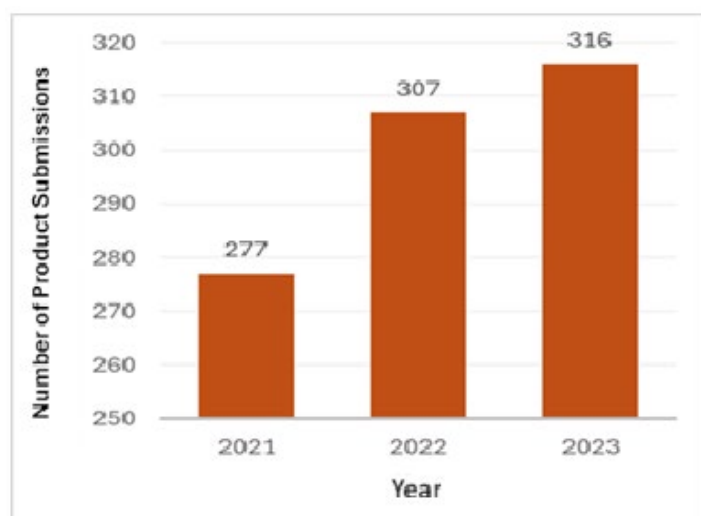


Figure 1. Number of Product Submissions

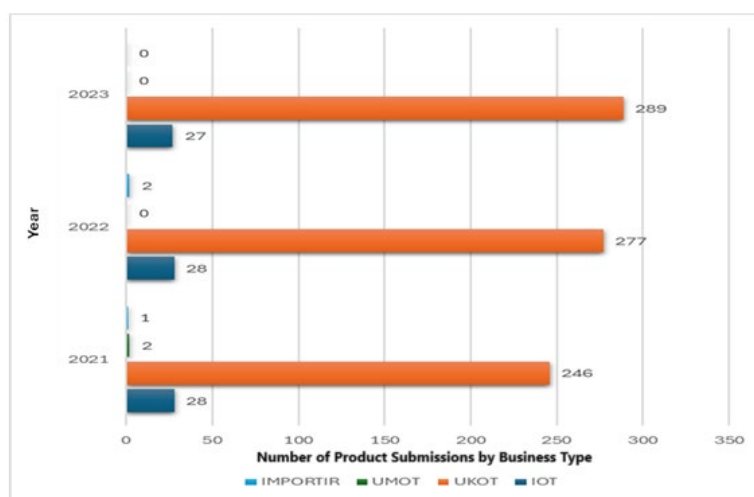


Figure 2. Number of Product Submissions by Business Type

As illustrated in **Figure 2**, most product submissions were registered by the Small-Scale Traditional Medicine Enterprises (UKOT). Both UKOT and Micro-Scale Traditional Medicine Enterprises (UMOT) fall under the Micro, Small, and Medium Enterprises (MSMEs) category; however, relatively few products were submitted by UMOT, with a submission ratio of 1:120 compared to UKOT. UMOT product submissions were extremely limited, totaling only 2 out of 900 products, and were restricted to raw herbal cuts. According to BPOM Regulation No. 25 of 2023, the dosage forms that UMOT can produce are limited to topical powders, plasters, ointments, external liquids, and raw herbal cuts. Meanwhile, herbal medicines for stunting prevention are commonly available in oral dosage forms, such as decoctions, powders, granules, pills, capsules, tablets, oral liquids, and other oral preparations, which can only be produced by UKOT or IOT. Importers rarely submitted herbal medicines for stunting prevention, as their target consumers mainly were middle- to upper-class groups who generally do not experience stunting. These findings align with a

study by Bustos et al. (2023), conducted among 3,005 children in the Philippines, which found a correlation between household welfare index and stunting prevalence, with children from low-welfare families more likely to suffer from stunting (Bustos et al., 2023).

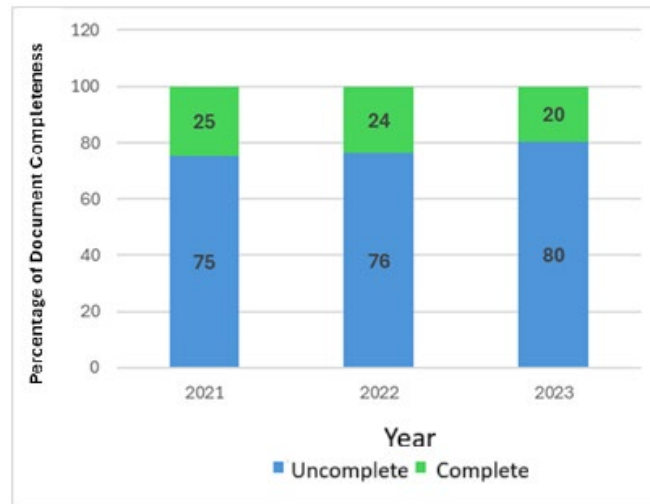


Figure 3. Percentage of Document Completeness

As shown in Figure 3, the proportion of incomplete documents at the time of submission was consistently higher than that of complete documents across all three years. The incompleteness rate, ranging between 75–80%, may be attributed to several factors, including limited understanding of registration regulations and procedures, as well as human resource constraints, which made it difficult for business actors to meet all requirements. This finding is consistent with Santiago and Estiningrum (2021), who demonstrated that the educational background of MSME operators significantly influences their level of understanding and perception (Santiago & Estiningrum, 2021). Businesses led by individuals with higher education levels tend to better comprehend registration requirements and procedures, thereby preparing documents more effectively.

3.2. Profile of Document Compliance

3.2.1 Compliance by Business Type

The mapping of incomplete registration submissions by business type revealed that the highest percentage of incomplete submissions came from UKOT, ranging from 88% to 91% (Figure 4). The rate of incompleteness remained consistently high and even increased by 3% in 2023 from 88% to 91%. This issue requires urgent attention, as the high percentage reflects insufficient understanding of the registration process among these businesses, necessitating more intensive and immediate interventions.

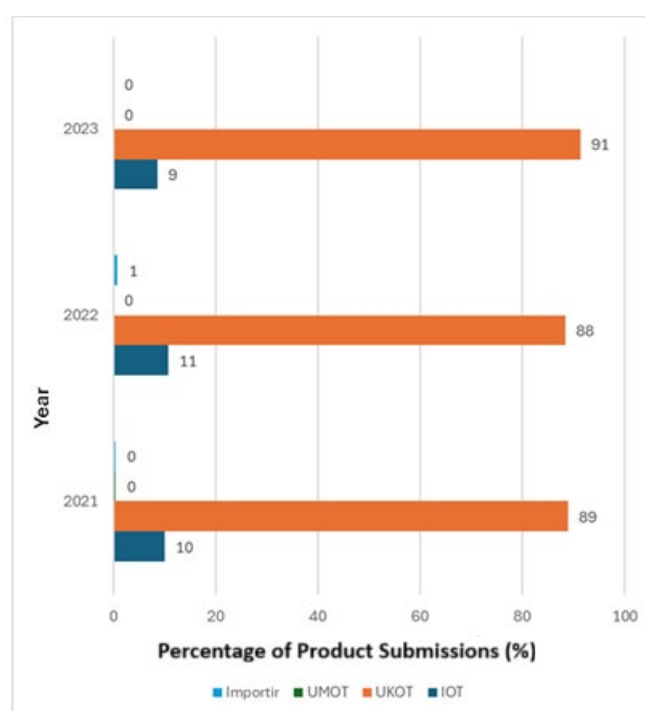


Figure 4. Percentage of Document Compliance by Business Type
(IOT: Traditional Medicine Industry, UKOT: Small-Scale Traditional Medicine Enterprise, UMOT: Micro-Scale Traditional Medicine Enterprise, Importers)

UKOT, as part of the MSME category, continues to face challenges in fulfilling registration document requirements, primarily due to the limited understanding of business actors regarding regulations and the requirements for registration. This analysis is supported by previous studies, which indicate that MSMEs generally have insufficient regulatory knowledge, largely due to limited access to information and outreach activities (Aisyah et al., 2023; Akim et al., 2019). Although these studies focused on food industry MSMEs, similar challenges are likely to occur among herbal medicinal product (HMP) business actors, considering that both sectors fall under the MSME category and share similar characteristics, such as limited human resources. This evidence suggests that lack of regulatory knowledge and restricted access to information can constitute a common barrier for MSMEs, including those in the herbal medicine sector. Human resources play a critical role in industry performance; therefore, enhancing competencies is essential to maintain competitive advantage over other enterprises (Tampubolon, 2016). Other studies also indicate that inadequate human resources and limited capital are significant constraints faced by MSMEs, which hinder their business development (Suryani, 2018).

Online product registration also requires business actors to possess adequate technological skills. Many MSMEs still face limitations in digital technology proficiency. The lack of technological capability among business actors has been identified as a factor contributing to difficulties in registering their products (Nugrahenti et al., 2021). This finding is consistent with research indicating that insufficient information technology skills hinder business actors during online registration processes (Ningrum, 2022). Providing guidance and support to business actors throughout the online registration process can serve

as an alternative solution to overcome these obstacles, enabling them to register their products independently. Based on Figures 2 and 4, UKOT accounted for the highest number of product submissions and a substantial proportion of incomplete documents, averaging 90%. Therefore, the discussion will focus on the UKOT group.

3.2.2 Compliance Profile within UKOT

Among the four required documentation aspects—administration, quality, efficacy/safety, and labeling—quality and labeling documents were most frequently incomplete. Labeling incompleteness often occurred because businesses prioritized marketing strategies to boost sales, designing visually attractive labels that did not comply with regulatory requirements. Research by Nurcahyani and Wahyudi (2024) found that 54% of 100 food MSMEs in Surabaya failed to comply with labeling regulations, while 33% did not include labels at all. Interviews with business operators revealed that these violations stemmed from internal factors, such as a lack of awareness and understanding of the importance of labeling, as well as external factors including market competition, regulatory complexity, associated costs, and regulatory ambiguity. (Nurcahyani & Wahyudi, 2024).

Meanwhile, the incompleteness of quality documentation was linked to the complexity of quality requirements, which not all UKOT could meet due to inadequate or incomplete laboratory facilities for product testing. The study showed that out of 98 UKOT in Central Java, only 5 UKOT, or approximately 5%, were able to fulfill all aspects of CPOTB. Sixty-three UKOT (64%) only met the requirements of CPOTB Stage I, while 26 UKOT (27%) had not yet met any of the CPOTB aspects (Suwarni et al., 2022). However, this study emphasizes the importance of quality documentation, as labeling deficiencies are not considered rigid requirements and may be included as supplementary notes in product approval if the other three aspects are met.

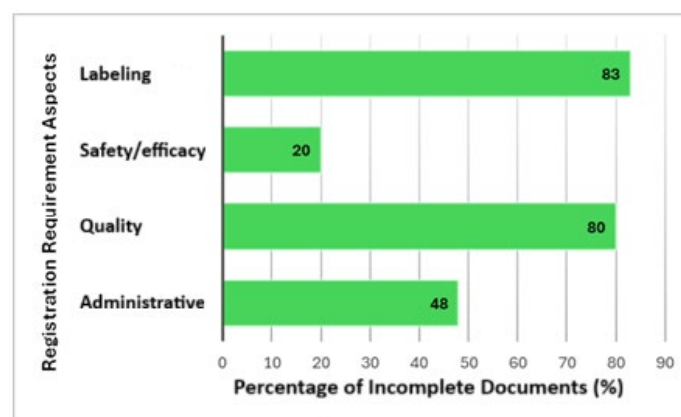


Figure 5. Compliance Profile within UKOT

This study highlights the diverse challenges faced by business actors in registering herbal medicines for stunting prevention in Indonesia from 2021 to 2023. The findings indicate that fulfilling administrative, safety, efficacy, and quality requirements remains a significant obstacle in obtaining marketing authorization, particularly regarding the provision of high-quality data. Nevertheless, compliance with these requirements is essential to ensure product

safety, quality, and efficacy. Therefore, interventions should focus on providing practical education for businesses, such as targeted awareness programs emphasizing quality documentation and continuous coaching clinics. The development of pocket guides illustrating registration procedures and requirements, supplemented with document samples, is also recommended to facilitate compliance.

This study provides an initial overview of the level of compliance with traditional medicine registration documents, which has not been previously investigated. However, the study has limitations in providing an in-depth explanation of the challenges causing incomplete registration documents. The primary limitation is the absence of survey or interview methods with business actors as a data collection approach. Therefore, the analyzed data are limited to information obtained from the product registration database, which does not comprehensively capture the root causes of the challenges faced by business actors. Further research using qualitative approaches (survey and interview methods) is necessary to complement these findings and provide a more thorough understanding. Additionally, measuring the impact of accelerating marketing authorization for herbal medicinal products (HMP) aimed at stunting prevention is required to assess its effect on reducing stunting rates as part of an evaluation process.

4. Conclusion

This study demonstrated an increase in the number of herbal medicinal product submissions for stunting prevention in Indonesia during the 2021–2023 period, reflecting a growing awareness among business actors of the importance of product registration. Nevertheless, significant challenges persist in meeting documentation requirements, with incompleteness rates ranging from 75% to 80%. The highest rate of incompleteness was observed in the UKOT group, ranging from 88% to 91%. This is likely due to a limited understanding of regulations, as well as constraints in human resources and technology.

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Analytical Hierarchy Process Approach in Determining the Weight of Crime Vulnerability Information in Food and Drug Control

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ABSTRACT / ABSTRAK

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Referring to the previous 2020-2024 RPJMN period, it has been identified that the existing court decision indicators for convictions do not encompass all functions within the Deputy of Law Enforcement of The Indonesian Food and Drug Authority (Indonesian FDA), thereby failing to holistically represent the effectiveness of law enforcement against drug and food crimes. One strategic activity not reflected in these indicators is the crime vulnerability mapping function within the Law Enforcement Dashboard (ADP). However, the crime vulnerability mapping system remains limited due to its inability to assign weighted values based on the accuracy of information during data input. Addressing this issue, a study was conducted to develop a crime vulnerability score for drug and food crimes based on information source criteria, serving as a proposed consideration for designing performance indicators for the upcoming RPJMN period. Employing a mixed-methods approach, the study utilized quantitative methods through Analytical Hierarchy Process (AHP) and qualitative methods through surveys, involving 33 respondents from diverse backgrounds. The findings revealed that the highest-weighted information source criteria in assessing crime vulnerability were Investigation Results on Drugs and Food (0.225), Intelligence Operations Results on Drugs and Food (0.150), and Surveillance Results on Drugs and Food (0.141). These findings can be further elaborated through broader surveys involving experts in drug and food crime prevention, enabling the proposed "Drug and Food Crime Vulnerability Index" to be advanced as an output indicator for the Indonesian FDA Law Enforcement program objectives.

Merujuk pada periode RPJMN 2020-2024, diketahui Indikator Kinerja putusan pengadilan yang dinyatakan bersalah belum mencakup seluruh fungsi di Deputy Bidang Penindakan Badan POM sehingga belum dapat menggambarkan secara holistik bagaimana efektivitas penegakan hukum terhadap kejahatan Obat dan Makanan. Salah satu kegiatan strategis yang belum tergambar dalam indikator tersebut adalah fungsi pemetaan kerawanan kejahatan yang terintegrasi pada Aplikasi Dashboard Penindakan (ADP). Namun, pemetaan kerawanan kejahatan masih memiliki keterbatasan karena belum mampu memberikan bobot nilai sesuai dengan akurasi informasi pada saat dilakukan input data. Berdasarkan permasalahan tersebut, maka dilakukan penelitian yang bertujuan untuk menyusun nilai kerawanan kejahatan Obat dan Makanan berdasarkan kriteria sumber informasi, sebagai salah satu pertimbangan usulan dalam pemantauan indikator kinerja. Penelitian dilakukan menggunakan metodologi mix method yaitu melalui pendekatan kuantitatif menggunakan Analytical Hierarchy Process (AHP) dan pendekatan kualitatif menggunakan survei, dengan melibatkan 33 responden yang berasal dari latar belakang yang beragam. Hasil penilaian menunjukkan bahwa kriteria sumber informasi dengan bobot tertinggi dalam penilaian kerawanan kejahatan Obat dan Makanan yaitu Hasil Penyidikan Obat dan Makanan (0,225), Hasil Kegiatan/Operasi Intelijen Obat dan Makanan (0,150), dan Hasil Pengawasan Obat dan Makanan (0,141). Temuan pada kajian ini dapat dielaborasi melalui survei lanjutan dengan cakupan lebih luas dan melibatkan ahli yang kompeten di bidang pencegahan kejahatan Obat dan Makanan, sehingga proyeksi usulan "Indeks kerawanan kejahatan Obat dan Makanan" dapat diusulkan menjadi salah satu indikator output pada sasaran program Deputy Bidang Penindakan.

Keywords: *crime vulnerability, crime prevention, law enforcement*

Kata Kunci: *cegah tangkal, indikator penindakan, kerawanan kejahatan*

1. Introduction

Currently, the handling and prevention of food and drug-related crimes remain largely based on a classical criminalistic approach, focusing primarily on the perpetrator, victim, and crime scene. This is reflected in the strategic objectives of the enforcement function outlined in the Regulation of The Indonesian Food and Drug Authority (BPOM, 2020a), concerning the Indonesian FDA's Strategic Plan for 2020–2024. According to the organizational vision document, the strategic objective of the enforcement function is to enhance the effectiveness of law enforcement against food and drug crimes, as measured by the output indicator of the percentage of court decisions resulting in guilty verdicts. However, referring to The Indonesian FDA Regulation Number 21 of 2020 concerning the Organization and Work Procedures of The Indonesian FDA (BPOM, 2020b), the Deputy of Law Enforcement is responsible for preventive, intelligence, and investigative functions. Therefore, the output indicator of guilty court decisions does not encompass all tasks within the Deputy of Law Enforcement and thus does not fully reflect the effectiveness of law enforcement against food and drug crimes.

A review of law enforcement performance indicators across several ministries and agencies reveals that some already have indicators that adequately reflect their assigned tasks and functions. The Directorate General of Customs and Excise, as per the Director General's Decision Number KEP-198/BC/2020, has a strategic objective of providing optimal protection and support for the economy and society, operationalized through performance indicators such as the percentage of effectiveness in supervising narcotics, psychotropics, precursors, and restricted goods. Activities include law enforcement in customs and excise, measured by indicators such as the percentage of completed investigations confirmed by the prosecutor (P21), rate of successful supervision of illegal excise goods (BKC), and percentage of operations resulting in actions against narcotics, psychotropics, and precursors (NPP). Similarly, the National Narcotics Agency, as per Head Regulation Number 6 of 2020 (BNN, 2020), emphasizes the strategic objective of increasing the prevention and eradication of illicit drug abuse and trafficking (P4GN), operationalized through the P4GN Index as a performance indicator.

At a global level, current discourse within the Criminal Justice System has reached a consensus that the key drivers of future law enforcement involve complex interactions. According to Silbergliet et al. (2015) in a study on the vision of law enforcement referenced by the U.S. Department of Justice for 2024–2034, two main clusters influence public order in norm compliance: societal trend changes and technological developments. In this context, law enforcement requires a multi-perspective approach, utilizing the PESTEL framework (Politics, Economy, Society, Technology, Environment, and Law).

Based on those data, it can be understood that there is a gap between the current representation of food and drug crime through The Indonesian FDA's output indicators and expected condition in the future within the global strategic environment. The output indicator for the strategic objective of increasing law enforcement effectiveness cannot rely solely on a single criminal law perspective. However, it must also include preventive and intelligent functions, incorporating political, economic, social, technological, and environmental perspectives. In the preventive function, the Deputy of Law Enforcement currently implements tasks through crime vulnerability mapping, analysis of food and drug crime, and stakeholder engagement. Among these business processes, crime vulnerability mapping can serve as an indicator of enforcement effectiveness.

Research specifically addressing crime vulnerability assessment in the food and drug sector is still very limited. Most studies focus on general crime vulnerability assessment, primarily using incident reports or crime statistics. Babenko et al. (2019) mapped narcotics crimes in Ukraine using cartography based on official crime data from government agencies and UNODC analysis. Furthermore, Snaphaan et al. (2024) measured territorial management quality for crime prevention by combining police crime data with community reviews from Google Places, while Deng et al. (2023) applied machine learning to predict crime risk based on crime data, environmental variables (presence of retail businesses, banks, hotels, hospitals), and demographic variables (poverty, unemployment, migration, population density, etc.). However, these approaches have not been widely adapted specifically for the food and drug sector, highlighting the need for further research.

Garcia (2020) emphasizes that vulnerability assessments usually utilize incident reports, intelligence, law enforcement data, and public information from media and government sources. This approach has begun to be adapted in The Indonesian FDA's food and drug crime vulnerability mapping. Crime Vulnerability Mapping for Food and Drugs involves mapping potential occurrences of food and drug crimes based on information analysis, media reports, and studies, including results from monitoring, intelligence, cyber, and investigative activities. This mapping covers products, distribution, sources, modus operandi, and inter-regional linkages related to food and drug crimes. Current sources of food and drug crime vulnerability information refer to The Indonesian FDA's Head Decision Number HK.02.02.1.2.01.22.12 of 2022 on Guidelines for the Implementation of Preventing Food and Drug Crimes, which consist of:

1. Results of Food and Drug Investigations
2. Results of Food and Drug Intelligence Operations
3. Results of Food and Drug Control
4. Results of Food and Drug Cyber Patrols
5. Sample Testing Requests from Law Enforcement Authorities
6. Expert Statements Requested by Law Enforcement Authorities in Enforcement Process for Food and Drug Crimes
7. Information from Cross-Sectoral Agencies
8. Public Complaint Reports
9. Monitoring Results of Food and Drug Issues in Online/Traditional Media
10. Monitoring Results of Food and Drug Regional Issues

Crime vulnerability mapping was conducted using the Aplikasi Dashboard Penindakan (ADP), specifically through the crime vulnerability module. Between 2020 and 2022, 9,351 verified vulnerability data points were recorded on the Enforcement Dashboard, with the highest vulnerability observed in the cosmetics (41%), followed by medicines (25%), traditional medicines (20%), processed foods (13%), and health supplements (1%). The crime vulnerability map is visualized in the form of zoning based on the dominant crime vulnerability commodities in each province, as shown in Figure 1.

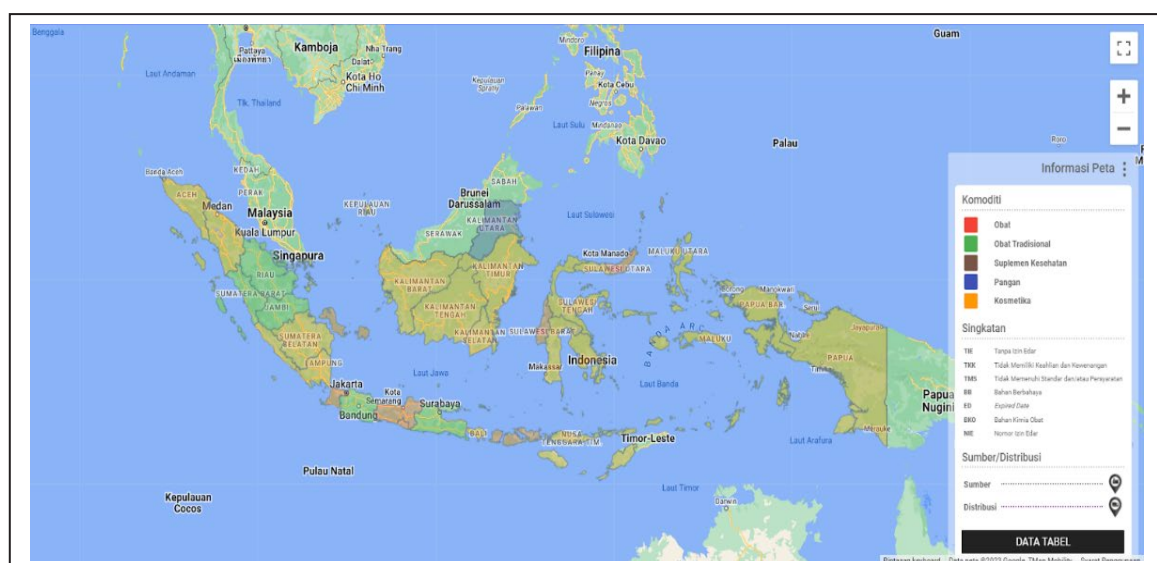


Figure 1. Food and Drug Crime Vulnerability Map, 2020–2022 (Source: Enforcement Dashboard Application, 2022).

The primary sources of crime vulnerability data for the 2020–2022 period were Results of Food and Drug Intelligence Operations (30%), Monitoring Results of Food and Drug Issues in Online/Traditional Media (26%), and Results of Food and Drug Control (20%). Other information sources accounted for 2–7% of the total data distribution. This indicates that crime vulnerability data are derived from a variety of sources, although some sources dominate. However, the management tools integrated into the Enforcement Dashboard for crime vulnerability mapping are still insufficient to provide a holistic perspective on food and drug crime risks, as all input data currently carry equal weight, despite differences in information sources.

Based on the issues described above, it is necessary to develop a crime vulnerability value for the information sources being inputted, so that it can serve as an indicator capable of representing policy direction, particularly in the enforcement function. Therefore, this study aims to conduct a self-assessment of the weighting of food and drug crime vulnerability scores based on information sources, as a consideration for the proposed outputs/indicators of the Deputy of Law Enforcement related to the implementation of relevant and measurable prevention and protection functions.

2. Methodology

The study was conducted from June 9 to 30, 2023, in Central Jakarta, East Jakarta, Tangerang Regency, and Bogor Regency, involving 33 respondents from the Deputy of Law Enforcement and law enforcement officers at The Indonesian FDA's regional offices (UPT). The research method used was a mixed-method approach, combining both quantitative and qualitative methods. The quantitative approach was based on comparative judgment, assessing crime vulnerability information sources using the Analytical Hierarchy Process (AHP) method with the SuperDecision software. The qualitative approach was conducted through questionnaire responses from the respondents.

The use of the AHP method encompasses three primary principles: decomposition, comparative judgment, and priority determination (Saaty, 1987). The quantitative

Indonesian FDA's Head Decision Number HK.02.02.1.2.01.22.12 of 2022 on Guidelines for the Implementation of Preventing Food and Drug Crimes. Respondents asked to provide preferences regarding the priority of information sources organized into 45 pairwise comparison questions with a scale of 1-9. If the consistency ratio of the assessment/weighting process exceeded 0.1 (10%), the judgment data had to be corrected. If the consistency ratio was less than or equal to 0.1, the calculation result was considered valid. In addition, the quantitative assessment also included evaluating the relevance of current food and drug crime vulnerability information sources, where respondents were asked to determine whether the current sources were sufficiently appropriate or required revision. The interface for assessing information sources using the AHP method in the SuperDecisions software is shown in Figure 2.

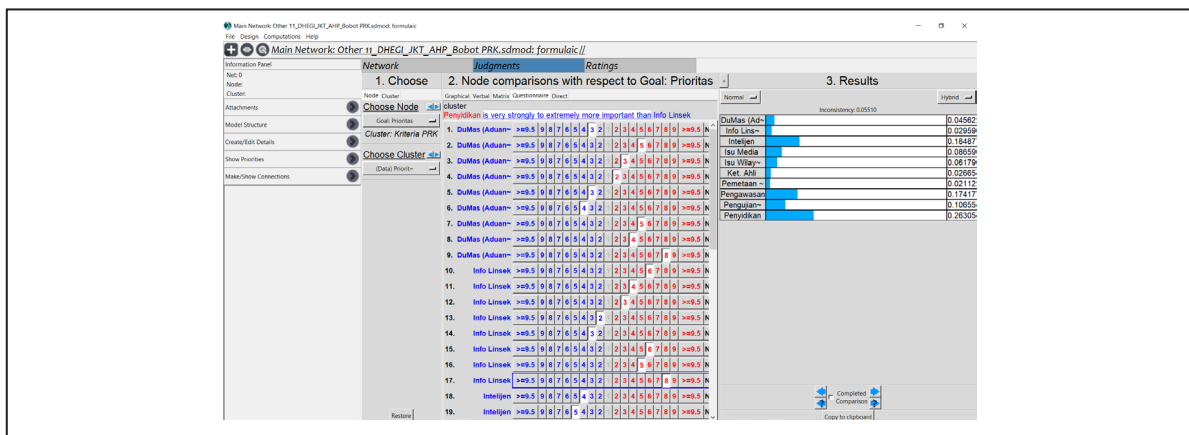


Figure 2. Interface for Assessing Crime Vulnerability Mapping Information Sources Using the AHP Method in SuperDecisions Software.

In the second stage, a qualitative approach was conducted through the completion of questionnaires by respondents to map respondent demographics and gather their opinions regarding the assessment of food and drug crime vulnerability. The qualitative approach focused on strengthening the quantitative assessment, particularly concerning respondents' perspectives on whether the crime vulnerability information sources accurately reflect actual crime risks, as well as collecting input for updating and improving the information sources.

3. Hasil dan Pembahasan

3.1. Mapping of Respondent Demographics for Crime Vulnerability Assessment

A survey was conducted with 33 respondents representing proportions of gender, education level, work experience, job position, and distribution across work units, which were obtained through an online survey. The detailed results of the demographic mapping of respondents for the assessment of food and drug crime vulnerability are presented in Figure 3.

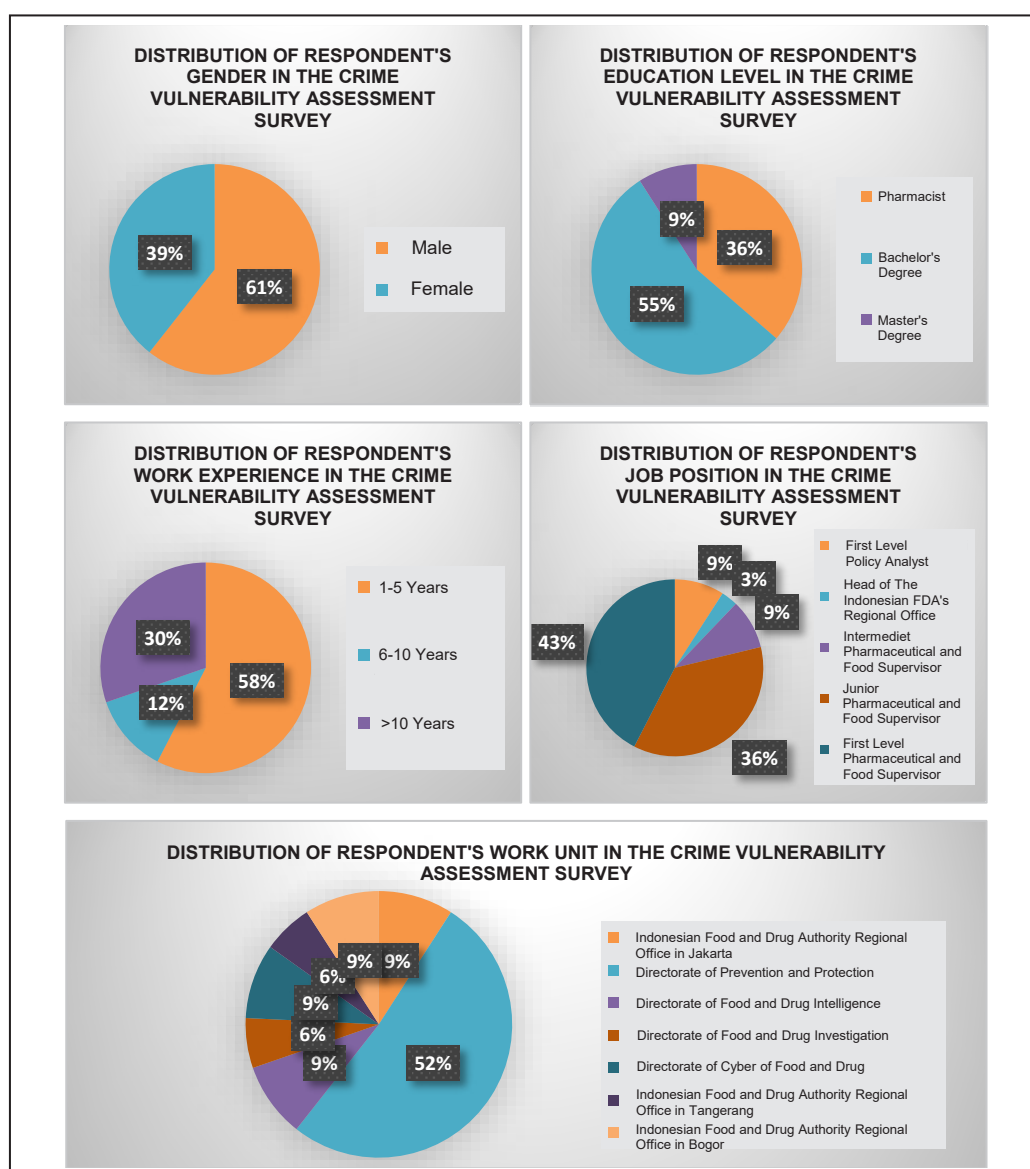


Figure 3. Demographics of Respondents for the Assessment of Food and Drug Crime Vulnerability

Based on gender distribution, the majority of respondents (61%) were male, while 39% were female. From an educational background perspective, most respondents (55%) held a bachelor's degree (S1), and the remaining 45% had higher education, including professional qualifications for pharmacists (36%) and a master's degree (S2) (9%). The majority of respondents were data input officers and crime vulnerability verifiers through the ADP information system, with 58% having 1–5 years of work experience, 12% having 6–10 years, and 30% having more than 10 years of experience. Regarding job positions, as reflected in work experience, the respondents were predominantly First Level Functional positions, consisting of First Level Pharmaceutical and Food Supervisors (43%) and First Level Policy Analysts (6%). In addition, 36% of respondents held positions as Junior Pharmaceutical and Food Supervisors, 9% as Intermediate Pharmaceutical and Food Supervisors, and 3% as Head of The Indonesian FDA's Regional Office. The respondents surveyed are individuals who have knowledge of and understand the process of crime vulnerability mapping. The majority of respondents (52%) are internal staff from the Directorate of Prevention

external units, including Directorate of Food and Drug Investigations, Directorate of Food and Drug Intelligence, Directorate of Cyber of Food and Drug, the Indonesian Food and Drug Authority Regional Office in Tangerang, and Indonesian Food and Drug Authority Regional Office in Bogor.

3.2. Establishment of Crime Vulnerability Values Based on Crime Vulnerability Mapping Information Sources

The establishment of values for crime vulnerability mapping information sources aims to assign weights/scores to the crime vulnerability database, ensuring that the vulnerability reflects the actual risk level of a region to food and drug crimes rather than being assessed solely based on data frequency. The results of the assessment/weighting of crime vulnerability mapping information sources are presented in Figure 4.

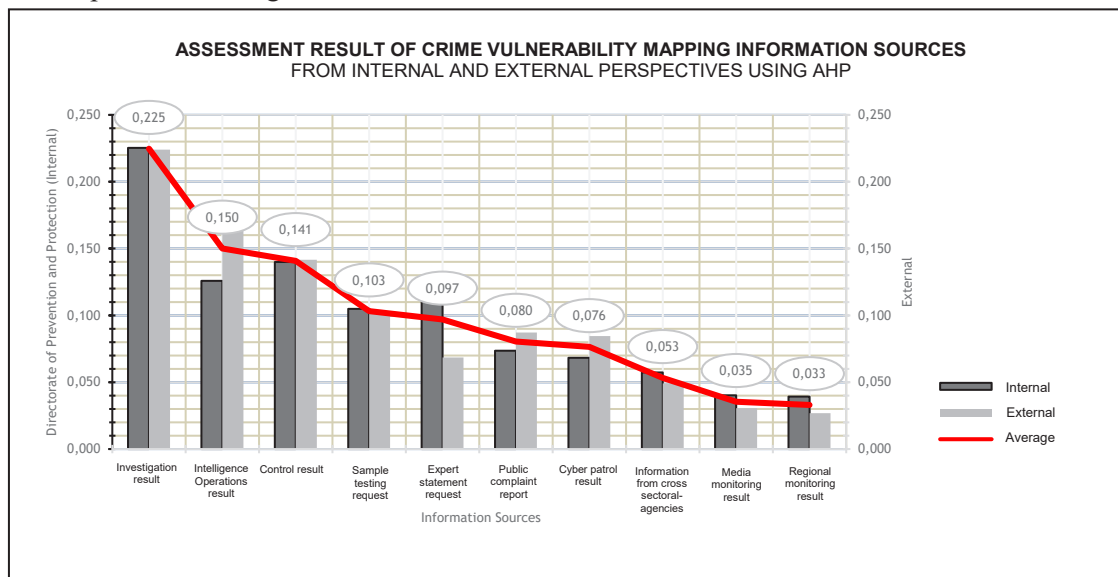


Figure 4. Assessment Result of Crime Vulnerability Mapping Information Sources from Internal and External Perspectives Using AHP

The assessment results indicated that the criteria with the highest weights in the evaluation of food and drug crime vulnerability were Investigation Results (0.225), Intelligence Operations Results (0.150), and Control Results (0.141). In detail, the explanation regarding the sources of crime vulnerability information is as follows:

Results of Food and Drug Investigations is the criterion with the highest weight in the assessment of food and drug crime vulnerability (0.225). This indicates that criminal offenses that are followed up through formal investigation processes constitute the most influential factual condition in depicting the vulnerability of food and drug crimes in a given region. Article 1, Number 2 of Law Number 8 of 1981 on the Criminal Procedure Code defines an investigation as a series of actions carried out by investigators, in accordance with procedures established by law, with the purpose of seeking and collecting evidence to clarify the occurrence of a criminal act and identify the suspects. At this stage, investigators have successfully identified key facts that can serve as a basis for prosecuting the offenders in court. Investigations provide greater legal certainty because the investigators' actions are conducted according to strictly regulated legal procedures, ensuring that the collected evidence carries stronger legal validity.

Results of Food and Drug Intelligence Operation carry a significant weight in evaluating food and drug crime vulnerability (0.150). According to Article 6 of Law Number 17 of 2011 on State Intelligence, one of the functions of national intelligence is investigative work, which constitutes a

information into actionable intelligence, which can then be used as input for policy formulation and decision-making. This process involves evaluating information, determining follow-up priorities, and validating reports to ensure data accuracy and relevance. In line with Rossmo (2021), the importance of intelligence results lies in the ability to assess the investigation situation by considering the nature of the initially collected information, the reliability of information sources, and the potential use of this data as valid evidence in case handling. In the context of crime vulnerability assessment, intelligence results provide a more comprehensive picture of crime patterns, perpetrators, and potential escalation in the food and drug sector.

Results of Food and Drug Control (average weight 0.141) also constitute an important criterion in identifying food and drug crime vulnerability. In this context, control refers to routine inspections of production and distribution facilities conducted by The Indonesian FDA, including the identification of criminal violations. The data obtained from these inspections not only reflect the compliance levels of business actors but also identify patterns of violations that may pose risks to public health. In line with situational crime prevention theory, Halford et al. (2024) emphasize that capable control is a key element in reducing target vulnerability while increasing the risk of apprehension for offenders. In the context of food and drugs, The Indonesian FDA's control functions as a situational control mechanism by exerting pressure on potential offenders to deter violations. This process also has a preventive effect, as consistent monitoring can reduce opportunities for crime by increasing business actors' awareness of the risks involved.

Sample Testing Requests from Law Enforcement Authorities (average weight: 0.103) play a crucial role in assessing the quality and safety of food and drug products. These data reflect the occurrence of crimes in a particular area, such as the circulation of adulterated beverages or the misuse of medicines and NAPPZA, which are the focus of police enforcement. Such requests not only provide insight into the intensity of crime but also illustrate the effectiveness of coordination between The Indonesian FDA and law enforcement authorities in handling food and drug crimes. Test results can reinforce evidence during investigations or in court, thereby supporting more effective law enforcement.

Expert Statements Requested by Law Enforcement Authorities in the Criminal Enforcement Process for Food and Drug Crimes (average weight 0.097) are crucial for evaluating crime vulnerability in the food and drug sector, as expert testimony is recognized as valid evidence under Article 184, Paragraph 1 of Law Number 8 of 1981 on Criminal Procedure. In criminal cases, expert statements are required to provide technical or scientific analysis of violation findings, strengthening the evidentiary basis in legal proceedings. These data not only indicate the complexity of the violations but also provide insights into crime patterns and vulnerability levels (Wulur, 2017). Although judges are not bound by expert testimony, it cannot be disregarded due to its relevance to the scientific accuracy underlying the case.

Public Complaint Reports (average weight 0.080) concerning suspected food and drug crimes serve as preliminary information on potential crime vulnerability. However, the level of public knowledge regarding criminal violations is a critical factor that affects the validity of reports. Therefore, multiple steps are still required to conclude that a particular region is truly vulnerable or affected by food and drug crimes. In 2022, according to The Indonesian FDA's Annual Report (2022), the agency received public complaints and information requests through the ULPK Central Unit, 73 technical units across Indonesia, and the HALOBPOM 1500533 Contact Center, with 1,554 cases (2.75%) classified as complaints. This represented an increase of 7.51% compared to 2021, highlighting the importance of regular monitoring of public complaints as a source of crime vulnerability information.

Result of Food and Drug Cyber Patrol Results (average weight 0.076) serve as a criterion for understanding the spatial distribution and potential patterns of food and drug crimes. In the context of crime vulnerability assessment, cyber patrol data play a critical role in detecting early threats, such as the circulation of illegal products on online platforms. However, limitations in data validation and difficulties linking digital evidence to offenders result in a lower weight compared to data from

investigations, intelligence, or direct supervision. According to Nawawi et al. (2023), identifying offenders, collecting evidence, and engaging the community are major challenges in enforcing cybercrime regulations.

Information technology, particularly user-generated content, is exploited by offenders to enhance the methods of distributing illegal food and drug products online. The online distribution of food and drugs poses a challenge in identifying regional vulnerability due to its borderless nature, allowing products to reach multiple regions, with sources originating both domestically and internationally (cross-border). Consequently, the accuracy in determining regional vulnerability requires further analysis, which also relies on the utilization of information technology in handling food and drug crimes. Since 1990, the U.S. Food and Drug Administration has developed data mining systems to accelerate the identification of potential safety issues in food and drug products and to assist in prioritizing safety concerns. This is considered essential for improved decision-making and real-time risk management of product safety issues.

Information from Cross Sectoral Agencies (average weight 0.053) emphasizes the importance of cooperation between different sectors in addressing food and drug crimes. Information such as the interception of illegal shipments by relevant agencies or reports from logistics service associations on the circulation of illegal products serves as an indicator of criminal activity. These data help identify distribution routes, smuggling methods, and vulnerable regions, enhancing the accuracy of crime vulnerability mapping. According to Garcia (2020), threat information collection must involve reviewing available data and coordinating with agencies possessing relevant intelligence. Law enforcement and intelligence agencies can further enrich perspectives for understanding the complexity of crime. Cross-sector collaboration allows for broader identification of threat patterns, from distribution networks to end consumers, facilitating more effective prevention and enforcement strategies.

Monitoring Results of Food and Drug Issues in Online/Traditional Media (average weight 0.035) is an important factor in providing information and raising public awareness about food and drug crimes. As a data source, media help map vulnerability by identifying crime patterns, locations, and types frequently reported. Media play a role in shaping public perception of crime, including trends and the frequency of reported cases. Garcia (2020) notes that threat information, including media sources, must be carefully evaluated to ensure data accuracy and relevance before use in vulnerability assessments.

Monitoring Results of Food and Drug Regional Issues (average weight 0.033) refers to geographical and environmental factors influencing food and drug crime vulnerability. Differences in regional characteristics, including demographics, accessibility, and supervision levels, can affect crime rates. Location or regional context influences crime dynamics, as Eck & Weisburd (2015) explain that the presence of various facilities in an area can either increase or reduce crime risk. This occurs because such areas attract different types of activities, including those involving offenders. Ellis et al. (2019) further highlight that demographic factors, such as gender composition, race, ethnicity, social status, and immigrant background, are linked to crime patterns in a region. Additionally, local cultural trends, such as consumption habits or distribution patterns of food and drug products, can affect the potential for specific crimes in a region. Nonetheless, these potential data points require in-depth investigation to assign adequate weights in assessing crime vulnerability.

The assessment of crime vulnerability information sources indicates that respondents emphasized effective investigation processes, accurate intelligence collection, and intensive supervision as key steps in determining the level of food and drug crime vulnerability. These results align with the view that food and drug crime management must involve more holistic and integrated efforts. On the other hand, media issues and regional issues, despite having relatively lower average weights, still play important roles in law enforcement. Balanced media coverage and information on regional characteristics contributing to crime vulnerability help the public remain vigilant and engaged in crime prevention and disclosure. Although all threat data tested positively contribute to depicting the

actual food and drug crime situation, the differences in weights clearly indicate how respondents assessed the relative contribution of each criterion in decision making.

3.3. Exploration of Perceived Appropriateness of Crime Vulnerability Values

The assessment of crime vulnerability information sources in this study has provided a solid framework for identifying and collecting information related to food and drug crime vulnerability. Investigations constitute an important criterion for uncovering criminal acts, identifying perpetrators, and collecting evidence. Intelligence provides in-depth insights into illegal activities and trends related to food and drugs. Supervision assists in detecting violations and ensuring compliance with existing regulations. Laboratory testing offers information on the safety, authenticity, and quality of food and drug products. Expert statements provide critical perspectives for understanding technical and scientific aspects related to food and drugs. Public complaints offer insights from the consumer perspective and help identify potential issues. Online mapping and cross-sectoral information provide access to relevant geographical and situational data. Media and regional issues provide insights into public attention and emerging issues in specific media and regional contexts. However, it is important to recognize that each of these information sources has strengths and limitations that need to be considered. The results of the survey on the perceived appropriateness of crime vulnerability mapping information sources are presented in Figure 5.

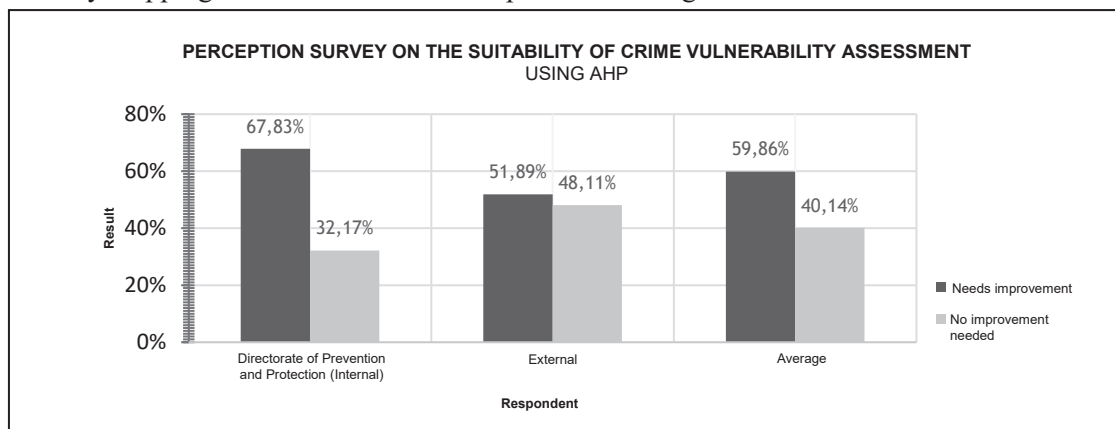


Figure 5. Perception Survey on The Suitability of Crime Vulnerability Assessment using AHP

The survey results indicate that 59.86% of respondents, both from the Directorate of Prevention and Mitigation and external stakeholders, believe that the current crime vulnerability information sources do not accurately reflect actual conditions and therefore require improvement or adjustment. Improvement to the crime vulnerability mapping information sources for assessing food and drug crime vulnerability in a region can be classified into several scopes, as explained in Table 1.

Tabel 1. Scope and Description of Improvements in the Assessment of Food and Drug Crime Vulnerability

Scope of Improvement	Description of Improvement
Crime Vulnerability Assessment	Vulnerability values are still accumulated based on the intensity of data input by technical units, so the weighting of information sources is important to reflect the actual vulnerability of food and drug crimes accurately.
Clustering of Information Sources	Clustering is needed to avoid repetition of information sources with similar meanings, for example: 1. Investigation data, expert statements, and laboratory testing results requested by law enforcement are grouped into a single criterion: food and drug case data or pro-justitia data. 2. Media issue data and regional issue data are grouped into a single criterion: media issue data
Elaboration of Information Sources	In general, existing information sources can represent the actual condition of food and drug crimes; however, to enrich vulnerability data, elaboration is required using dynamic strategic environmental conditions that illustrate complex interactions among vulnerability factors. Additionally, vulnerability data can be supplemented by publications from journals, theses, or survey data from authorized institutions.

It is clear that vulnerability cannot be determined exclusively based on crime vulnerability mapping information sources. Other aspects, such as legal regulations, government policies, supervision infrastructure, public participation, and economic, social, and cultural factors, must also be considered.

According to Eck & Weisburd (2015), crime occurs due to the absence or ineffectiveness (capacity) of control when offenders encounter their targets. Clear, firm, and effective legal regulations are required to protect the public from food and drug crimes. Good government policies in the supervision of food and drugs, including segregation and delegation of authority to local governments, also have strong potential to support the reduction of crime vulnerability. Synergy among government entities must be strengthened with clear plans and strategies for prevention, enforcement, and legal action against food and drug crimes. Additionally, adequate supervision infrastructure—including regulatory agencies, testing laboratories, monitoring systems, and supporting facilities—can support early detection, evidence collection, and law enforcement against food and drug crimes. Deficiencies in supervision infrastructure may create gaps in law enforcement and increase vulnerability.

Crime vulnerability can also be influenced by social, economic, cultural, and environmental conditions, such as employment availability, economic inequality, low education levels, social interactions, cultural background, and physical environmental conditions that facilitate criminal opportunities, such as unmonitored areas and access to targets and escape routes Barnum et al. (2017). Understanding the social and cultural context is crucial for designing effective prevention strategies. Active public participation in reporting, detecting, and providing information on food and drug crimes is vital. Informed and engaged communities can help identify illegal or high-risk practices and provide valuable information to law enforcement. A public aware of food and drug crime risks can serve as an effective “eyes and ears” in prevention and enforcement efforts.

3.4. Crime Vulnerability as a Database for the Redesigned Enforcement Planning System

Crime forecasting is a complex issue in criminology and urban security research. This process involves analyzing and modeling various factors, including environmental and demographic variables that may influence crime. To assess the crime situation, structure, and future trends in a region over a specific period, various methods are applied, including crime hotspot detection. This method has proven effective in identifying spatial and temporal crime distribution patterns, involving

the identification of high-risk areas, typically based on the geographical location of criminal incidents. (Deng et al., 2023).

Currently, institutions in most countries actively work on crime prevention. The establishment of monitoring and warning systems has become a mandatory tool for territorial management (Quesada-Ruiz et al., 2023). In line with this, to achieve The Indonesian FDA's vision and mission, integrated efforts are implemented in focus areas and loci of food and drug supervision. The policy direction to be implemented by the Deputy of Law Enforcement includes increasing public understanding, awareness, and participation in food and drug supervision through: enhancing stakeholder engagement for crime prevention and training; strengthening law enforcement activities, including expanding and improving the quality of investigations through enhanced monitoring of illegal food and drug circulation online and offline and accelerating case resolution; improving the quality of human resources in the Deputy of Law Enforcement and stakeholders, performance accountability, and institutional capacity through the development of analysts, intelligence officers, and Civil Servant Investigators (PPNS).

During the implementation of the 2020–2024 Strategic Plan, the output produced by The Indonesian FDA regional offices related to enforcement was the number of food and drug criminal cases, with output achievement based solely on investigative activities conducted by The Indonesian FDA regional offices. This approach is considered no longer relevant to The Indonesian FDA's organizational development. Therefore, improvement are needed for outputs and output indicators that reflect the overall performance of enforcement-related regional offices, with specific targets to be achieved. These adjustments should take into account the weighted results of food and drug crime vulnerability data. The weighting of crime vulnerability data indicates data quality and reflects the enforcement activities conducted by regional offices, which are directly related to the required budget.

The results of the self-assessment on the weighting of crime vulnerability information sources can serve as a tool to determine food and drug crime vulnerability in a relevant and measurable way. Weighting should be carried out comprehensively through surveys of the food and drug crime ecosystem, supported by experts competent in crime prevention, so that in the future, the "Food and Drug Crime Vulnerability Index" can be proposed as a measurable output indicator to achieve the strategic objectives of the Deputy of Law Enforcement.

3.5. Research Limitations

The study on the development of food and drug crime vulnerability values has several limitations that must be considered. Currently, such studies are rarely conducted by supervisory institutions abroad, indicating that the framework for food and drug crime vulnerability values has not yet become a primary focus of international research. Therefore, the limited literature and data from similar studies in other countries may affect the accuracy and generalizability of the findings.

Secondly, the limited scope of survey respondents is another important aspect. Although the study involved respondents from the Deputy of Law Enforcement and enforcement officers from The Indonesian FDA regional offices, weighting should be carried out comprehensively through surveys of the food and drug crime ecosystem, supported by experts in the field of crime prevention. Furthermore, benchmarking with relevant institutions is necessary to ensure the relevance and validity of the proposed food and drug crime vulnerability indicators.

4. Conclusion

Based on this study, it can be concluded that each information source carries a different weight, with the highest weights in assessing food and drug crime vulnerability assigned to Result of Food and Drug Investigation (0.225), Result of Food and Drug Intelligence Operations (0.150), and Result of Food and Drug Control (0.141). A holistic assessment of crime vulnerability is necessary to reflect

the actual vulnerability of food and drug crimes accurately. It is essential to review crime vulnerability mapping information sources, particularly clustering factors related to legal regulations, government policies, supervision infrastructure, public participation, and economic, social, and cultural factors.

The results of the self-assessment on the weighting of crime vulnerability information sources can serve as a tool to determine food and drug crime vulnerability in a relevant and measurable way. However, this study still has limitations regarding the completeness of literature sources and the scope of survey respondents. Weighting should be conducted comprehensively through surveys of the food and drug crime ecosystem, supported by experts competent in crime prevention, so that in the future, the “Food and Drug Crime Vulnerability Index” can be proposed as a measurable output indicator to achieve the strategic objectives of the Deputy of Law Enforcement and directly reflect the planning of enforcement activities to be conducted by The Indonesian FDA regional offices.

As a collective effort to diversify the performance of the Enforcement Division during the 2025–2029 RPJMN period, further collaboration among cross-sector stakeholders within the enforcement function is proposed to develop criteria and weights for crime vulnerability information capable of measuring regional risk levels in terms of food and drug crimes. Through these efforts, it is expected that actual issues related to food and drug enforcement can be objectively represented, allowing the proposed “Food and Drug Crime Vulnerability Index” to be adopted as one of the output indicators in the program targets of the Deputy of Law Enforcement in the next RPJMN period.

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Development of an Analytical Method for Lidocaine Identification in Magic Tissue Using Gas Chromatography Mass Spectrometry

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Antiseptic tissue to help clean the skin in men's sensitive areas (magic tissue) is a class I (low risk) health supplies product. Several marketed products are also claimed to have benefits for preventing premature ejaculation, which is suspected to be associated with the addition of lidocaine that is not disclosed on the product label. Lidocaine, an amide local anesthetic, is used in medicine to inhibit the sensation of pain. This research was conducted to determine the lidocaine content in magic tissue. The research method used is an experimental method, involving validation methods and testing samples. Lidocaine was identified using Gas Chromatography Mass Spectrometry, with test parameters of specificity, Limit of Detection, stability test, and resistance test. Sample preparation was carried out by dissolving one layer of tissue as a sample using methanol. The Standard Solution used is lidocaine compound with a concentration of 100 ppm. The results confirmed method specificity, as the sample and spiked solutions showed identical ion extracts, fragmentation, and intensity ratios to the standard solution. The LOD was determined to be 10 ppm, indicating sufficient sensitivity. Stability testing showed consistent mass-to-charge spectra between the first and fifth days, while resistance testing demonstrated that temperature variations affected peak retention times but not the mass spectra. Analysis of five different samples revealed positive results for lidocaine. Overall, these findings indicate that the developed GC-MS method meets validation parameters and can be reliably applied to identify lidocaine in magic tissue products.

Produk tissu antiseptik untuk pembersih area sensitif pria (magic tissue) dikategorikan sebagai perbekalan kesehatan kelas I (risiko rendah). Beberapa produk di pasaran dilaporkan mengklaim manfaat sebagai pencegah ejakulasi dini, yang diduga terkait dengan penambahan senyawa lidokain tanpa pencantuman pada etiket kemasan. Lidokain merupakan anestesi lokal golongan amida yang secara farmakologis berfungsi menghambat transmisi sensasi nyeri. Penelitian ini dilakukan untuk mengetahui kandungan lidokain dalam produk magic tissue yang beredar di Indonesia. Metode penelitian yang digunakan adalah metode eksperimental, dengan melakukan validasi metode dan pengujian sampel. Identifikasi lidokain dilakukan menggunakan Kromatografi Gas Spektrofotometri Massa, dengan parameter validasi metode berupa uji spesifisitas, Limit of Detection (LOD), uji stabilitas dan uji ketahanan metode. Selanjutnya, pengujian sampel dilakukan dengan melarutkan 1 lembar magic tissue menggunakan pelarut metanol. Larutan Baku sebagai kontrol positif yang digunakan adalah senyawa lidokain dengan konsentrasi 100 ppm. Hasil uji spesifisitas Larutan Sampel dan Larutan Spiked memiliki ekstrak ion, fragmentasi ion, dan perbandingan rasio intensitas ion yang sama dengan Larutan Baku. Nilai LOD adalah 10 ppm. Hasil uji stabilitas menunjukkan bahwa pada hari kelima, Larutan Sampel dan Larutan Baku memiliki spektrum massa per muatan yang sama dengan pengujian pada hari

pertama. Pada uji ketahanan metode, perubahan rentang suhu pengujian menyebabkan perubahan waktu retensi puncak namun spektrum massa per muatan masih sama dengan Larutan Baku. Pada penelitian ini dilakukan pengujian terhadap lima sampel yang berbeda dengan hasil positif mengandung lidokain. Metode uji yang dikembangkan memenuhi parameter validasi dan dapat digunakan untuk identifikasi lidokain dalam produk magic tissue.

Keywords: Magic tissue, Lidocaine, Gas Chromatography Mass Spectrometry, Validation Method
Kata Kunci: Tisu magic, Lidokain, Kromatografi Gas Spektrofotometri Massa, Validasi Metode

1. Introduction

Lidocaine is an amide-type local anesthetic commonly used in medical practice to inhibit pain sensation (Karnina et al., 2021). Its chemical formula is $C_{14}H_{22}N_2O$. The compound consists of a lipophilic subunit (tertiary amine) and a hydrophilic subunit (unsaturated aromatic ring) (Vardanyan & Hruby, 2006). The lipophilic portion determines the local anesthetic activity (Johansson, 2012). Lidocaine is widely used in medical practice, ranging from minor surgery to local anesthesia. Its topical use has also been applied in certain products for preventing premature ejaculation in men (Hisasue, 2016). For some patients, topical therapy with local anesthetics, including lidocaine and/or prilocaine, may be an effective treatment option (Hisasue, 2016; Shah et al., 2023). Topical anesthetics such as lidocaine and/or prilocaine in the form of creams, gels, or sprays are known to be effective in delaying ejaculation. They act by reducing glans sensitivity and are thought to inhibit spinal reflexes responsible for ejaculation (Hisasue, 2016).

Magic tissue is an antiseptic tissue product used for cleansing sensitive areas in men and preventing sexually transmitted diseases, thereby helping to maintain hygiene and health. Magic tissue is categorized as a health supply product, typically containing ingredients such as ethyl alcohol (ethanol), polyethylene oxide, benzalkonium chloride, and fragrance. Some products may also include natural ingredients, such as aloe vera extract, for skin softening, or other additives, like triclosan and cocamidopropyl betaine.

According to Law Number 17 of 2023 on Health, health supplies refer to all materials and equipment necessary for health efforts. Based on the Regulation of the Minister of Health of the Republic of Indonesia Number 62 of 2017 on Distribution Permits for Medical Devices, In Vitro Diagnostic Devices, and Household Health Supplies, magic tissue falls under class I (low risk) health supplies, which, in its use, does not cause significant adverse effects such as irritation, corrosiveness, or carcinogenicity.

In the market, magic tissue is also known for its claimed benefit in preventing premature ejaculation in men. It is often preferred over modern herbal remedies due to its lower cost, immediate effect, and relatively mild side effects, typically including numbness in the genital area (Hardon et al., 2015). It is suspected that lidocaine, as an active substance, is added to the magic tissue to provide this effect. However, the presence of lidocaine in these products is often not declared on the label, making such an addition “illegal.”

Traditionally, the analysis of lidocaine in known pharmaceutical preparations has been performed using High-Performance Liquid Chromatography (HPLC) (Ministry of Health, 2020). However, since the type of active ingredient added to the magic tissue is unknown, this study employed Gas Chromatography-Mass Spectrometry (GC-MS) equipped with a compound database for identification. This research aimed to develop a method for lidocaine

identification in magic tissue products using GC-MS, with a simple sample preparation process to facilitate routine laboratory testing.

2. Methodology

2.1. Time and Place of Study

This research was conducted at the Laboratory of Pharmaceutical Chemistry, Active Pharmaceutical Ingredients, Narcotics, Psychotropics, Precursors, and Addictive Substances, Center for National Quality Control Laboratory of Drugs and Food (PPPOMN), The Indonesian Food and Drug Authority, from July to August 2022.

2.2. Materials and Instruments

The materials used in this study included magic tissue suspected of containing lidocaine, obtained as case samples from law enforcement authorities who collected them from the market and submitted them to The Indonesian Food and Drug Authority for testing of hazardous substances, methanol (MS grade) as the solvent for the GCMS system (Agilent, Germany) (Huber, 2010), and lidocaine reference standard obtained from the Reference Standard Laboratory, PPPOMN.

The instrument used was a GC-MS system (Agilent 7890B) equipped with a DB-5MS column (30 m in length, 0.25 mm internal diameter, and a 5% phenyl–95% methyl polysiloxane stationary phase). The chromatographic system specifications are presented in Table 1 (The Indonesian Food and Drug Authority, 2021).

2.3. Identification Using GC-MS

The identification test of lidocaine in magic tissue was performed using a GC-MS instrument with the specifications listed in Table 1, which represents the development of an internal method by PPPOMN. The preparation of the standard solution was carried out by weighing approximately 5 mg of lidocaine, obtained from the Indonesian Pharmacopeia Reference Standard (BPFI), which was then placed into a 10 mL volumetric flask. Five milliliters of methanol were added, and the solution was sonicated for 2 minutes. Afterward, the solution was diluted with methanol to volume. A 200 μ L aliquot of the standard solution was transferred to a vial and diluted with 800 μ L of solvent, resulting in a concentration of 100 ppm.

The sample solution was prepared by weighing one sheet of tissue, which was placed in a 100 mL Erlenmeyer flask and extracted with 25.0 mL of methanol by sonication for 15 minutes. A 200 μ L aliquot of the sample solution was transferred to a vial and diluted with 800 μ L of solvent. Both the standard and sample solutions were each pipetted 500 μ L into separate vials and mixed to create a spiked solution.

Before sample testing was conducted, the analytical method to be used was first validated with the following test parameters: selectivity/specificity, Limit of Detection (LOD), stability test, and method robustness test. The selectivity/specificity test was performed by comparing the standard solution, sample validation solution, and spiked solution by observing the retention time of the target analyte peak (lidocaine) and the spectrum showing the fragmentation pattern of the compound. The test was carried out twice. The Limit of Detection (LOD) was determined by observing the signal-to-noise ratio produced by the standard solution with six repetitions. The stability test was performed by observing the test

results from the standard solution, sample validation solution, and spiked solution that had been stored for 5 days under the specified storage conditions, in accordance with the standard operating procedure applied at the research location.

The robustness test was performed by testing temperature variations and evaluating five different brand samples (The Indonesian Food and Drug Authority, 2010). Sample testing was conducted using five different samples with three repetitions for each sample.

Table 1. GC-MS Chromatographic System

GCMS System	Explanation
Column	DB-5 MS, 30 m × 0.25 mm i.d., 5% phenyl–95% methyl polysiloxane
Detector	Mass Spectrophotometer
	Injector temperature 290 °C
	Column temperature 100 °C (held 2 min)
	ramp 10 °C/min to 290 °C (held 10 min)
	MS Source 230°C
	MS Quard 150°C
Carrier gas	Helium Ultra Pure
Flow rate	1,5 mL/min
Flow Control Mode	Linear Velocity
Split ratio	10:1
Injection volume	1 µL
Solvent Cut Time	2,5 min
MS mode	Scan
m/z range	40-550

3. Results and Discussion

In this study, the identification method was designed to be as simple as possible, with straightforward sample preparation, to facilitate its application in routine laboratory testing. Gas Chromatography Mass Spectrometry (GC-MS) was chosen due to its high sensitivity and the availability of a compound library in the instrument, which significantly aids in the detection of analytes. The validation results obtained in this study are described as follows:

3.1. Selectivity/Specificity

Chromatograms of solvent, standard solution, sample solution, and spiked solution are presented in Figure 1. The chromatograms show no interfering peaks at the retention time of lidocaine (tr 12.994–13.658 min). No peaks from the solvent overlapped with the retention time of the target analyte peak in the standard solution.

Specificity was demonstrated by the fact that the sample and spiked solutions showed the identical mass spectra per charge (m/z) as the standard solution (Figure 2). Furthermore, the sample and spiked solutions exhibited identical extracted ions to the standard solution, with at least three fragment ions (87, 58, and 72). The ion intensity ratios were calculated and compared against the acceptable tolerance limits (Table 2).

For peaks with relative intensities ≤10% of the base peak, the tolerance for relative ion intensity in mass spectrometry is ±50% (Ferrer & Thurman, 2003). The ion intensity ratio results confirmed that the peaks detected in the sample and spiked solutions corresponded to lidocaine, as confirmed by the standard solution.

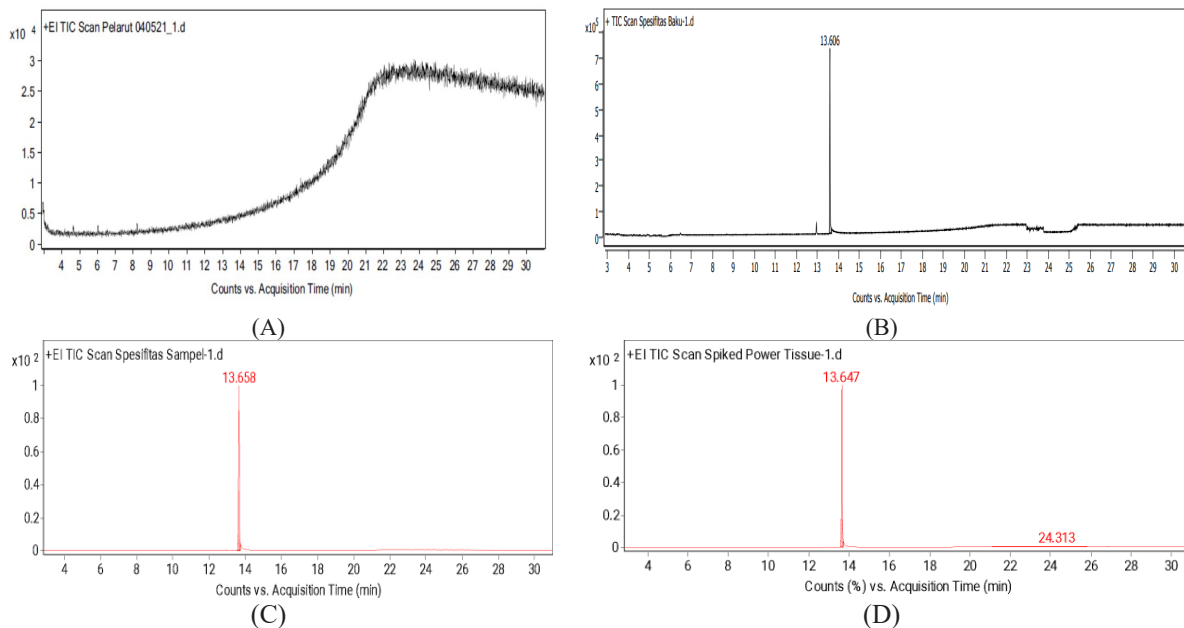


Figure 1. Chromatograms of lidocaine in solvent (A), standard solution (B), sample solution (C), and spiked solution (D)

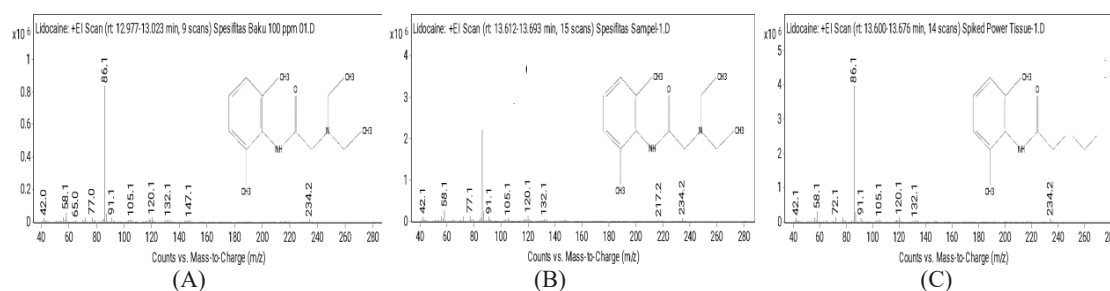


Figure 2. Ion fragmentation of lidocaine in standard solution (A), sample solution (B), and spiked solution (C)

Table 2. Comparison of ion intensity ratios

Solution	Mass-to-Charge ratio (m/z)	Relative Value	Acceptance Range (Relative Deviation)	Conclusion
Standard Solution (Lidocaine)	87	6,11	3,06 – 9,17	-
	58	6,89	3,44 – 10,33	
	72	2,85	1,42 – 4,27	
Sample Solution	87	6,98	-	Accepted
	58	8,20		
	72	3,32		
Spiked Solution	87	6,60	-	Accepted
	58	7,51		
	72	3,14		

3.2.Limit of Detection (LOD)

The LOD is the minimum concentration of analyte that can be reliably detected (Gandjar & Rohman, 2007). In this study, several concentrations of the standard solution, near the expected detection limit, were prepared, and the signal-to-noise (S/N) ratios were observed.

At 10 ppm, the standard solution consistently produced detectable signals across six replicate injections, with an average signal-to-noise ratio (S/N) of 5.7 (Table 3). This indicates that the minimum detectable concentration of lidocaine using this GC-MS method is 10 ppm. The LOD value depends on the instrument sensitivity, detector performance, column resolution, and instrument noise. Generally, an S/N ratio of $\geq 3:1$ is considered acceptable for the LOD. In this experiment, reproducibility was confirmed by consistent signals across repeated injections.

Table 3. Limit of Detection (LOD) for Lidocaine

Solution	Concentration (ppm)	Area	Signal/Noise (S/N)
Standard Solution Lidocaine 01	10	64489,95	5,9
Standard Solution Lidocaine 02	10	68055,43	7,3
Standard Solution Lidocaine 03	10	68055,43	5,5
Standard Solution Lidocaine 04	10	54893,00	6,1
Standard Solution Lidocaine 05	10	53856,28	5,0
Standard Solution Lidocaine 06	10	47247,30	4,3
			Average: 5,7

Lidocaine testing in pharmaceutical preparations is typically performed using HPLC, as outlined in official monographs, such as the Indonesian Pharmacopoeia VI Edition (2020). However, this method is generally intended for the detection of pharmaceutical dosage forms containing relatively high concentrations of lidocaine, making them easily detectable and quantifiable. In contrast, this study revealed the presence of lidocaine in wet tissues, which was previously unknown, as it was not declared in the product composition. Therefore, the use of GC-MS in this method aimed to detect any active substances present in the product, with lidocaine being identified as one of them.

The LOD value helps determine the smallest amount of analyte in a sample that the instrument can still detect. The detection limit of 10 ppm obtained in this study was determined based on the signal-to-noise (S/N) ratio. The analyte signal at the LOD must be significantly distinguishable from instrument noise. In general, an S/N ratio of at least 3:1 is acceptable for LOD determination. At the LOD concentration, the method must demonstrate adequate reproducibility, meaning that detection at this level must be consistent when the analysis is repeated under the same conditions. In the experiment, six replicate injections yielded consistent signal-to-noise (S/N) ratios (greater than 3). The LOD value also depends on the instrument's sensitivity, specifically the detector's performance, column separation efficiency in GC, and instrument noise.

3.3. Stability Test

Stability testing was performed on standard, sample, and spiked solutions after five days of storage at room temperature. The results (Table 4) demonstrated that all solutions maintained the identical mass spectra per charge (m/z) as on day one, indicating that lidocaine remained stable under the tested conditions for up to five days.

Table 4. Stability test results of lidocaine

Solution	Mass-to-Charge Ratio (m/z)	
	Day 1 Testing	Day 5 Testing
Standard Solution	87	87
	58	58
	72	72
Sample Solution	87	87
	58	58
	72	72
Spiked Solution	87	87
	58	58
	72	72

3.4. Robustness Test

In robustness testing, temperature variations of ± 1 °C from the setpoint (9 °C and 11 °C deviations) caused slight shifts in retention time for lidocaine in the standard, sample, and spiked solutions. However, the mass spectra per charge remained consistent with the standard solution (Table 5). This indicates that minor temperature changes did not affect compound identification.

Table 5. Robustness test results with temperature variation

Solution	Retention Time (minute) dan Mass-to-Charge Ratio (m/z)					
	10°C		9°C		11°C	
Standard Solution	12,994	87	13,845	87	12,271	87
		58		58		58
		72		72		72
Sample Solution	13,658	87	13,979	87	12,382	87
		58		58		58
		72		72		72
Spiked Solution	13,641	87	13,973	87	12,376	87
		58		58		58
		72		72		72

Robustness was further confirmed by testing five different brands of magic tissue from the market. Lidocaine was positively identified in all samples (Table 6). These results demonstrate that the developed method is robust and suitable for routine application.

Table 6. Robustness test results with various commercial samples

Solution	Mass-to-Charge Ratio (m/z)	Relative Value	Acceptance Range (Relative Deviation)	Conclusion
Standard Solution	87	6,11	3,06 – 9,17	-
	58	6,89	3,44 – 10,33	
	72	2,85	1,42 – 4,27	
Sample 1	87	8,68		Accepted
	58	9,19		
	72	4,09		
Spiked 1	87	7,21		Accepted
	58	7,78		
	72	3,42		

Table 6 (Continued).

Solution	Mass-to-Charge Ratio (m/z)	Relative Value	Acceptance Range (Relative Deviation)	Conclusion
Sample 2	87	8,86		Accepted
	58	9,24		
	72	4,17		
Spiked 2	87	7,61		Accepted
	58	8,04		
	72	3,57		
Sample 3	87	7,93		Accepted
	58	8,37		
	72	3,70		
Spiked 3	87	6,64		Accepted
	58	7,61		
	72	3,08		
Sample 4	87	7,66		Accepted
	58	8,33		
	72	3,61		
Spiked 4	87	6,71		Accepted
	58	7,54		
	72	3,14		
Sample 5	87	7,62		Accepted
	58	8,31		
	72	3,54		
Spiked 5	87	7,54		Accepted
	58	7,94		
	72	3,53		

3.5. Sample Testing

Sample testing using the developed analytical method was performed on five different brands of magic tissue. The test was conducted to determine whether an active substance, lidocaine, had been added to the product. The results showed that the samples were positively detected to contain lidocaine (Table 7).

Table 7. Sample testing results

Solution	Retention time (minutes)	m/z	Conclusion
Standard Solution	12,994	87 ; 58 ; 72	Positive for Lidocaine
Sample 1	13,676	87 ; 58 ; 72	Positive for Lidocaine
Sample 2	13,670	87 ; 58 ; 72	Positive for Lidocaine
Sample 3	13,670	87 ; 58 ; 72	Positive for Lidocaine
Sample 4	13,659	87 ; 58 ; 72	Positive for Lidocaine
Sample 5	13,658	87 ; 58 ; 72	Positive for Lidocaine

The validation results demonstrated that lidocaine can be identified using GC-MS with acceptable specificity, detection limit, stability, and robustness. Previously, lidocaine

identification and quantification were performed using HPLC. Compared to HPLC, GC-MS provides higher sensitivity and selectivity due to its integrated compound library and lower detection limit. Additionally, GC-MS enables compound identification without requiring a reference standard for every analysis.

The detection of lidocaine in all five commercial magic tissue products confirms the suspicion that lidocaine was deliberately added. According to regulations, antiseptic tissue products must clearly declare their composition on the product label. If lidocaine is added, the product is reclassified as a medicinal product requiring the Indonesian Food and Drug Authority registration, since lidocaine is a prescription-only drug under the Ministry of Health Regulation No. 3 of 2021 on Drug Classification. Therefore, accurate labeling of lidocaine is critical for both manufacturers and regulators, and it is necessary to conduct monitoring and supervision of magic tissue products circulating in Indonesia.

Lidocaine is an anesthetic drug used to inhibit pain sensation, consisting of a lipophilic subunit (tertiary amine) and a hydrophilic subunit (unsaturated aromatic ring) (Vardanyan & Hruby, 2006). The lipophilic part determines the local anesthetic activity (Johansson, 2012). Lidocaine works by blocking sodium ion channels, thereby reducing cell membrane permeability and preventing depolarization, which in turn blocks the conduction of electrical impulses that cause pain (Fozzard et al., 2011). Lidocaine can be used for the treatment of premature ejaculation as it reduces gland sensitivity and is believed to inhibit the spinal reflex responsible for ejaculation (Hisasue, 2016; Shah et al., 2023).

4. Conclusion

The validation results of the analytical method demonstrated that the method used fulfilled the requirements for selectivity/specificity, limit of detection (LOD), stability, and robustness. Gas Chromatography Mass Spectrometry (GC-MS) met the validation criteria and can therefore be applied for the identification of lidocaine in magic tissue samples.

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