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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. 1, December 2024 Edition, presents seven articles to address these challenges.

These seven articles include: (1) Study of Chloramphenicol Antibiotic Residues in Processed Food Products of Honey, Shrimp, and Fish in Sulawesi and Maluku, by Ma'rifah Ebtasari, Alifah Nur Aini; (2) Prospective Study on Regulatory Sandbox as a Conceptual Innovation in Processed Food Control in Indonesia by Yulian Dwi Anggraeni Puspa Handoko, Andi Wibowo, Yovia Rizki Arrahman, Pepi Fauziah, Yuliani; (3) Detection of Salmonella spp. in Laboratory Animal Pellet Feed using Real-Time Polymerase Chain Reaction (qPCR) and Loop-Mediated Isothermal Amplification (LAMP) by Fitra Yovita Delviona P, Puspita Dewi Fortuna, Nur Aini; (4) Communication Audit of the School Snack Food Program of the Food and Drug Supervisory Agency in Yogyakarta by Wulandari Wulandari, Basuki Agus Suparno, Prayudi Prayudi; (5) Development of an Analytical Method for Determination of Dexchlorpheniramine Maleate Level in Tablet Preparations by UV Detector High-Performance Liquid Chromatography by Lilik Budiati, Nurul Ilmiyati; (6) Analysis of the Results of Supervision of Advertisement of Processed Food Products Circulating in DKI Jakarta Province in 2021 - 2023 by Umar Saifudin, Tenri Noviardani; (7) Assessment of Compliance of Palm Cooking Oil Production Facilities in the Working Areas of Indonesian FDA Regional Office in Bandung and Surabaya in Conducting Vitamin A Fortification by Setyo Utami, Dinny Andriany.

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. 1, December 2024 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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Study of Chloramphenicol Antibiotic Residues in Processed Food Products of Honey, Shrimp, and Fish in Sulawesi and Maluku

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ABSTRACT

Antibiotic residues in food products can cause significant public health problems. Using antibiotics in livestock farming can potentially cause antibiotic residues in animal-based foods. We conducted this study to determine the results of chloramphenicol residue testing in processed honey, shrimp, and fish food products in the Sulawesi and Maluku regions. This study can determine the distribution of test results based on business type. This study is expected to produce recommendations to stakeholders to minimize the use of chloramphenicol, which is not covered by the provisions. The research samples came from processed honey, shrimp, and fish food products distributed in the Central Sulawesi, Ambon, Sofifi, Mamuju, Morotai, and Tanimbar regions in 2021-2022. Testing was carried out at the laboratory of the Indonesian Food and Drug Authority Regional Office in Palu according to the analysis method of PPPOMN 071/PA/17 concerning the Determination of Chloramphenicol Residue Levels in Shrimp by ELISA and MA PPPOMN 11/PA/09 concerning the Determination of Chloramphenicol Residue Levels in Honey by ELISA. Based on the test results, processed honey, shrimp, and fish food products were found to contain chloramphenicol residues. Of the total 92 samples tested, there were 15 honey products, four processed shrimp food products, and seven processed fish food products that did not meet the requirements (TMS). Chloramphenicol residue levels ranged from 0.01 to 0.09 ppb. The number of TMS samples in honey and fish food products with PIRT distribution permits was more significant in percentage when compared to products with MD/ML distribution permits. The rate of TMS in honey and processed fish food products with PIRT distribution permits was 53% and 21%, respectively. Further research on the source of chloramphenicol residues and the origin of honey, shrimp, and fish-producing areas needs to be conducted by relevant institutions or academics. In addition, it is necessary to conduct socialization and education among the public regarding the use of chloramphenicol antibiotics according to the provisions for both the treatment of diseases and livestock practices to minimize the presence of chloramphenicol residues in processed food products.

Residu antibiotik dalam produk makanan dapat menimbulkan masalah kesehatan masyarakat yang signifikan. Praktek penggunaan antibiotik pada budidaya ternak berpotensi menimbulkan residu antibiotik pada pangan berbahan dasar dari hewan. Penelitian ini dilakukan untuk mengetahui hasil pengujian residu kloramfenikol pada produk pangan olahan madu, udang, dan ikan di wilayah Sulawesi dan Maluku. Selain itu, melalui penelitian ini dapat diketahui sebaran hasil uji berdasarkan jenis izin edar. Pada akhirnya diharapkan menghasilkan suatu rekomendasi kepada stakeholder terkait untuk meminimalisir penggunaan kloramfenikol yang tidak sesuai ketentuan. Sampel penelitian berasal dari produk pangan olahan madu, udang, dan ikan yang terdistribusi di wilayah Sulawesi Tengah, Ambon, Sofifi, Mamuju, Morotai, dan Tanimbar tahun 2021-2022. Pengujian dilakukan di laboratorium Balai POM Palu sesuai metode analisis PPPOMN 071/PA/17 tentang Penetapan Kadar Residu Kloramfenikol dalam Udang secara ELISA dan MA PPPOMN 11/PA/09 tentang Penetapan Kadar Residu Kloramfenikol dalam Madu secara ELISA. Berdasarkan hasil pengujian ditemukan produk pangan olahan madu, udang, dan ikan yang mengandung residu kloramfenikol. Dari total 92 sampel yang diuji, terdapat 15 produk madu, 4 produk pangan olahan udang, dan 7 produk pangan olahan ikan yang tidak memenuhi syarat. Kadar residu kloramfenikol berkisar dari 0,01-0,09 ppb. Jumlah sampel

TMS pada produk pangan madu dan ikan dengan izin edar PIRT lebih besar persentasenya jika dibandingkan dengan produk dengan izin edar MD/ML. Presentase TMS produk madu dan pangan olahan ikan dengan izin edar PIRT secara berturut -turut 53% dan 21 %. Riset lebih lanjut mengenai sumber residu kloramfenikol dan asal wilayah penghasil madu, udang, dan ikan perlu dilakukan oleh lembaga atau akademisi terkait. Selain itu, perlu dilakukan sosialisasi dan edukasi kepada masyarakat mengenai penggunaan antibiotik kloramfenikol sesuai ketentuan baik untuk pengobatan penyakit ataupun praktik peternakan untuk meminimalisir adanya residu kloramfenikol pada produk pangan olahan.

Keywords: *antibiotic residue*, *chloramphenicol, honey, processed fish, processed shrimp*
Kata Kunci: residu antibiotik**,** kloramfenikol, madu, olahan ikan, olahan udang.

1. Introduction

Food safety has become an essential issue in the era of globalization and international trade; consumers are increasingly aware of the quality and safety of products to be consumed. One aspect that is important to note is the presence of antibiotic residues. In 2014-2023, there were 77 cases of rejection of fresh fishery food exports from the US Food and Drug Administration (US FDA) due to residues of chloramphenicol, nitrofurans, and veterinary drugs. (BPOM, 2023)

Antibiotic residues in food products pose a public health problem, as they can trigger antibiotic resistance and adversely affect consumer health. (Menkem et al., 2019). According to the Food and Agriculture Organization (FAO) (2021), 700,000 people die from infectious diseases every year due to antibiotic-resistant microbes. (BPOM, 2023).

Exposure to antibiotic residues can occur from consuming seafood that contains residues or while processing products that contain residues. (Aly and Albutti, 2014). According to FAO and the World Veterinary Association, residues of chloramphenicol and its metabolites are hazardous if found in food. (Wang et al*.,* 2021). One of the effects that can be caused by residual chloramphenicol in food is spinal cord toxicity. (Nisha, 2008)

According to Adi Saputra and Arfi (2021), consuming shrimp containing chloramphenicol residues in excess for a long time causes spinal cord depression. This can disrupt the red blood cell production, causing aplastic or hypoplastic anemia, thrombocytopenia, and granulocytopenia. In addition, several studies have shown a direct correlation between antibiotic resistance in humans and animals and the use of antibiotics in pet food. (Aly and Albutti, 2014).

Chloramphenicol is an antibiotic used in livestock. Apart from therapeutic purposes, it is also used as a growth-inducing substance. Usually, it is added to artificial feed. (Wibowo et al., 2010). Antibiotics are commonly used in beekeeping to treat bacterial infections that attack honey bee larvae.

The Indonesian government has realized the potential dangers of chloramphenicol contaminating food, so relevant ministries and agencies have made several regulations. The Indonesian Ministry of Health regulates the chloramphenicol contamination limit in Permenkes Number 33 of 2012 (Kemenkes, 2012) . In addition, the Indonesian Food and Drug Authority (BPOM) regulates the use of chloramphenicol in PerBPOM Number 7 of 2018 regarding Prohibited Raw Materials in Processed Food. (BPOM, 2018). The National Standardization Agency also regulates the maximum limits of microbial contaminants and residues in food ingredients of animal origin in SNI 01-6366 of 2000. (BSN, 2000).

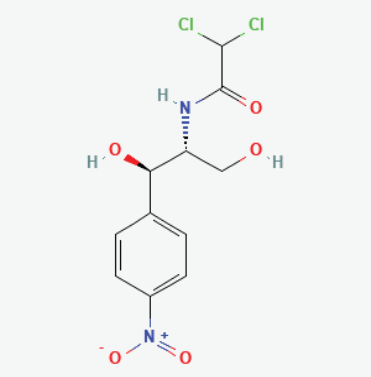

Figure 1. Chemical structure of chloramphenicol antibiotic
(source: *National Center for Biotechnology Information* (2023)).

To ensure that food products are safe, BPOM supervises products both before they are distributed and after they are on the market. Products in circulation were randomly sampled for laboratory testing according to requirements. The test results on honey, shrimp, and fish processed food products at the Indonesian Food and Drug Authority Regional Office in Palu in 2021-2022 showed that there were samples that did not meet the requirements (TMS) for the chloramphenicol residue test. The Indonesian Food and Drug Authority Regional Office in Palu conducted chloramphenicol residue testing of honey, shrimp, and fish processed food products from the Central Sulawesi, Ambon, Sofifi, Mamuju, Morotai, and Tanimbar regions. The comprehensive coverage of the sampling area provides results that are pretty representative of chloramphenicol residue tests on food products in circulation.

Previous studies have analyzed chloramphenicol residue levels in honey, shrimp, and carp products. The methods used were Enzyme-Linked Immunosorbent Assay (ELISA) and High-Performance Liquid Chromatography (HPLC) (Wibowo et al., 2010). Other research on different regions has been carried out, such as the Analysis of Chloramphenicol Antibiotic Residue Levels in *Vannamei* Shrimp (*Litopenaeus Vannamei*) in Bangkalan Regency with the ELISA Method by Sari and Hafiludin (2023). Research on chloramphenicol residue levels in processed food products in the Sulawesi and Maluku regions has never been done. Thus, it is necessary to conduct this research to find out how big the risk of processed food made from honey, shrimp, and fish containing chloramphenicol residues is.

This study will analyze the test results of chloramphenicol residue content in processed food products of honey, shrimp, and fish in Sulawesi and Maluku regions, analyze the type of business in samples that do not meet the requirements (TMS), and the distribution of TMS samples based on the type of business.

2. Methodology

This research is a retrospective quantitative analysis. All research samples came from processed food products of honey, shrimp, and fish tested by the food laboratory of the Indonesian Food and Drug Authority Regional Office in Palu in 2021-2022. Honey samples were in the form of honey products in bottles or cassettes. Shrimp-based samples are in the form of cikua products and shrimp meatballs. The fish samples are shredded products, sardines in cans, fish balls, tempura, and fish pempek. In 2021, the samples tested came from processed food products distributed in the Central Sulawesi region. In 2022, the samples came from processed food products distributed in the Central Sulawesi, Ambon, Sofifi, Mamuju, Morotai, and Tanimbar regions. Sampling is carried out randomly at distribution facilities scattered in the area. The random sampling method can provide an overview of samples circulating in the community.

The test was carried out using the PPPOMN 071/PA/17 analytical method on determining Chloramphenicol Residue Levels in Shrimp by ELISA and the PPPOMN 11/PA/09 analytical method on determining Chloramphenicol Residue Levels in Honey by ELISA. In the ELISA analysis, a positive control is used to ensure the validity of the test results. In addition, a standard series is used to ensure the validity of the results.

The data obtained were then categorized based on the conclusion of the test results, namely samples that meet the requirements (MS) and samples that do not (TMS). The samples were grouped based on the type of business to see the profile of TMS samples. The first group is nationally produced TMS products with Domestic Food (MD) and Foreign Food (ML) distribution permits. The second group of locally produced TMS products had a Home Industry Food (PIRT) distribution permit. The two data groups were analyzed descriptively to determine the trend and distribution of the data.

3. Results and Discussion

Based on the test results of the Indonesian Food and Drug Authority Regional Office in Palu, chloramphenicol residues were still found in several samples. Details of the test results of chloramphenicol residue levels are listed in Table 1.

Table 1. Chloramphenicol Residue Testing Results of Indonesian Food and Drug Authority Regional Office in Palu in 2021-2022

Types of processed food products	Total Samples Tested	Product Qualified (MS)		Unqualified Product (TMS)	
		Total	MS percentage (%)	Total	TMS Percentage (%)
2021					
Honey	13	0	0,00	13	100,00
Shrimp	5	1	20,00	4	80,00
Fish	0	0	0,00	0	0,00
Total	**18**	**1**	**5,56**	**17**	**94,44**
2022					
Honey	26	24	92,31	2	7,69
Shrimp	8	8	100,00	0	0,00
Fish	40	33	82,50	7	17,50
Total	**74**	**65**	**87,84**	**9**	**12,16**

The results of chloramphenicol residue testing in honey experienced a decrease in TMS samples from 100.00% (2021) to 7.69% (2022). Likewise, the results of chloramphenicol residue testing in shrimp experienced a decrease in TMS samples from 80.00% (2021) to 0.00% (2022). Despite the decrease in TMS samples, the threat of chloramphenicol residues in these processed food products still exists. This is in line with the results of research by Sari and Hafiludin (2023), where chloramphenicol residues were still found in *Vannamaei* shrimp. In addition, Luo et al. (2021) Also, chloramphenicol residues in shellfish, fish, and shrimp were found based on research conducted in South China waters. This indicates that chloramphenicol residues in food products derived from aquaculture are still a real threat. Using antibiotics in animal farming can result in antibiotic residues in fresh food from fish (PSAI), which are eventually carried over into processed food products. (BPOM, 2023).

Tables 2, 3, and 4 list the detailed test results for chloramphenicol residue levels in honey, shrimp, and fish products.

Table 2. Testing Results of Chloramphenicol Residue Levels in Honey Based on Business Type

Tested Products	Business Type	Chloramphenicol residual level (ppb)	Test Results
Honey 1	PIRT	0,02	TMS
Honey 2		0,02	TMS
Honey 3		0,02	TMS
Honey 4		0,01	TMS
Honey 5		0,01	TMS
Honey 6		0,01	TMS
Honey 7		0,02	TMS
Honey 13		0,02	TMS
Honey 20		0,08	TMS
Honey 24		0,05	TMS
Honey 8	MD/ML	0,04	TMS
Honey 9		0,05	TMS
Honey 10		0,05	TMS
Honey 11		0,04	TMS
Honey 12		0,06	TMS

Table 3. Testing Results of Chloramphenicol Residue Levels in Shrimp by Business Type

Tested Products	Business Type	Chloramphenicol residual level (ppb)	Test Results
Shrimp 1	MD/ML	0,02	TMS
Shrimp 3		0,02	TMS
Shrimp 4		0,03	TMS
Shrimp 5		0,02	TMS

Table 4. Chloramphenicol Residue Test Results in Fish by Business Type

Tested Products	Business Type	Chloramphenicol residual level (ppb)	Test Results
Fish 22	PIRT	0,01	TMS
Fish 23		0,01	TMS
Fish 38		0,01	TMS
Fish 13	MD/ML	0,05	TMS
Fish 14		0,09	TMS
Fish 17		0,01	TMS
Fish 35		0,01	TMS

ppb = *part per billion* (µg/Kg)
TMS = Does not meet the requirements for chloramphenicol residue based on Permenkes No. 33 of 2012
PIRT = Home Industry Food
MD= Domestic Food (domestically produced food products)
ML= Outside Food (imported food products produced abroad)

Honey residue levels detected ranged from 0.01 to 0.08 ppb, processed shrimp food products ranged from 0.02 to 0.03 ppb, and processed fish food products ranged from 0.01 to 0.09 ppb. Based on the results of research conducted by Sari and Hafiludin (2023), chloramphenicol antibiotic residue levels in *Vannamei* shrimp in Bangkalan Regency ranged from 0.006 to 0.027 ppb. The results of research conducted by Adi Saputra and Arfi (2021) showed that the residual levels of chloramphenicol antibiotics in Windu shrimp from the Kutaradja Ocean Fishing Port (PPS) were 2.4634 ppb—likewise, the results of research conducted by Virgianti et al. (2022). The residual levels of chloramphenicol antibiotics in white shrimp ranged from 0.12 to 0.14 ppb. From the results of these studies, it appears that chloramphenicol residue levels in fresh shrimp are higher than in processed shrimp food products. The processing of food products may be able to reduce chloramphenicol residue levels. The process of washing repeatedly or heating at certain temperatures can be a factor in significantly reducing chloramphenicol residue levels. Research conducted by

Gowtham et al. (2020) showed that food processing reduces antibiotic residue levels that vary in food products.

Research on the use of antibiotics in beekeeping, which is at risk of causing antibiotic residues in honey, has been carried out. The results of a study entitled Detection of Antibiotic Residues in Blossom Honeys from Different Regions in Turkey by LC-MS/MS Method showed that of the 80 honey samples tested, various types of antibiotic residues were still found in them. (Demirhan and Demirhan 2022). Several other international reports also reported antibiotic residues in honey samples. Antibiotics can cause antibiotic residues in honey to treat bee diseases caused by bacteria. Antibiotic residues mostly come from the environment and improper beekeeping practices. (Al-Waili et al., 2012). Honey products do not undergo many processes during production, so the levels are not significantly different after harvesting or packaging.

Apart from the composition of the main ingredient, residual chloramphenicol can come from other raw materials used. For this reason, the composition label listed on the product packaging was observed. Other raw materials suspected of containing chloramphenicol residues are milk and eggs. Of the 11 samples of shrimp/fish-based processed food products with TMS test results, four samples included egg white, either egg white powder, premix flour, or *batter* flour containing eggs. Chloramphenicol residues can be found in chicken eggs due to the use of antibiotics as growth promoters for chicken animals. Chicken farmers intentionally add chloramphenicol to these animals' artificial feeds and drinks.

Furthermore, this study analyzed the type of business with chloramphenicol residue content. Business types for processed food were divided into two major groups, namely national-scale and local-scale business types. The national scale includes products with BPOM MD and BPOM ML distribution permit numbers. The local-scale category includes products with PIRT distribution permits. The distribution of TMS products based on the type of distribution permit is listed in Figure 2.

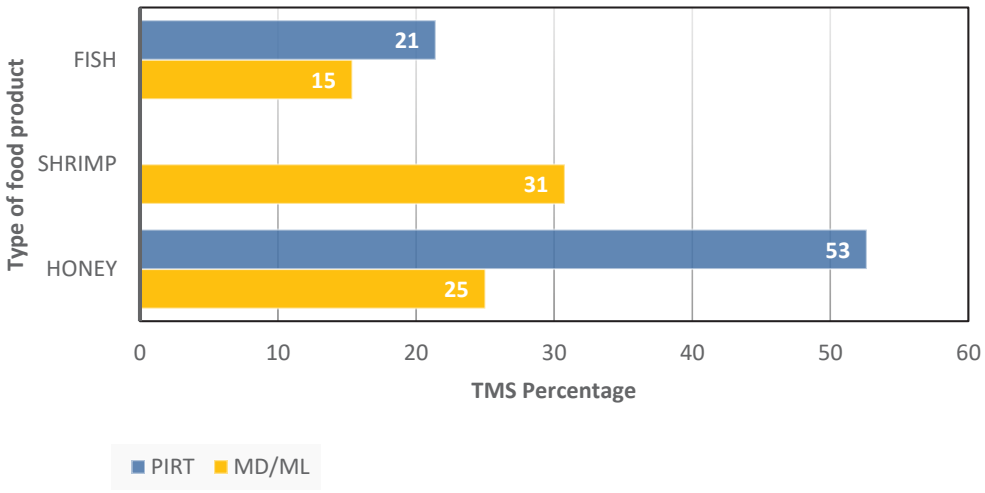

Figure 2. Percentage of TMS Samples by Circulation Permit Category
PIRT = Home Industry Food
MD= Domestic Food (domestically produced food products)
ML= Outside Food (imported food products produced abroad)

Samples of TMS honey with a PIRT distribution permit amounted to 21%, which is higher than the MD/ML distribution permit (15%). Most of the honey with PIRT distribution permits were sourced from areas around Sulawesi and Maluku. Improper beekeeping practices can lead to chloramphenicol residues in honey. According to Al Waili et al. (2012), antibiotic residues consumed with food and honey can cause resistance in bacterial populations. This

global public health issue continues to be a challenging problem. (Al-Waili et al., 2012). It is challenging for the government to investigate local honey farming practices in Sulawesi and Maluku.

The shrimp-based food products tested by the Indonesian Food and Drug Authority Regional Office in Palu are products with the MD/ML distribution permit number, so they cannot be compared with local products. Both types of products still have the same risk of chloramphenicol residue. Products with an MD/ML distribution permit are not guaranteed to be free from the risk of chloramphenicol residues. This concerns relevant stakeholders, who must be more prudent in using chloramphenicol. Likewise, for PIRT products, local raw materials should be more selective so that the products are safe for public consumption.

Samples of TMS-processed fish products with PIRT distribution permits were also more significant than those with MD/ML distribution permits. The raw material source area can be one of the factors causing samples to contain chloramphenicol residues. Of the 7 TMS samples, three were sampled from Central Sulawesi, two in Ambon, and two in Mamuju. Central Sulawesi and Mamuju samples were local products with PIRT distribution permit numbers. PIRT-scale businesses usually use fish raw materials from the waters of the area. Based on the description of the composition label, it appears that the fish used is marine fish, not farmed fish. This needs to be a concern, especially for the governments of Central Sulawesi and West Sulawesi (Mamuju), to be more aware of chloramphenicol contamination in their regional marine waters.

The use of antibiotics in the treatment of fish or farmed animals has been commonly practiced. This is regulated by the Ministry of Marine Affairs and Fisheries Number 1 of 2019, which regulates the types of antimicrobials permitted in fish farming. However, the use should be under the supervision of a veterinarian. Inappropriate antibiotic use practices can trigger antibiotic residues in food products made from aquaculture. (BPOM, 2023).

The Indonesian Food and Drug Authority (BPOM), which grants distribution permits for processed food products, has set product criteria that must be met. These criteria are regulated in BPOM Regulation Number 27 of 2017 Regarding the Registration of Processed Food. The first is safety criteria, including physical, chemical, and biological safety. Processed food that will be circulated must be free from these three contaminants. In addition, food additives (BTP) and auxiliary materials must be used according to applicable requirements. The second criterion is quality requirements according to predetermined requirements. Third, nutritional criteria must be met; the product must be ensured to contain nutritional value by the requirements before obtaining a distribution permit number.

In addition to these three criteria, the registered processed food must also meet the labelling requirements. Production facilities must also meet the requirements of suitable processed food production methods (CPPOB). Implementing some of these regulations is expected to ensure that MD/ML and PIRT products are of the same quality. To improve the competitiveness of PIRT products, household food industries, before producing processed food, must have a certificate of processed food production for household industries by the provisions of laws and regulations. Basic knowledge about food safety is expected to be a provision for producers to produce quality products.

All products that had been tested were products that obtained MD/ML or PIRT numbers, indicating that the producers followed good CPPOB. However, honey, shrimp, and fish products were still found to contain chloramphenicol residues. The presence of this substance cannot be confirmed as coming from environmental contamination or deliberately added by honey, shrimp, and fish suppliers. Further research on the source of chloramphenicol residues in honey, shrimp, and fish must be conducted by relevant institutions or academics to minimise chloramphenicol residues in food products.

Related institutions or academics need to conduct further research on the source of chloramphenicol residues in honey, shrimp, and fish. In addition, it is necessary to socialize and educate the public regarding using chloramphenicol according to the provisions for animals and humans to reduce chloramphenicol residues in food products spread across Sulawesi and Maluku. In addition, The Indonesian Food and Drug Authority (BPOM) can consider making a policy of listing the source of raw materials on product labels so that it is easier to trace if chloramphenicol residue results exceed the predetermined threshold.

4. Conclusion

The results of testing the residual chloramphenicol content of the laboratory of the Indonesian Food and Drug Authority Regional Office in Palu in 2021-2022 from a total of 92 tests showed that there were 15 samples of honey products, four samples of processed shrimp food products, and seven samples of processed fish food products that did not meet the requirements (TMS). Chloramphenicol residue levels in the samples ranged from 0.01 to 0.09 ppb. Honey and processed fish products with PIRT distribution permits showed a higher percentage of TMS than those with MD/ML distribution permits. Raw materials for honey, shrimp, and fish from Sulawesi and Maluku must be studied further to determine the primary source of chloramphenicol residues. This is important as a basis for policy-making in maintaining the quality of processed honey, shrimp, and fish products.

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Prospective Study on Regulatory Sandbox as a Conceptual Innovation in Processed Food Control in Indonesia

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ABSTRACT

The enhancement of innovation in processed food products in Indonesia faces regulatory challenges that often limit the speed and flexibility of development, particularly for high-risk products. The recent implementation of the Omnibus Law has brought significant changes to the food oversight framework, including the exemption of criminal sanctions for low to medium-risk business activities and the transition of distribution permits into business licenses. However, these regulations have not fully addressed the barriers to innovation in processed food development. The concept of a regulatory sandbox has been identified as a promising prospective approach to overcoming these challenges, providing a controlled testing environment for businesses to develop innovative products within a more adaptive ecosystem. This article explores the potential of a regulatory sandbox as a creative tool for overseeing high-risk processed food products through a qualitative literature review method. The study indicates that the success of implementing a sandbox depends on several key factors: collecting robust experimental data to assess product safety and efficacy, developing adaptive procedures responsive to industry feedback, and granting limited yet flexible authorization for testing new technologies. Other factors, such as limitations on the duration, scope, and use of the sandbox, must be established to avoid consumer safety risks. As a recommendation, The Indonesian Food and Drug Authority (BPOM) may consider adopting a regulatory sandbox as a strategic framework to support the oversight of processed food products with a dynamic approach, accelerating innovation while maintaining a balance between consumer safety and industry growth.

Peningkatan inovasi dalam produk pangan olahan di Indonesia dihadapkan pada tantangan regulasi yang sering membatasi kecepatan dan fleksibilitas pengembangan, terutama pada produk berisiko tinggi. Penerapan Undang-Undang Cipta Kerja baru-baru ini membawa perubahan signifikan dalam kerangka pengawasan pangan, termasuk pengecualian sanksi pidana bagi kegiatan usaha berisiko rendah hingga menengah dan transisi izin edar menjadi perizinan berusaha. Namun, peraturan ini belum sepenuhnya memberikan solusi terhadap kendala pengembangan inovasi pangan olahan. Regulatory sandbox diidentifikasi sebagai pendekatan konseptual prospektif yang potensial untuk mengatasi hambatan ini, memungkinkan lingkungan uji coba yang terkendali bagi pelaku usaha untuk mengembangkan produk inovatif dalam ekosistem yang lebih adaptif. Artikel ini mengeksplorasi potensi regulatory sandbox sebagai alat inovatif dalam pengawasan pangan olahan berisiko tinggi melalui metode kualitatif berbasis kajian pustaka. Kajian menunjukkan bahwa keberhasilan implementasi sandbox bergantung pada beberapa faktor utama: pengumpulan data eksperimental yang kuat untuk menilai keamanan dan efektivitas produk, pembentukan prosedur adaptif yang responsif terhadap masukan industri, serta pemberian otorisasi terbatas namun fleksibel untuk pengujian teknologi baru. Di samping itu, faktor-faktor lain, seperti batasan dalam durasi, ruang lingkup, dan penggunaan sandbox, juga perlu ditetapkan untuk menghindari risiko keamanan konsumen. Sebagai rekomendasi, Badan Pengawas Obat

dan Makanan (BPOM) dapat mempertimbangkan regulatory sandbox sebagai kerangka kerja strategis yang mendukung pengawasan produk pangan olahan dengan pendekatan dinamis, mempercepat inovasi sambil tetap menjaga keseimbangan antara keamanan konsumen dan pertumbuhan industri.

Keywords: Regulatory Sandbox, Control, Processed Food
Kata Kunci: *Regulatory Sandbox, Pengawasan, Pangan Olahan*

1. Introduction

Innovation in processed food control is vital for national food security and public health amid accelerating technology and diversification of food products. In Indonesia, the urgency to develop a flexible and responsive food control system is increasingly prominent, particularly in high-risk processed foods with unique nutritional products. While Indonesia's *pre-market approval* system ensures product safety before marketing, the procedure is often perceived as stifling innovation, especially among resource-constrained small and medium-sized enterprises (SMEs). (Eggers & Turley, 2018). Establishing uniform regulations for all businesses often does not align with dynamic market needs and rapidly evolving product innovations. This leads to violations, such as circulating processed food products without distribution permits.

To overcome this obstacle, the Indonesian government, through the Job Creation Law Number 6 Year 2023, has introduced additional flexibilities in the formal regulatory perspective, including exemptions from criminal sanctions for low- to medium-risk businesses. While these measures are expected to support economic growth and innovation, these regulatory changes have not fully addressed the key challenges in controlling high-risk processed food, especially for processed food for special nutritional needs (PKGK) products, which are one of the focuses in mitigating *stunting* in Indonesia. (Presidential Regulation of the Republic of Indonesia, 2021). Based on data from the Food and Drug Administration (BPOM), processed food products without a distribution permit (TIE) dominate regulatory violations from year to year, namely 60% of 158 cases in 2018, 47% of 306 cases in 2019, 56% of 333 cases in 2020, 63% of 388 cases in 2021, 66% of 442 cases in 2022, and 62% of 173 cases in 2023. This condition shows that conventional *pre-market approval-based* control faces limitations in supporting the development of innovative yet safe food products.

In the face of these limitations, the *regulatory sandbox* approach is considered an innovative and prospective solution that can assist regulators in creating a more adaptive supervisory ecosystem. According to Brown and Piroska (2022), the *regulatory sandbox* is defined as a framework created by regulators that allows innovators to conduct hands-on experiments in a controlled environment under the supervision of regulators. The *regulatory sandbox* framework will enable innovators to experiment and innovate without significant risks, while regulators can understand the potential impact of new products or services before issuing formal regulations. This bridges the gap between strict regulation and unbridled innovation growth and creates a conducive environment for technological evolution while keeping in mind the limits of consumer protection. *Regulatory sandboxes* offer a controlled test bed for the food industry to develop and test new products in a flexible yet supervised environment. As a concept that has been applied successfully in the financial technology sector in various countries, *sandboxes* allow regulators to interact directly with innovators to understand risks and opportunities and shape a regulatory framework that is more in line with industry dynamics. (Sherkow, 2022). For the food sector, particularly in the case of PKGK food, the *regulatory sandbox* approach is projected to provide an experimental pathway that allows product innovations to be tested directly in the market under the close supervision of regulators, providing valuable empirical data for evidence-based policy decision-making.

This approach offers several relevant mechanisms to overcome the main obstacles in developing high-risk food products. First, the *sandbox* enables the collection of comprehensive

experimental data, providing a foundation for evaluating product safety and effectiveness more dynamically than rigid *pre-market* procedures. Second, establishing adaptive procedures responsive to industry input allows regulators to quickly adjust regulations based on market developments and technological innovations without compromising consumer safety. Third, the *regulatory sandbox* allows for limited but flexible authorizations for trials of new food technologies or products that do not yet have a definitive regulatory framework. (Burd, 2021). Thus, this approach can potentially reduce the circulation of illegal food products through a more constructive and innovative regulatory framework.

This article aims to assess the potential of implementing a *regulatory sandbox* in controlling high-risk processed food in Indonesia, focusing on the key elements that determine the successful implementation of this concept. As such, this study seeks to answer the main questions: What is the potential of the *regulatory sandbox* as an effective solution in controlling high-risk processed food in Indonesia, and what are the determinants of success that need to be considered in its implementation? This study is expected to contribute significantly to the collective crime prevention strategy in the processed food sector and offer recommendations for BPOM to develop a more innovative and adaptive supervisory policy that meets the needs of the growing food industry in Indonesia.

2. Methodology

This study adopts a qualitative approach based on *a literature review to assess the potential application of a regulatory sandbox* in controlling high-risk processed food in Indonesia, focusing on Processed Food for Special Nutritional Purposes (PKGK) products. This method was chosen to develop a comprehensive overview of the concept, best practices, and challenges and opportunities of implementing the *sandbox* as an innovative regulatory framework that can be adapted in the context of Indonesian food control. Secondary data were obtained through literature searches from significant databases, namely Scopus, PubMed, and Google Scholar, using keywords such as "regulatory sandbox," "high-risk food products," and "pre-market approval in the *food industry*." Additional keywords such as "high-risk processed food" and "food control in Indonesia" were also used to ensure relevance to the local context. The range of publication years reviewed was limited from 2018 to 2023 to ensure that the research only refers to the most recent and relevant literature.

Inclusion and exclusion criteria were applied to maintain the quality and focus of the analysis. The literature selected were publications relevant to the *regulatory sandbox* in the food, health, or financial sectors, emphasising high-risk food products such as PKGK, which directly impact public health. Literature inclusion also considers publications that provide empirical data or concept-based analysis to give depth to the research. Meanwhile, literature not directly related to food control or merely opinions without empirical basis is excluded. The review also includes studies in English and Indonesian to maximize the relevance and accessibility of the data.

The data collected was then analyzed using thematic methods, enabling the identification of key patterns such as the benefits and challenges of the *regulatory sandbox* framework, its potential application in food regulation, and its adaptability in the Indonesian context. Thematic analysis was chosen for its flexibility in grouping the data into meaningful categories, thus facilitating the drawing of conclusions and the formulation of recommendations. The limitations of this study, including reliance on secondary data and limited access to contextual literature, were managed by selecting diverse data sources with high validity and considering a variety of international perspectives to compensate for the limited local literature specific to the *regulatory sandbox* in the business process of Food and Drug Control.

3. Results and Discussion

3.1. New Approach to Processed Food Control

The current control of processed food in Indonesia focuses on the *pre-market approval* approach, where every food product must undergo strict evaluation before it can be marketed. This approach aims to ensure the safety of food products, especially high-risk products such as Processed Food for Special Nutritional Purposes (PKGK), which directly affect public health. (Eichler *et al*., 2012). PKGK is processed food that is specially processed or formulated to meet specific nutritional needs due to certain physical/physiological conditions and diseases/disorders. PKGK consists of Processed Food for Special Diets (PDK), such as infant formula, and Processed Food for Special Medical Purposes (PKMK), such as PKMK, for patients with chronic kidney disease.

While effective in maintaining safety standards, the *pre-market approval* system has significant limitations. High costs, lengthy processes, and administrative complexity can be barriers to innovation, especially for small businesses that do not have the resources to fulfil these requirements. As such, conventional *pre-market approval is* considered less adaptive to evolving market dynamics and the need to accelerate access to safe, innovative consumer products. These limitations create an urgency for regulators in Indonesia to explore more flexible methods that still meet stringent food safety standards.

Regulatory sandbox, as an alternative approach implemented in sectors such as finance and healthcare in many developed countries, offers an innovative solution to overcome the limitations of *pre-market approval*. In case studies from the UK and Singapore, the *sandbox* approach has created a controlled environment that allows businesses to test products with more flexible regulatory schemes while remaining under the watchful eye of regulators. (Allen *et al*., 2019; Tan & Taeihagh, 2021). The success of this model, particularly in driving accelerated innovation in the medical technology and financial sectors, suggests that *regulatory sandboxes* can provide a safe experimental space where innovation can flourish without putting consumers at risk. Another example is in the health sector of European countries, where *sandboxes* are used to accelerate the adoption of medical technologies such as artificial intelligence in medical devices, focusing on improving *post-market* surveillance to reduce the burden of complex *pre-market approval* and enable faster innovation in a safe environment. (Sherkow, 2022; Buocz *et al*., 2023).

As for Indonesia, adopting a *regulatory sandbox* in food control faces specific challenges that must be considered in the local economic and regulatory context. Uneven digital infrastructure, capability variation among stakeholders, and a low understanding of the benefits of the *sandbox* approach in the food sector may hinder its implementation. However, the successful implementation of a *regulatory sandbox* by the Ministry of Health through the *e-malaria* program shows the potential to be adapted to the food sector. This is illustrated by the *e-malaria regulatory sandbox* trial by the Ministry of Health on 4 (four) digital health service innovation clusters (ILKD), carried out from November 30, 2021, to June 30, 2022. The e-malaria regulatory sandbox implementation results are stated with the status of ILKD recommended, improved, or not recommended. (Malaria *Working Group*, 2021). This program, which involves testing innovations in a controlled environment, indicates that the *sandbox* model can accelerate innovation while maintaining oversight. Nonetheless, implementing sandboxes in the food sector will require more comprehensive policies, including integrating digital surveillance and stronger consumer data protection to ensure food safety (Fuad *et al*., 2023; Gromova & Ivanc, 2020). With close supervision from the Indonesian Food and Drug Authority (BPOM), *sandboxes* can enable innovative food products such as PKGK to be tested in the local market without going through the entire *pre-market* process, thus accelerating product access to consumers with holistically managed risks.

Globally, *regulatory sandboxes* have proven effective in balancing the need for innovation with strict safety standards, a balance that is much needed in Indonesia's processed food sector. In the UK, for example, *sandbox* implementation allows health technology companies to test innovations with

the support of regulators, who act as watchdogs and strategic partners (Eggers & Turley, 2018). A closer look at the theory described in Figure 1 shows that collaboration between the government and the private sector through the *regulatory sandbox* can create a more inclusive innovation ecosystem, thus encouraging the birth of safer and more innovative products at a higher speed. Implementation in other countries provides an essential perspective for Indonesia, which still focuses on rigid conventional control and requires reforms to support innovation acceleration without compromising safety.

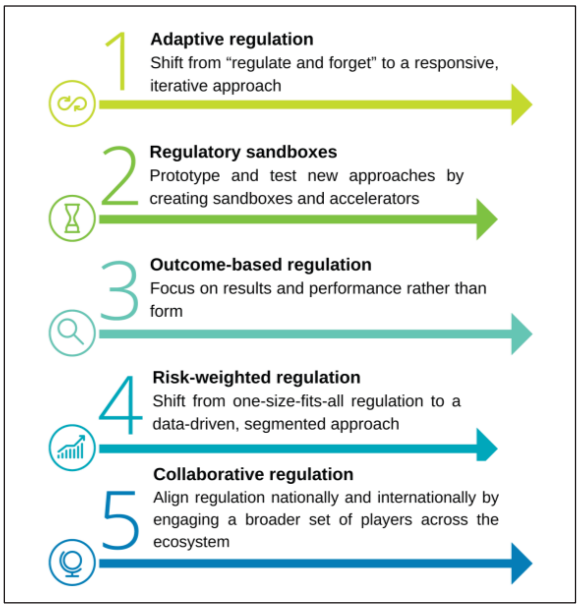

Figure 1: Regulatory Principles in Support of Innovation Ecosystems (Eggers & Turley, 2018)

The *regulatory sandbox* approach is predicted to be a solution for Indonesia to increase flexibility in food control without sacrificing safety aspects. With the implementation of the *sandbox*, high-risk processed food businesses can distribute products in a controlled environment without having to follow all applicable standards and regulations but still under the supervision of BPOM. This approach also allows for the collection of empirical data directly in the market, improving BPOM's understanding of the effectiveness and risks of innovative products. (Sherkow, 2022; Eichler *et al*., 2012). By strengthening *post-market* surveillance that emphasizes *real-time* risk detection, *the regulatory sandbox* can be an effective bridge between the needs of innovation and food safety, making Indonesia more responsive to developments in food technology.

3.2. History: The Pharmaceutical Sector that Inspired the *Regulatory Sandbox*

Regulatory sandboxes were first introduced in 2015 in the UK in response to the need for innovation in the financial sector. Originally developed based on the concept of clinical trials in pharmaceuticals, the *sandbox* provides a safe space for testing new technologies or products under the supervision of regulators but with more flexible regulatory constraints. Referring to the development of the *Regulatory Sandbox* in the financial sector, it is known that this approach accelerates innovation without compromising system stability. (Gromova & Ivanc, 2020). In this context, the health sector has also demonstrated the potential of the *regulatory sandbox* through the implementation of *Emergency Use Authorization* (EUA) by the US FDA during the COVID-19 pandemic. In the process, the EUA mechanism allows health products still in development to be used in emergencies as long as preliminary safety data are available. The EUA model inspires the implementation of a regulatory sandbox by BPOM in the processed food sector, especially for

products with high risks but the potential to provide significant benefits to the community. (Sherkow, 2022) as illustrated in Figure 2.

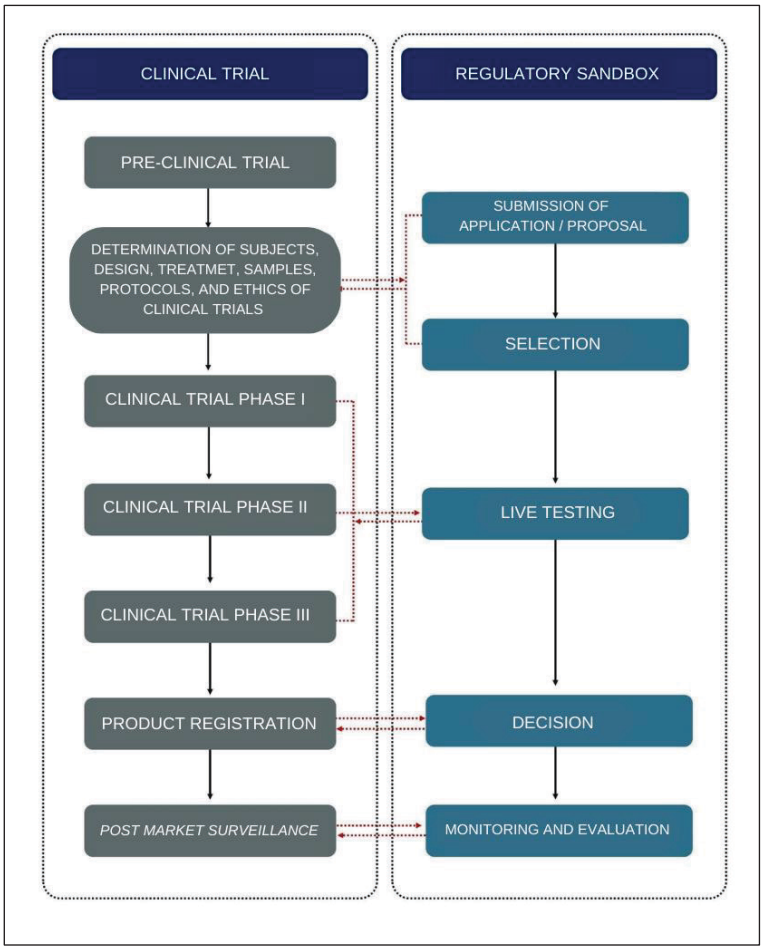

Figure 2: Comparison of Clinical Trial and *Regulatory Sandbox* Stages

In the Indonesian case study, the *regulatory sandbox* has great potential to support innovation in controlling processed food products without going through the time-consuming *pre-market approval* process. This is important as the existing *pre-market approval* system is often a significant obstacle in accelerating market access for innovative products containing certain active ingredients, such as functional drinks or probiotic products, which must be thoroughly tested before circulation. (Holle, 2018). Regarding potential implementation scenarios, the regulatory sandbox can be applied to processed food products with new health claims or innovative formulas. For example, manufacturers could conduct product testing with a limited scope of circulation to collect empirical data that would help BPOM conduct an evidence-based evaluation of the product's safety. This data collection includes direct monitoring of consumer response to the product in the market, providing more realistic and direct data on the impact of the product in a real-world setting. (Ranchordas, 2021).

Implementing a *sandbox* for these products will allow BPOM to monitor and collect data directly from consumers while still providing greater flexibility to manufacturers. The data collected may include consumer health responses, allowing for more accurate and evidence-based evaluations. However, significant challenges may arise regarding implementing adaptive regulations, especially given the uneven digital infrastructure in various regions and local supervision limitations. Looking at China, for example, the *sandbox* for the supervision of technology-based products has shown that flexible policy adaptation is necessary to deal with the complexity of local regulation. (Feng *et al*.,

2021). In addition, the *regulatory sandbox* also needs to be balanced with a strict consumer data protection framework to ensure that data collected during the testing phase is not misused or jeopardizes consumer privacy.

Overall, the *regulatory sandbox* bridges the need for innovation and consumer protection in Indonesia's processed food sector. By adopting elements from *regulatory sandbox* models in the global financial and healthcare industries, Indonesia can create an environment that encourages the development of new food products with controlled risks. The *sandbox* institution also allows BPOM to be a strategic partner in developing innovations rather than just a regulator overseeing compliance. To achieve this, the *sandbox* framework should include strong *post-market surveillance* policies and regular monitoring of product safety and effectiveness data. As implemented in the EUA by the FDA, this approach has proven to balance innovation with strict safety standards in emergencies, which provides essential inspiration for BPOM to apply the *sandbox* to the processed food sector in Indonesia. (Wallach *et al.,* 2018).

3.3. *Regulatory Sandbox* as an Approach to *Pre-Market* Control of Processed Food Products (PKGK Context)

Stunting in Indonesia remains a significant public health challenge, with the prevalence rate reaching 21.6% by 2022, according to the Indonesian Nutrition Status Survey (SSGI). This *stunting* reduction program is included in the national priorities, as stipulated in Presidential Regulation 72 of 2021, which encourages various parties at the central and regional levels to support nutritional interventions. In terms of *stunting* prevention, one of the roles of BPOM is to standardize food products, especially for the First 1000 Days of Life. The scope of standardization of food products, especially for 1000 HPK, includes products 1) Infant formula, advanced formula, and growth formula; 2) Complementary Food for Mother's Milk (MP-ASI); 3) Special Drinks for Pregnant Women and/or Breastfeeding Mothers; and 4) Processed Food for Special Medical Purposes for Infants and Children, of which the four types of products are included in PKGK products.

However, BPOM also faces challenges in regulating licensing, including distribution permits and clinical trials, often barriers to innovation. Nonetheless, interventions through PKGK have shown promising results. A study conducted by Devaera *et al.* (2018) using the *Randomized Control Trial* (RCT) method on children under five with inadequate nutrition in three villages in Central Jakarta (Manggarai, Kenari, and Paseban) showed that a specially formulated nutritional supplementation liquid milk product (Nutrinidrink multi FibeR) with calorie levels of 1.5 kcal/mL and 1.0 kcal/mL, was effective in increasing toddlers' weight over the 28-day study period. These results emphasize the importance of targeted nutritional interventions in Indonesia's stunting prevention efforts.

Regulatory sandboxes can potentially accelerate market access for PKGK products while ensuring safety through strict supervision. For example, a PMT biscuit product produced by PT Satoria Agro Industri obtained a BPOM distribution permit in 2018 and extended it in 2022, presented in Figure 3. This product has become part of the Supplementary Feeding Program (PMT) to support the nutrition of children under five. (Amarawardani *et al*., 2023).. However, the conventional licensing process is costly and often takes a long time. The licensing process of assessing the safety, quality, nutrition, and labelling of PKGK is carried out comprehensively on all documents filled in and uploaded to the system before a distribution permit is issued no later than 30 (thirty) days after the registration fee has been received and validated. However, suppose there are new nutrients, microorganisms, or types of PKGK that have not been regulated. In that case, they must be assessed first through the Directorate of Processed Food Standardization with a *timeline* of 85 (eighty-five) working days since the file is declared complete. (Directorate of Processed Food Registration of BPOM RI, 2024).. In the case of product registration for Food Category 13.0 (Processed Food for Special Nutritional Purposes), the non-tax state revenue (PNBP) fee rate is

regulated in Government Regulation (PP) No. 32/2017 on Types and Tariffs of Non-Tax State Revenues Applicable to the Food and Drug Supervisory Agency, which is IDR 3,000,000. The PNBP fee is Rp. 3,000,000 for new registration, Rp. 1,500,000 for data changes, and Rp. 2,500,000 for re-registration.

Figure 3: PMT biscuit products from PT Satoria Agro Industri that received a BPOM distribution license in 2018 and extended in 2022.

From a regulator's perspective, the *regulatory sandbox* offers an adaptive approach to respond to innovation needs without compromising safety standards. This approach allows BPOM to implement market trials with more flexible yet controlled requirements. In a *sandbox* environment, risks associated with PKGK products can be mitigated through close supervision and product circulation restrictions, allowing for rapid response to potential hazards. Meanwhile, from an industry perspective, the *regulatory sandbox* provides greater flexibility in the innovation process. Manufacturers can test new functional food or probiotic products without waiting for the entire complex licensing process, which often slows down product launches. The *sandbox* model allows companies to reduce costs and time through empirical data obtained during the limited testing phase, which can then strengthen the evidence base for a more thorough product evaluation. (Alaassar *et al*., 2020).

From a consumer perspective, the *regulatory sandbox* allows faster access to innovative food products. However, challenges related to risk perception and consumer protection need to be addressed. Studies show that while consumers favour access to food innovations, they still expect high safety assurance. (Zhu *et al*., 2021). Therefore, BPOM must ensure transparency in risk communication and consumer engagement through clear labelling and public communication strategies. A robust *post-market* surveillance system is essential to monitor risks and maintain public trust, especially for products with high health claims.

Overall, the *regulatory sandbox* offers a more dynamic and responsive framework to accommodate innovation while maintaining food safety in Indonesia. BPOM can serve as a strategic partner that supervises and supports product development by providing direct supervisory access during the trial period. This model allows BPOM to play an active role in ensuring that PKGK products are safe for consumption while collecting relevant empirical data to support a more holistic evaluation process. Through the *regulatory sandbox*, BPOM has the potential to create a more inclusive and adaptive innovation ecosystem, allowing Indonesia to respond more effectively to public health challenges.

3.4. *Best Practice Regulatory Sandbox* in the Healthcare Sector

Regulatory sandboxes were initially implemented in the financial sector in response to fast-growing innovations requiring close control to maintain market stability. While more and more sectors are adopting this concept, *sandbox* implementation in the healthcare sector is still limited in

several countries. The complexity of the health sector, which is directly related to public safety and strict safety standards, makes its adoption a challenge. Only a few countries, such as Singapore, Japan, Canada, the United States, the United Kingdom, and Germany, have successfully implemented *regulatory sandboxes* in the health context with various approaches that enable a balance between innovation and public protection (Leckenby *et al*., 2021; Fuad *et al.,* 2023).

In Singapore, the *Licensing Experimentation and Adaptation Programme* (LEAP), launched in 2018, provides a platform for developing *telemedicine* and *mobile health* services in a controlled environment. The program demonstrates that *sandboxes* can accelerate digital health technology innovation while meeting safety standards. In Japan, the *regulatory sandbox* supports the development of artificial intelligence (AI)-based technologies and *the Internet of Things* (IoT) in healthcare. This initiative allows Japan to accelerate the adoption of the latest medical technologies, ensuring innovations are accessible to the public without neglecting safety aspects. (Tsai *et al*., 2019).

Canada uses *sandboxes* to test advanced therapeutic products, such as medical devices and innovative drugs. This approach allows companies to conduct limited testing before full launch, allowing for faster evaluation on a limited scale while maintaining public safety. (Leckenby *et al*., 2021).. In the United States, *the FDA's Emergency Use Authorization (EUA)* is a *sandbox-like* approach that accelerates public access to essential medical products during emergencies such as the COVID-19 pandemic. EUAs allow the use of innovative medical technologies under scrutiny, mirroring how *sandboxes* can accelerate access in times of need while maintaining safety standards. (Sherkow, 2022). Germany has also used *sandboxes* in the healthcare sector to support the development of AI-based digital medical devices. Through this approach, Germany creates a safe environment for health technology innovations that require further testing, facilitating rapid adaptation to disruptive technologies that are difficult to integrate into conventional regulatory systems. (Leckenby *et al*., 2021).

In Indonesia, the *regulatory sandbox* is beginning to be explored through the *e-malaria* program, which uses digital technology to support malaria surveillance. The program involves collaboration between the Ministry of Health and other stakeholders, providing a foundation for Indonesia to overcome regulatory barriers to disruptive health technologies. Despite challenges such as limited digital infrastructure and the need for stronger data protection, this step demonstrates Indonesia's commitment to adopting a *regulatory sandbox* approach to support health innovations with adequate oversight. (Fuad *et al*., 2023).

Regulatory sandboxes in the healthcare sector offer an interesting alternative approach and have great potential to accelerate innovation, especially for rapidly evolving health technologies. However, like all regulatory approaches, the *sandbox* has advantages and disadvantages that must be comprehensively considered from a technical, economic, social, and cultural perspective. The main advantages of the *regulatory sandbox* are known to lie in its flexibility and speed of adoption. Technically, the *sandbox* allows companies and healthcare institutions to test new technologies in a controlled environment, where oversight can be applied immediately without waiting for the time-consuming full regulatory approval. This supports faster iterative testing, allowing technology developers to make immediate adjustments based on findings in the field. This flexibility is significant in the healthcare sector, where medical technology constantly evolves with innovations such as artificial intelligence, IoT devices, and *telemedicine*. In an economic context, *sandboxes* allow companies to reduce regulatory costs, often a significant barrier for small- and medium-sized enterprises entering the market. With a *sandbox* setup, the cost and time for product testing can be reduced, providing substantial financial benefits to the company and encouraging innovation in the broader market.

However, despite its considerable economic potential, the *regulatory sandbox* has technical drawbacks that cannot be ignored. As the *sandbox* operates in a looser regulatory setting, there is a risk that the tested products may not fully meet the safety and effectiveness standards required in formal trials. This risk can directly impact consumer safety, which could result in decreased public

confidence in the health technologies resulting from the *sandbox* framework. The regulatory sandbox also poses potential challenges from a social and cultural perspective. People in different countries, especially countries with more conservative cultures regarding public health and safety, may feel uncomfortable with the idea of testing health products under looser regulatory conditions. Cultural sensitivity to safety and conservatism in the application of medical technology can be barriers to widespread acceptance of innovations developed through the *sandbox*, especially in countries with strict health systems.

Overall, *regulatory sandboxes* offer significant advantages in speed of adoption and economic efficiency, particularly valuable in fast-evolving health technologies. However, sandbox implementation must be balanced with adequate oversight mechanisms and precise transparency arrangements toward consumers to maximise these advantages. Ultimately, while the technical and economic potential of the *sandbox* is likely to be favourable, its success in the healthcare sector will depend on the balance between flexibility and accountability. If implemented carefully and tailored to each country's social and cultural context, *sandboxes* can effectively encourage healthcare innovation while protecting public safety.

3.5. Proposed Implementation of *Regulatory Sandbox* on the Registration of Food Products for Special Nutritional Purposes

In order to achieve a significant reduction in *stunting*, WHO, through World Health Assembly Resolution 65.6, set a reduction target of 40% by 2015, with baseline data in 2012. Despite efforts, the 2021 edition of the UNICEF/WHO/World *Bank Group* report states that Indonesia is still *off-track* in achieving this target. With *stunting* remaining high at 24.4% in 2021, the Indonesian government made reducing stunting a national priority in the 2020-2024 National Medium-Term Development Plan (RPJMN), with a target of reaching 14% by 2024. This challenge emphasizes the importance of quick access to Special Nutritional Needs Food (PKGK) products, especially those that support the nutritional needs of under-fives and pregnant women.

Implementing the *regulatory sandbox* offers a strategic opportunity to accelerate the market access to PKGK products. With a risk-based approach, the *sandbox* can support innovative programs such as Supplementary Feeding for Undernourished Toddlers and Pregnant Women with Chronic Energy, even though these products are not explicitly regulated in BPOM regulations. Based on a review of various international practices, such as the implementation of *sandboxes* for *telemedicine* in Singapore, therapeutic devices in Canada, and testing of emergent health products in the US, *regulatory sandboxes* have proven to be an effective tool to overcome the limitations of conventional regulation and accelerate product access to the market. (Leckenby *et al*., 2021; Sherkow, 2022).

Figure 4 shows the elements of the *regulatory sandbox* process that BPOM can adopt to ensure safe and effective sandbox implementation in PKGK. These elements include:

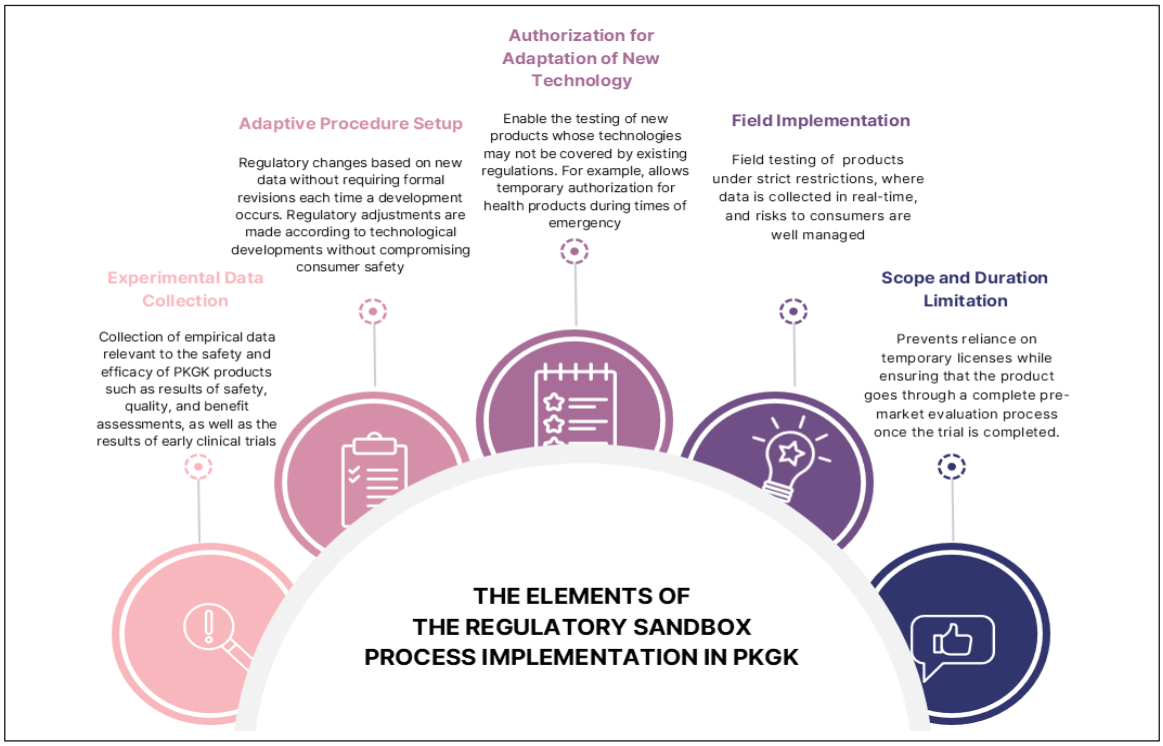

Figure 4: *Regulatory Sandbox* Process Elements for PKGK Product Regulation

a. Experimental Data Collection

The *regulatory sandbox* provides a controlled environment for collecting empirical data relevant to the safety and efficacy of PKGK products. This approach is used in the UK and Canada to collect comprehensive *post-market* data. In the context of PKGK in Indonesia, the data collected includes the results of safety, quality, and benefit assessments and early clinical trials. This process ensures that regulators have a sufficient evidence base to assess a product's appropriateness before allowing it to be widely circulated. (Gromova & Ivanc, 2020).

b. Adaptive Procedure Setup

Setting up adaptive procedures is essential to ensure the *sandbox* remains responsive to technological innovation and industry input. This approach allows for regulatory changes based on new data without requiring formal revisions each time a development occurs. In Japan, adaptive procedures in the *regulatory sandbox* have helped facilitate the application of AI and IoT technologies in the healthcare sector, where regulatory adjustments are made according to technological developments without compromising consumer safety. (Tsai *et al*., 2019).

c. Authorization for Adaptation of New Technology

Adaptive authorization is essential to enable testing new products whose technologies may not be covered by existing regulations. In the US, for example, the *Emergency Use Authorization* (EUA) approach allows temporary authorization for health products during times of emergency. EUA inspired BPOM to provide flexible authorization for CCPs by leveraging consensus technical standards adapted to technological developments. This enables accelerated access to new products without compromising basic safety standards. (Sherkow, 2022).

d. Field Implementation

One of the advantages of a *regulatory sandbox* is the ability to test products under controlled market conditions. These tests are conducted in a supervised environment, essential for maintaining product safety. In the UK, for example, sandboxes allow field testing of new health

products under strict restrictions, where data is collected in *real time,* and risks to consumers are well managed. This approach can be adapted to the PMT program in Indonesia as part of the effort to prevent *stunting* through innovative PKGK products. (Ahern, 2019).

e. Scope and Duration Limitation

Limiting the scope and duration of *sandbox* implementation on the PKGK aims to ensure that only products directly relevant to the target population are tested in the *sandbox*. For MGT, the duration of testing can be limited to a specific period in the *stunting* prevention program cycle. At the same time, the scope is restricted to vulnerable groups such as high-risk children and pregnant women. This restriction prevents reliance on temporary licenses while ensuring the product goes through a complete *pre-market* evaluation process once the trial is completed. (Heymann *et al.,* 2021).

f. Economic Relevance and Impact of *Regulatory Sandbox* Implementation

Experience from other countries shows that the *regulatory sandbox* serves as a tool to accelerate innovation and provides significant economic impact. According to a study by Leckenby *et al.* (2021), *regulatory sandboxes* in the healthcare sector can lower administrative costs usually imposed on companies and reduce the waiting time for products to enter the market. Another study by Maci & Marešová (2022) also shows that effective *sandbox* implementation can improve the efficiency of product time to market, which is relevant for maintaining the competitiveness of the PKGK industry in local and global markets. This indicates the enormous economic potential of *sandboxes* for the food and health sector if implemented with a pro-innovation approach in Indonesia. (Frazier & Walter, 2020). Adapting this model in the context of PKGK not only helps lower costs for businesses but also improves BPOM's responsiveness to the evolving nutritional needs of the public.

By adapting the elements of a structured *regulatory sandbox*, BPOM has the potential to establish a more flexible and adaptive supervisory environment for PKGK. This process will allow BPOM to obtain empirical data essential in evaluating innovative products without compromising safety. If effectively implemented, the regulatory sandbox will support the faster launch of PKGK products, enable Indonesia to better respond to the stunting challenge, and create new economic opportunities for the food and health sectors.

3.6. Impact of *Regulatory Sandbox* Implementation on Food and Drug Crime Control and Prevention

a. Public Trust

Applying a *regulatory sandbox* in the Food and Drug control context, especially in the *pre-market approval* process, can impact public trust, depending on how it is implemented. Public trust has the potential to increase, especially towards innovation, because it provides space to develop innovative product solutions without having to be trapped in bureaucracy and regulations that tend to be rigid. Conversely, implementing a *regulatory sandbox* that is considered flexible and loose will erode public confidence in the safety of the food products produced.

Sherkow (2022)warns regulators to act cautiously in implementing regulatory sandboxes. However, if the good intentions are to cut bureaucracy and accelerate innovation, the public may misinterpret them. To avoid eroding public trust in implementing the *regulatory sandbox*, transparency is needed, which means being open and explicit that implementing the *regulatory sandbox* is inherently risky and experimental.

b. Political Tools

The *Regulatory Sandbox* is a form of recognition that there are other mechanisms to obtain *pre-market approval* from regulators. The existence of this mechanism can be an opportunity to be utilized as a political tool and purpose. In the United States, at least for products

used in handling COVID-19 (*Emergency Use Authorization* / EUA), it is used as a subject for political purposes by the Government, including hydroxychloroquine products, convalescent plasma, *neutralizing antibody therapy*, and vaccines. Even BPOM, as a regulator, has also experienced political pressure, especially for the availability of COVID-19 vaccines in Indonesia, such as the archipelago vaccine and similar new technologies.

To protect regulators from such political interference, the first thing that is needed is the formalization of *regulatory sandbox* procedures, especially to meet the needs of the public regarding processed food products for special needs such as *stunting.* In addition, transparency of data related to the *regulatory sandbox* is needed as a bulwark against political interference. Transparency can provide opportunities for the public and/or academics to take part in monitoring policies related to product innovation; they can undoubtedly assess whether the policy is *scientifically based* or whether there is political pressure/interference. (Sherkow, 2022).

c. Relaxation of Standards/Regulations

Implementing the *regulatory sandbox* is a form of relaxing the standards or regulations. Still, some things that must be emphasized are that the approval given is temporary and can be cancelled, and in parallel, the pre-market approval process continues to run with the same methods. Despite the relaxation of standards, innovators must prioritize food safety aspects.

d. Accelerating Innovation

The application of a *regulatory sandbox,* although limited and temporary, provides convenience and/or simplification to experimentation. In addition, it can give tremendous acceleration to innovation, increase effectiveness and efficiency, and even provide significant cost reductions before products enter the market.

e. Optimizing Food and Drug Crime Prevention

The relaxation of distribution permits due to implementing the *regulatory sandbox* can motivate the public and/or business actors to register their products legally. This is one of the positive effects of the *regulatory sandbox* approach in promoting compliance and product registration with the competent authority. However, it is essential to note that the relaxation of distribution permits must be balanced with strict supervision by regulators. Tested products must still meet food safety standards to protect consumers. With the right approach, the relaxation of distribution permits in the *regulatory sandbox* can be an essential motivator for businesses to operate within a legitimate legal framework.

4. Conclusions and Recommendations

Regulatory sandboxes can be a practical strategic framework for accelerating innovation in health and food products, particularly Special Nutritional Needs Food (PKGK), which is critical in supporting Indonesia's *stunting* reduction targets. Through a flexible and risk-based approach, the *sandbox* enables PKGK product trials in a controlled environment that accelerates innovation without compromising safety. This makes the *regulatory sandbox* an approach that can support BPOM in accelerating *the pre-market approval* process, reducing administrative barriers, and opening up more excellent space for industry innovation while maintaining safety and consumer health standards.

However, the success of *regulatory sandbox* implementation will depend on BPOM's readiness to adopt adaptive procedures, an integrative supervisory system, and collaboration with other sectors. *A regulatory sandbox implemented with the support of regular and empirical evidence-based evaluations can strengthen BPOM's position as a facilitator of innovation with integrity and* a consistent supervisor in protecting public health.

4.1 Implementation Recommendation

To ensure that the *regulatory sandbox* can function optimally and is aligned with national health policies and international standards, the following are recommendations that BPOM can implement:

a. Development of Integrated National Policy

BPOM can align the *regulatory sandbox* policy with national health programs related to *stunting* and consider international standards from WHO and FDA as a reference. This is important so that the *regulatory sandbox* meets local innovation needs and global standards in food and health product control.

b. Periodic and Dynamic Evaluation of *Regulatory Sandbox* Effectiveness
BPOM needs to implement periodic evaluations to assess the effectiveness of the *regulatory sandbox*, covering aspects of product safety, innovation, and consumer satisfaction. These evaluations allow BPOM to dynamically adjust and improve the sandbox framework based on market *feedback* and empirical data collected from field trials.

c. Provision of Digital Infrastructure and Resources for *Real-Time* Data Collection
BPOM should prioritize digital infrastructure for real-time data reporting and monitoring. This system will enable BPOM to monitor trials more effectively, accelerate the evidence-based decision-making process, and ensure safety during PKGK product trials.

d. Collaboration with Academia and Industry for Procedural Adjustment
BPOM needs to build strategic collaborations with academia and industry to improve the quality of experimental data and research in the *sandbox*. This collaboration can also accelerate the adjustment of risk-based licensing procedures, including applying *risk-benefit analysis* that prioritizes product safety and benefits.

e. Strengthening Public Education and Transparency
Regulatory sandboxing requires greater public involvement to maintain consumer confidence in PKGK products. BPOM needs to ensure that the public understands the trial process and the benefits of PKGK products through optimal education and transparency so that consumers can understand the potential benefits and risks of the products being tested.

4.2 Challenges and Mitigation Strategies

The implementation of the *regulatory sandbox* in Indonesia will face several challenges that require special attention, namely:

a. Limited Supervisory Resources and Infrastructure
Limited human resources and uneven supervisory infrastructure may hinder the implementation of the *sandbox*. BPOM is advised to increase investment in the training of supervisory personnel and develop a digital surveillance system that allows *real-time* remote monitoring.

b. High Consumer Safety Risk
As the *sandbox* accelerates innovative products' access to the market, potential risks to consumer safety need to be mitigated through restrictions on the use, scope, and duration of product trials. In addition, BPOM should conduct close monitoring during and after trials to ensure that risks are identified and managed effectively.

c. Complexity in Regulatory Adjustments and Updates
Regulatory change is a complex and time-consuming process. BPOM can simplify this process by implementing an adaptive policy that allows changes to *sandbox* procedures without formal regulatory revisions by developing flexible technical standards that can be adjusted dynamically based on the results of periodic evaluations.

By implementing a *regulatory sandbox* that is structured, adaptive, and integrated with national frameworks and international standards, BPOM can accelerate the development of innovative PKGK products, accelerate the achievement of *stunting* reduction targets, and improve industry competitiveness. The *regulatory sandbox* not only accelerates the innovation process in the food and health sector but also enhances the role of BPOM as an adaptive facilitator and reliable supervisor. Implementation accompanied by flexible policies, digital infrastructure support, and cross-sector

collaboration will make BPOM more responsive and able to accommodate innovation while maintaining public health.

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Detection of *Salmonella* spp. in Laboratory Animal Pellet Feed using Real-Time Polymerase Chain Reaction (qPCR) and Loop-Mediated Isothermal Amplification (LAMP)

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ABSTRACT

Salmonella spp. contamination in animal feed is challenging for the commercial feed industry and laboratory animal facilities. Salmonellosis is a term used for Salmonella infection. Salmonellosis is a zoonosis directly transmitted to humans through contaminated feed, food, water, or infected animals. Nevertheless, infection in animals is mainly caused by contaminated feed. Since it provokes a significantly high economic loss due to its high mortality, accurate and rapid Salmonella detection methods are necessary for monitoring the quality of animal feed. The standard method for Salmonella detection in animal feed, which refers to ISO 6579, is based on the culture method, which takes about 5-7 days. Thus, an alternative method is required to give valid results faster. This study aims to develop alternative methods for Salmonella spp. detection in animal feed using Loop isothermal Amplification (LAMP) and Real-time Polymerase Chain Reaction (PCR) methods. Salmonella detection has been carried out on animal feed pellets artificially inoculated with Salmonella Typhimurium *ATCC 14028 at three concentration levels, namely 1, 3, and 9 cfu per test portion (25-gram samples). e-LOD range values between the LAMP method and Real PCR are compared with the culture method and analyzed descriptively. Salmonella detection method using LAMP and Real-Time PCR showed the value e-LOD50 at 0.62 cfu/portion in mouse feed and e-LOD50 at 0.37 cfu/portion in rabbit feed. Compared to the LOD of the culture method, the e-LOD of LAMP and PCR showed similarity. This e-LOD value is the same as the e-LOD culture method. Related laboratories can utilize the results of this study to monitor the quality of animal feed.*

Kontaminasi Salmonella spp. pada pakan hewan merupakan tantangan bagi industri pakan komersial dan juga laboratorium hewan uji. Salmonella dapat menyebabkan penyakit salmonellosis pada hewan uji dengan tingkat mortalitas yang tinggi, sehingga menyebabkan kerugian ekonomi yang signifikan. Penularan penyakit ini kepada manusia dapat terjadi melalui kontak langsung dengan pakan yang terkontaminasi atau melalui hewan terinfeksi yang menularkan Salmonella pada pangan manusia dan sumber air. Pakan hewan merupakan sumber utama penularan Salmonella pada hewan. Karena menyebabkan kerugian yang besar akibat angka mortalitas yang tinggi, metode deteksi Salmonella spp. yang cepat dan akurat diperlukan untuk pemantauan kualitas pakan hewan. Metode deteksi Salmonella yang akurat dan cepat diperlukan dalam pemantauan kualitas pakan hewan. Metode standar untuk deteksi Salmonella pada pakan mengacu pada ISO 6579 yaitu menggunakan metode kultur. Metode kultur membutuhkan waktu pengujian sekitar 5-7 hari, sehingga diperlukan metode alternatif yang memberikan hasil valid dalam waktu lebih singkat. Penelitian ini bertujuan untuk memverifikasi metode alternatif untuk deteksi Salmonella pada pakan menggunakan metode Loop Isothermal Amplification (LAMP) dan Real-time Polymerase Chain Reaction (real-time PCR). Deteksi Salmonella telah dilakukan pada pakan mencit dan kelinci berbentuk pelet yang dicemari dengan Salmonella Typhimurium ATCC 14028 pada tiga tingkat konsentrasi, yaitu ±1, ±3, dan ±9 cfu per porsi uji (25 gram sampel). Nilai rentang e-LOD antara metode LAMP

dan Real-time PCR dibandingkan dengan metode kultur, lalu dianalisis secara deskriptif kualitatif. Metode deteksi Salmonella menggunakan LAMP dan Real-time PCR menunjukan nilai e-LOD$_{50}$ sebesar 0,62 cfu/porsi uji pada pakan mencit dan e-LOD$_{50}$ sebesar 0,37 cfu/porsi uji pada pakan kelinci. Nilai e-LOD ini sama dengan e-LOD metode kultur. Hasil penelitian ini dapat dimanfaatkan oleh laboratorium terkait dalam pemantauan kualitas pakan hewan.

Keywords: *Salmonella*, animal feed, LAMP, PCR
Kata Kunci: *Salmonella*, pakan hewan, LAMP, PCR

1. Introduction

Salmonella spp. is a genus of bacteria from the *Enterobacteriaceae* family, Gram-negative, motile, aerobic or facultatively anaerobic, rod-shaped, negative oxidase, non-spore-forming, measuring about 0.7-1.5 µm wide and 2.0-5.0 µm long (Billah & Rahman, 2024). *Salmonella* spp. is pathogenic to humans and animals (Pal *et al*., 2020). These bacteria grow at 2-54°C, pH 3.7-9.4 (Oludairo *et al*., 2023). *Salmonella* spp. are classified into several subspecies/species of organisms based on O (*somatic*) antigen, phase I H (*flagellar*) antigen, and phase II H antigen (Spickler & Larson, 2005)—another classification system of *Salmonella* spp. is based on the clinical symptoms which are divided into two types, typhoid/typhoidal *salmonella* (TS) with enteric fever symptoms and non-typhoid/non-typhoidal *salmonella* (NTS) (Eng *et al*., 2015). In humans, *Salmonella* spp. infections provoke gastrointestinal infections, systemic infections and enteric fever, while in animals, *Salmonella* spp. Infections cause enteric fever (Billah & Rahman, 2024). Furthermore, all rodents are susceptible to *Salmonella* spp. Infection.

Animal feed is the primary source of *Salmonella* spp. transmission in animals. The presence of *Salmonella* spp. in various feed raw materials, especially those rich in protein, means that feed can act as a direct or indirect route of *Salmonella* spp. Transmission. In pellet feed that has been heated, *Salmonella* spp. can still be detected due to contamination of the production environment or during transportation and storage. *Salmonella* spp. can easily survive in the environment by forming biofilms on the surface of objects, water, and soil (Sargeant *et al*., 2021). *Salmonella enteritidis* can survive for more than 26 months in feed artificially contaminated with *Salmonella* spp. (Meerburg & Kijlstra, 2007). Therefore, routine monitoring of *Salmonella* spp. in animal feed is necessary (Sargeant *et al*., 2021). The presence of *Salmonella* spp. in feed can also affect human health through direct contact with contaminated feed or infected animals to human food and water sources (Sargeant *et al.*, 2021).

Salmonella spp. can be isolated from non-selective pre-enrichment media and cultured on selective media containing inhibitors. Furthermore, Salmonella spp. can be confirmed using bacteriological or molecular methods (Pal *et al*., 2020). Testing with the culture provides the best results for detecting *Salmonella* spp. However, this test generally takes a long time, around 5-11 days. In ISO 6579, the standard method of *Salmonella* spp., the testing procedure is carried out using pre-enrichment media in the form of *buffered peptone water* (BPW), followed by enrichment on modified semisolid Rappaport-Vassiliadis (MSRV) media and isolation on xylose-lysine-deoxycholate (XLD) agar and selected plate media as complementary. This method is characterized by its simplicity and economic efficiency (Demirbilek, 2018) compared to molecular methods such as polymerase chain

reaction (PCR). However, the PCR method offers the advantage of a shorter testing duration even though it comes with the disadvantage that it costs more.

In addition to PCR, another molecular method applicable for detecting *Salmonella* spp. is loop-mediated isothermal amplification (LAMP). This method is used to detect pathogens in clinical specimens and feed matrices. LAMP is a novel nucleic acid amplification test (NAAT) that has become an alternative to PCR testing because it can rapidly detect various bacteria, fungi, parasites and viruses. In 2005, Hara-Kudo et al. conducted a study on detecting *Salmonella* spp. in eggs artificially inoculated with *Salmonella* spp. The study results stated that the LAMP method is fast, specific and sensitive for detecting *Salmonella* spp. (Yang *et al.*, 2021).

The LAMP testing process is faster than the PCR method because it can amplify target DNA more efficiently, with 10^9 in one hour, while PCR generally takes 1-2 hours and produces almost 20 times less DNA than LAMP. Another advantage of the LAMP method is its high tolerance to biological substances in clinical and food samples. In contrast, PCR is generally susceptible to various inhibitors contained in food or feed matrices. Therefore, LAMP is preferable (Yang et al., 2021).

After that, various tests for *Salmonella* spp. in food samples using the LAMP method continued to develop. They began to develop in animal feed samples, but there were no studies on testing *Salmonella* spp. with LAMP and PCR in laboratory animal pellet feed samples (Yang et al., 2018). Various alternative methods have been developed to detect *Salmonella* spp., but they still cannot replace the culture method (Demirbilek, 2018).

Because *Salmonella* spp. is a pathogen harmful to animals and can be transmitted to humans, including through feed, the Federation of European Laboratory Animal Science Associations (FELASA) recommends that Salmonella spp. testing in laboratory animals is carried out routinely every three months.

This study aims to develop an alternative method of *Salmonella* testing in laboratory animal feed that can provide fast and valid results. In this study, verification of *Salmonella* spp. Detection tests in laboratory animal feed using PCR and LAMP as alternative methods were conducted. The animal feed used in this test is mice and rabbit feed in pellets. Mice feed has a different content of water, fiber, and other nutrients, so it becomes a matrix that can affect the survival rate of *Salmonella* spp. Related laboratories can use the results of this study to monitor the quality of laboratory animal feed.

2. Methodology

2.1. Time and Place of Research

This research was conducted at the National Quality Control of Drug and Food (NQCLDF), Indonesia Food and Drug Authority, in October-November 2022.

2.2. Research Materials and Instruments

The materials used in the study were laboratory animal feed for mice and rabbits in the form of pellets and raw microbes *of Salmonella* Typhimurium ATCC 14028 obtained from the Laboratory of Microbiology and Molecular Biology of NQCLDF, Indonesian FDA.

The media used were Buffered peptone water (BPW), Rappaport Vassiliadis-Soya (RVS) Xylose Lysine Deoxycholate (XLD), Brilliant Green Agar (BGA), Tryptic Soy Agar

(TSA), Plate Count Agar (PCA) and Bacto™ Peptone. The reagents used were PCR reagents from iQ-Check *Salmonella* spp. II BIORAD® ready-to-use PCR Reagent kit consisting of Lysis reagent, Fluorescent probes, Amplification mix, PCR negative control and PCR positive control, LAMP reagent from 3M™ Molecular Detection Assay 2 - *Salmonella* consisting of Color Coded Reagent Tubes, Pre-Dispensed and Ready-To-Use Lysis Solution (LS), Extra Caps, Reagent Control Tubes, Quick Start Guide, 70% Alcohol, distilled water/ddH2O, Cleaning reagent (DNA/RNase AWAY), Bleach (NaOCl) 5%, Sodium chloride 0.85% and McFarland standard.

Research Instruments: The instruments used in this study are *Real-time* PCR (qPCR) and Loop-Mediated Isothermal Amplification (LAMP), a computer that already contains real-time PCR software and 3M™ Molecular Detection System software, Stomacher, Vortex, Centrifuge plate rotor, Centrifuge tube 1.5 mL rotor, spin down, heating block, cooling block, analytical balance, hot plate, autoclave deconstruction and autoclave sterilization, Bio Safety Cabinet (BSC), Laminar Air Flow (LAF), Incubator 36±2° C Incubator 41.5±1° C and Vitek 2 compact system instrument.

2.3. Sample Preparation

The test samples were divided into three types, namely sample A (sample without microbial addition), sample B (sample added with standard microbes at several levels of contamination) and sample C (dilution media contaminated with standard microbes at high concentrations). Sample preparation was carried out based on the sample preparation method in ISO 6887-1:2017. Samples consisted of mice and rabbit feed in the form of pellets, weighed as much as 25 grams and then mashed using a sterile mortar and pestle. The feed was put into a sterile screw cap bottle containing 225 mL of BPW solution. In sample A, nothing was added to the sample mixture. In sample B, a bacterial inoculum spike was added from the standard microbe *Salmonella* Typhimurium ATCC 14028 with several dilution levels from 10^{-5}, 10^{-6}, 10^{-7}, and 10^{-8}. In sample C, a high concentration of bacterial inoculum was added to the BPW medium.

2.4 Preliminary Test of Standard Microbial

This preliminary test was conducted to determine the concentration of the microbial standard by calculating the Total Plate Count (TPC) on *Salmonella* Typhimurium ATCC 14028. The microbial standard was mixed into 0.85% NaCl solvent, and the turbidity level was compared with 0.5 Mc Farland, then dilutions were increased to 10^{-8}. The microbial standard from the dilution levels of 10^{-5}, 10^{-6}, 10^{-7}, and 10^{-8} was taken 1 mL and put into a Petri dish and then mixed with PCA media with the pour plate method and then incubated at 37 ± 1 °C for 24 hours for TPC counting.

2.5 Determination of Limit of Detection (LOD)

The alternative method should give the same or better results than the standard method (culture method). The potential contamination of *Salmonella* spp. with low concentrations in animal feed causes the need to determine the LOD value for each *Salmonella* spp.—detection test method used in the laboratory. LOD determination was carried out on samples A and B, referring to ISO 16140-3: 2021, with an *experimental design* using protocol 1 (appendix 1). Bacterial inoculum from the microbial standard with a known concentration in the preliminary test was added to sample B. This inoculum was made into

three levels of contamination. The first is low contamination level (1 x LOD_{50} colonies/test portion with four replications), the second is medium contamination level (3 x LOD_{50} colonies/test portion with four replications), the third is high contamination level (9 x LOD_{50} colonies/test portion with one replication) and testing sample A (sample without microbial addition with one replication).

Since there is no information regarding the LOD_{50} method for this animal feed sample, the LOD $value_{50}$ is considered one colony/test portion. To obtain concentrations of ±1, ±3 and ±9 CFU/test portion, *Salmonella* inoculum containing approximately 1, 3 and 9 colonies was added to the sample mixture according to the TPC results in the preliminary test. To determine the actual bacterial concentration of the *spiking* that has been done, the TPC calculations were made again at dilutions of 10^{-5}, 10^{-6}, 10^{-7}, and 10^{-8} of microbial spiking in sample B. Furthermore, the spike of sample C was carried out by adding standard microbial inoculum into BPW media using a bacterial inoculum with a high concentration according to the ALT results in the preliminary test.

2.6 Test stages

2.6.1 Non-selective Enrichment Stages (Enrichment Sample)

All samples described in point 2.5 were homogenized and incubated at 36 ± 2 °C for 18 ± 2 hours. This stage is a selective pre-enrichment stage on BPW enrichment media by ISO 6579-1: 2017. Samples that have finished incubating for 18 ± 2 hours are then tested in parallel by PCR, LAMP and culture methods.

2.6.2 PCR test stages

DNA Extraction. Extraction stages were performed using the procedures in the PCR reagent kit manual (iQ-Check *Salmonella* spp. II BIORAD®). In samples that have been enriched, gently shaking is done, and as much as 1 mL is taken and then put into a 1.5 mL tube. *Shaking* too much is avoided so that food debris is not carried away. Next, centrifugation of the sample was carried out at a speed of 10,000-12,000 x g for 5 minutes. The supernatant formed was discarded, then 200 µL of lysis reagent was added to the sample sediment, resuspended and vortexed the sample until homogeneous. The sample was placed on a dry heat block with a temperature of 95˚ C - 100˚ C for 10-15 minutes, then a second homogenization using a *vortex* and a second centrifugation with the same speed and time as the first. The supernatant formed after this process was transferred to a 1.5 mL tube for further PCR analysis.

Preparation of PCR mix and addition of Template DNA. The reaction mix was prepared using 40 µl Amplification mix and five µl Fluorescent probes in each well. A total of 45 µl reaction mix was piped into each well, adjusted to the number of samples to be run. A total of 5 µl of DNA extracted from samples A, B, and C, positive control kit and negative control kit were each included in the wells. Centrifugation ensures no bubbles in the wells for 1 minute (quick spin). This centrifugation stage also intends to reduce the reagents still attached to the sound wall. The plate is inserted into the Real-time PCR machine, and the plate placement is ensured by the PCR map that has been made.

Data Analysis and Interpretation of Results. This stage is performed on the appropriate PCR software, and the data is interpreted according to the kit manual's

requirements. Verifying the validity of positive and negative controls was performed before analyzing the sample results. If both controls meet the requirements, the controls and samples are declared valid according to the validity requirements presented in Tables 1 and 2.

Table 1. Validity of positive control and negative control on PCR kit reagents

Parameters	*Salmonella* spp. detection (FAM channel)	Internal Control Detection (HEX channel)
Negative Control	Cq = N/A*	28 ≤ Cq ≤ 40
Positive Control	26 ≤ Cq ≤ 36	N/A

*A Cq value indicating N/A (not applicable) occurs when the sample's fluorescence does not appear significantly above the noise or crosses the threshold.

Table 2. Validity of test samples on PCR kit reagents

Salmonella spp. detection (FAM channel)	Internal Control Detection (HEX channel)	Interpretation
Cq ≥ 10	N/A	Positive
Cq = N/A	Cq ≥ 28	Negative
Cq = N/A	Cq = N/A	Inhibition*

*When the sample and internal control have a Cq value = N/A, the sample should be diluted at 1:10 and retested.

2.6.3 Stages of LAMP Test

DNA Isolation. DNA isolation stages were carried out by the procedures in the LAMP reagent kit manual (3M™ Molecular Detection System and 3M™ Molecular Detection Assay 2). The tube containing Ready-to-Use Lysis Solution (LS), which still has a lid, is flipped before use so that it is homogeneous. The tube cap was then opened using a lysis tube, disappeared, and the cap was removed. A total of 20 µL of the sample mixture with BPW was introduced into the LS tube. One LS tube without a sample was prepared as negative control and another as reagent control. The tubes were then put into a heating block and heated at 100°C for 15 min without capping. The LS liquid, which is pink before heating, will turn yellow when heated. After heating, the tubes are cooled using a heating block at room temperature (20-25°C) for 5 minutes. The colour of LS liquid will return to pink after cooling.

Amplification. Colour-coded reagent Tubes were opened using a reagent tube disappear, and then the caps were removed. A total of 20 µL of DNA isolation results were taken from the top of the LS tube (to avoid taking from the bottom of the tube) and inserted into a tube containing lysis reagent, then homogenized by resuspension. A total of 20 µL each of LS from negative control and LS control reagents were also put into Color-Coded Reagent Tubes. The tubes filled with samples, negative controls and reagent controls were then closed using a new tube cap. The closed tubes were inserted into the loader tray, and the 3M™ Molecular Detection System connected to a PC was run according to the tool manual. The results were read and viewed on the LAMP software.

Interpretation of Results. Results are positive if a peak appears, and a positive symbol is in the image. Results are negative if there is no peak and a negative symbol in the image—salmonella spp. Detection results using 3M™ can be reported if the negative control and reagent control provide valid results.

2.6.4 Stages of the culture method

2.6.4.1. Selective Enrichment Stages for the Culture Method

Pre-enrichment culture from each sample in BPW was introduced into 0.1 mL of *Rappaport Vassiliadis-Soya* (RVS) medium and incubated at 41.5 ± 1°C for 24 ± 3 hours (ISO 6579-1:2017).

2.6.4.2. Isolation on Selective Media Culture Method

One clutch of culture from RVS media was inoculated on the surface of XLD and BGA selective media and then incubated at 36 ± 2°C for 24 ± 3 hours. Colonies that grew on the media were observed. On XLD media, *Salmonella* spp. Positive cultures were characterized by red colonies with or without a black spot in the center. On BGA media, Salmonella spp. Colonies are characterized by transparent, colourless, pink, or cloudy white colonies with a pink-to-red zone around them (ISO 6579-1:2017).

2.6.4.3. Biochemical test confirmation

Specific colonies on BGA and XLD media were then inoculated on the surface of TSA media **and** incubated at 36 ± 2°C for 24 ± 3 hours. The growing colonies were identified using the Vitek 2 *compact system* instrument.

2.7 Data Analysis

Data were measured using descriptive statistics by comparing qualitative data from each bacterial growth medium with the instruments used for confirmation tests.

3. Results and Discussion

3.1. Total Plate Numbers of *Salmonella* Typhimurium ATCC 14028

Stock suspensions of Salmonella spp. were counted using the Total Plate Count (TPC) method to obtain the spike concentration. The TPC results of *Salmonella* spp. 0.5 Mc Farland are as follows:

Table 3. Total Plate Count value of *Salmonella* Typhimurium ATCC 14028

Microbial Test	Dilution							
	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}
Simple	TMTC	TMTC	TMTC	TMTC	TMTC	542	63	7
Duplo	TMTC	TMTC	TMTC	TMTC	TMTC	545	44	10
Average	TMTC	TMTC	TMTC	TMTC	TMTC	543,5	53,5	8,5

Description: TMTC = Too many to count

Table 3 shows the proportional growth of *Salmonella* spp. from low to high dilutions. At low dilutions, the number of colonies was too many to count (above 550 colonies/plate).

Colonies can be counted from dilution 10^{-6} until a unit value is obtained at dilution 10^{-8}. The TPC values are calculated from the average number of colonies at dilutions, which shows growth of less than 300 in Petri dishes. In the preliminary test, the total plate count (TPC) of *Salmonella* Typhimurium ATCC 14028 was 53.5 x 10^7 cfu/mL. This TPC value was then used as a reference value in contaminating each feed sample with a concentration of 1xLOD_{50}, 3xLOD_{50}, and 9xLOD_{50} colonies per test portion using 25 grams of sample. The e-LOD_{50} value in each sample will be calculated based on the *real* TPC value of *Salmonella* spp at the time of treatment and testing in each sample.

3.1 Determination of LOD for *Salmonella* Detection Method in Pelleted Mouse Feed

The *Salmonella* spp. Detection methods used in this study were the culture method, a molecular method using Loop-mediated isothermal amplification (LAMP) technique and Real-time Polymerase Chain Reaction (Real-time PCR). Samples prepared and contaminated with *Salmonella* spp. with several concentrations are tested using these three methods. The LOD test results can be seen in Table 4.

Table 4. Detection test results of *Salmonella* spp. in mice pellet feed samples using the culture method

Treatment	Repeatability	*Concentration of contaminants*	Culture Method				Biochemical Confirmation
			BPW	RVS	XLD	BGA	
Sample B 1 x LOD50	1	1 cfu	+	+	+	+	very good identification
	2	1 cfu	+	-	-	-	NA
	3	1 cfu	+	+	+	+	very good identification
	4	1 cfu	+	-	-	-	NA
Sample B 3 x LOD50	1	3 cfu	+	+	+	+	very good identification
	2	3 cfu	+	-	-	-	NA
	3	3 cfu	+	+	+	+	very good identification
	4	3 cfu	+	+	+	+	very good identification
Sample B 9 x LOD50	1	9 cfu	+	+	+	+	very good identification
Sample C	1	9 cfu	+	+	+	+	very good identification
Sample A	1	NA	-				
Media Control	1	NA	-				

*NA = not available

Table 4 shows the concentration level of *Salmonella* spp. In a spike of as much as one cfu/test portion, Salmonella spp. can be detected again in 2 out of 4 replicates, while for a spike of three cfu/test portion, it can be detected again in 3 out of 4 replicates. As for the spike of nine cfu/test portion, it was detected in 1 out of 1 test replicates.

Table 5. Detection test results of *Salmonella* spp. in pelleted mice feed samples using Real-time PCR method

Contaminants	Repeatability (Cq value)			
	1	2	3	4
Sample B (1 x LOD50)	24,44	Undetermined	22,91	Undetermined
Sample B (3 x LOD50)	22,22	Undetermined	20,74	20,7
Sample B (9 x LOD50)	19,65			
Sample C	14,55			
Sample A	Undetermined			
Media Control	Undetermined			

Table 5 shows the detection test results of *Salmonella* spp. in mice feed samples using the *Real-time* PCR method. The cq value of the amplification cycle when the curve cuts the *threshold* limit so it can provide information that the target DNA is detected in the tested sample. The Cq value is inversely proportional to the sample's target DNA amount. The smaller Cq value indicates that the amount of target DNA is increasing so that the target DNA can be detected in the initial PCR cycle—samples contaminated with *Salmonella* spp. A concentration of 9 cfu showed the lowest Cq value compared to samples contaminated with three cfu and one cfu. The table above shows that at the concentration level of *Salmonella spike* one cfu / test portion, *Salmonella* spp. can be detected again in 2 out of 4 replicates. In contrast, for *spike* three cfu / test portion, *Salmonella* spp. can be detected again in 3 out of 4 replicates. As for the *spike* of 9 cfu/test portion, *Salmonella* spp. was detected in 1 out of 1 test replicates. These results are 100% in agreement with the culture method test results.

Table 6 shows the results of the *Salmonella* spp. Detection test on pellet-shaped mice feeds samples using the LAMP method**.** From the results above, the concentration of *spike* one cfu / test portion, *Salmonella* spp., can be detected again in 2 out of 4 replicates. In contrast, for spike three cfu / test portion, Salmonella spp. can be detected again in 3 out of 4 replicates. As for the spike of 9 cfu/test portion, *Salmonella* spp. was detected in 1 out of 1 test replicates. These are 100% with the test results using culture and real-time PCR methods.

Table 6: Detection test results of *Salmonella* spp. in pelleted mice feed samples using LAMP method

Contaminants	Repeatability			
	1	2	3	4
Sample B (1 x LOD50)	+	-	+	-
Sample B (3 x LOD50)	+	-	+	+
Sample B (9 x LOD50)	+			
Sample C	+			
Sample A	-			
Media Control	-			

Table 7. Comparison of detection test results of *Salmonella* spp. in mice pellet feed samples using culture, LAMP and Real-time PCR methods

Treatment	Replication	Concentration of contaminants	Culture Method	PCR	LAMP
Sample B 1 x LOD50	1	1 cfu	+	+	+
	2	1 cfu	-	-	-
	3	1 cfu	+	+	+
	4	1 cfu	-	-	-
Sample B 3 x LOD50	1	3 cfu	+	+	+
	2	3 cfu	-	-	-
	3	3 cfu	+	+	+
	4	3 cfu	+	+	+
Sample B 9 x LOD50	1	9 cfu	+	+	+
Sample C (Control Salmonella)	1	9 cfu	+	+	+
Sample A	1	NA	-	-	-
Media Control	1	NA	-	-	-

Table 7 shows that at all spiking concentrations, the three methods show the same results, so the e-LOD values for the three methods can be determined based on the number of positive results for each level of contamination using Protocol 1 ISO 16140-3: 2021, which can be seen in table 8.

Table 8. e-LOD values for mice feed using PCR, LAMP and Culture Methods

Sample	Contamination level				e-LOD50 cfu/test portion
	High level 9 x LOD50 /test portion	Intermediate level 3 x LOD50 / test portion	Low level 1x LOD50 /test portion	Blank	
Mouse Feed	1/1	3/4	2/4	0/1	1.3* x LIL** 1,3* x 0,48
	Real inoculum (cfu) at each level				
	4,2	1,4	0,48		**e-LOD$_{50}$ = 0.62**

* Value is determined based on the e-LOD determination table$_{50}$ ISO 16140-3: 2021 (attachment 1)
** LIL=Low Inoculum Level. The LIL value is determined based on the TPC test result of 40 x 10^7 cfu/mL, considering the pipetting volume and dilution factor of the suspension taken

Protocol 1 of ISO 16140-3:2021 was used to determine e-LOD$_{50}$ because, in this study, the concentration of inoculum in the test portion is uncertain. The preliminary test to calculate the suspension of the test inoculum is used as a reference for calculating the volume of suspension to be included in the sample. The actual calculation of the inoculum concentration must be determined by calculating the TPC when testing the sample, so there may be a shift in the TPC value.

Table 9. The TPC value of *Salmonella* Typhimurium ATCC 14028 stock suspension used as *spike* for mice feed samples

Microbial Test	Dilution							
	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}
Simplo	TMTC	TMTC	TMTC	TMTC	TMTC	361	48	6
Duplo	TMTC	TMTC	TMTC	TMTC	TMTC	367	32	12
Average	TMTC	TMTC	TMTC	TMTC	TMTC	364	40	9

Description: TMTC = Too many to count

The total plate count (TPC) test result of *Salmonella* Typhimurium ATCC 14028 stock suspension used as a spike for pellet-shaped mouse feed samples (Table 9) is 40 x 10^7 cfu/mL. This TPC value determines the low inoculum level (LIL) used during the study. The LIL value is then used to determine the e-LOD value$_{50}$ method on mouse feed samples.

The e-LOD value$_{50}$ for culture, LAMP and PCR methods on mice feed showed the exact value of 0.62 cfu/test portion. This e-LOD value of 50 is the estimated LOD value for the entire procedure, including the enrichment stage. The acceptability requirement of e-LOD$_{50}$ < 4.0 cfu/test portion, so these three methods meet the requirements (ISO 16140).

3.2 Determination of LOD for *Salmonella* Detection Method in Pelleted Rabbit Feed

Pelleted rabbit feed samples contaminated with *Salmonella* spp. have also been tested using culture methods, molecular methods using LAMP and Real-time PCR with the following results:

Table 10. Detection test results of *Salmonella* spp. in pelleted rabbit feed samples using the culture method

Treatment	Replication	Concentration of contaminants	Culture Method				Biochemical Confirmation
			BPW	RVS	XLD	BGA	Biochemical identification
Sample B 1 x LOD50	1	1 CFU	+	-	-	-	NA
	2	1 CFU	+	+	+	+	very good identification
	3	1 CFU	+	+	+	+	NA
	4	1 CFU	+	+	+	+	very good identification
Sample B 3 x LOD50	1	3 CFU	+	+	+	+	NA
	2	3 CFU	+	+	+	+	very good identification
	3	3 CFU	+	+	+	+	very goodt identification
	4	3 CFU	+	+	+	+	very good identification
Sample B 9 x LOD50	1	9 cfu	+	+	+	+	very good identification
Sample C (control *Salmonella*)	1	9 cfu	+	+	+	+	
Sample A	1	NA	-				
Media Control	1	NA	-				

In **Table 10**, the concentration level of Salmonella spp. during the spike one cfu /test portion, Salmonella spp. can be detected again in 3 out of 4 replicates, while during the spike three cfu/test portion, it can be detected again in all replicates. As for the spike nine cfu/test portion, *Salmonella* spp. was detected in 1 out of 1 test replicates.

Table 11 shows the detection test results of *Salmonella* spp. in rabbit feed samples using the *Real-time* PCR method. The Cq value is inversely proportional to the sample's target DNA amount. The smaller Cq value indicates that the amount of target DNA is increasing so that

the target DNA can be detected in the initial cycle of PCR—samples contaminated with *Salmonella* spp. A concentration of 9 cfu showed the lowest Cq value compared to samples contaminated with three cfu and one cfu at the concentration level of *Salmonella* spp. In spike one cfu/test portion, *Salmonella* spp. can be detected again in 3 out of 4 replicates, while for spike three cfu/test portion, *Salmonella* spp. can be detected again in all replicates. As for the spike of 9 cfu/test portion, *Salmonella* spp. was detected in 1 out of 1 test replicates. This result is 100% with the test results using the culture method.

Table 11. Detection test results of *Salmonella* spp. in rabbit pellet feed samples using Real-time PCR method.

Contaminants	Replication (Cq value)			
	1	2	3	4
Sample B (1 x LOD50)	Undetermined	15,49	14,96	15,01
Sample B (3 x LOD50)	15,79	17,01	18,46	15,38
Sample B (9 x LOD50)	13,93			
Sample C	14,18			
Sample A	Undetermined			
Media Control	Undetermined			

Table 12. Detection test results of *Salmonella* spp. in pelleted rabbit feed samples using LAMP method

Contaminants	Replication			
	1	2	3	4
Sample B (1 x LOD50)	-	+	+	+
Sample B (3 x LOD50)	+	+	+	+
Sample B (9 x LOD50)	+			
Sample C	+			
Sample A	-			
Media Control	-			

Table 12 shows the detection test data of *Salmonella* spp. in rabbit pellet feed samples using the LAMP method. At the *Salmonella* spp. *spike* concentration level of 1 cfu/test portion, *Salmonella* spp. It could be detected in 3 out of 4 replicates, while for spike three cfu/test portion, *Salmonella* spp. it could be detected in all replicates. As for the *spike* nine cfu/test

portion, *Salmonella* spp. was detected in 1 out of 1 test replicates. This result is 100%, and the test results were obtained using culture and real-time PCR methods.

Table 13. Comparison of detection test results of *Salmonella* spp. in pelleted rabbit feed samples using culture, LAMP and Real-time PCR methods

Treatment	Replication	Concentration of contaminants	Culture Method	PCR	LAMP
Sample B 1 x LOD50	1	1 cfu	-	-	-
	2	1 cfu	+	+	+
	3	1 cfu	+	+	+
	4	1 cfu	+	+	+
Sample B 3 x LOD50	1	3 cfu	+	+	+
	2	3 cfu	+	+	+
	3	3 cfu	+	+	+
	4	3 cfu	+	+	+
Sample B 9 x LOD50	1	9 cfu	+	+	+
Sample C	1	9 cfu	+	+	+
Sample A	1	NA	-	-	-
Media Control	1	NA	-	-	-

*NA = *not available*

Table 14. e-LOD values for rabbit feed using PCR and LAMP

Sample	Contamination level				e-LOD50 cfu *portion*
	High level 9 x LOD50 /test portion	Intermediate level 3 x LOD50 / test portion	Low level 1 x LOD50 /test portion	*Blank*	
Rabbit Feed	1/1	4/4	3/4	0/1	0.5* x LIL 0,5 x 0,74
	***Real* inoculum (cfu) at each level**				
	6,51	2,17	0,74		**e-LOD50 =**

*Values obtained from ISO 16140-3:2021 Table (appendix 1)
**LIL=Low Inoculum Level. The LIL value was determined based on the TPC test result of 62 x 10^7 cfu/mL, considering the pipetting volume and dilution factor of the suspension taken.

Table 13 shows that at all *spiking* concentrations, the three methods show the same results, so the e-LOD values for the three methods can be determined based on the number of positive results for each level of contamination using Protocol 1 ISO 16140-3: 2021.

Table 15. The TPC value of *Salmonella* Typhimurium ATCC 14028 stock suspension used as a spike for rabbit feed samples

Microbial Test	Dilution							
	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}
Simplo	TMTC	TMTC	TMTC	TMTC	TMTC	TMTC	60	8
Duplo	TMTC	TMTC	TMTC	TMTC	TMTC	TMTC	65	5
Average	TMTC	TMTC	TMTC	TMTC	TMTC	TMTC	62,5	6,5

Description: TMTC = Too many to count

The total plate count (TPC) test result of *Salmonella* Typhimurium ATCC 14028 stock suspension (Table 15) was used as a spike for rabbit feed samples, and it was 62.5 x 10^7 cfu/mL. This TPC value is used to determine the low inoculum level (LIL), which is the low inoculum level used during the study; then, the LIL value is used in determining the e-LOD value$_{50}$ method on rabbit feed samples. The e-LOD50 value for culture, LAMP and PCR methods on rabbit feed showed the exact value of 0.37 cfu/test portion. This e-LOD value of 50 is the estimated LOD value for the entire procedure, including the enrichment stage. The acceptability requirement of e-LOD$_{50}$ < 4.0 cfu / test portion so that these three methods meet the acceptability criteria for method verification (ISO 16140). This study conducted secondary validation (verification) for the LAMP and Real-time PCR methods using previously validated reagents/kits. The LAMP method for *Salmonella* spp. has been validated against AOAC Official Method 2016.01 and by AFNOR Certificate No. 3M 01/16-11/16 against ISO 6579. *The Real-time* PCR method using the IQ check Salmonella II kit has been approved by AOAC in 2021 for several matrices, including dry dog food, raw ground chicken, and ham, based on the results of the probability of detection (POD) statistical model that there is no difference between the PCR method using iQ check and the standard method. Thus, the LAMP and PCR methods verified in this study can be used as alternative methods for *Salmonella* detection in rabbit feed because they have been proven to perform equivalent to the golden method (culture method).

3.3. Characteristics of culture methods compared to molecular methods

The culture method is the standard for detecting *Salmonella* spp. in food and feed. It is based on the characteristics of microbial growth on BPW non-selective enrichment media, selective enrichment media, and colony growth on selective media, followed by biochemical and serological confirmation. In this study, biochemical confirmation was carried out using a rapid identification instrument with a kit for *Salmonella* spp., while serological test was not carried out as it did not identify the species or strain level.

In this study, molecular methods such as LAMP and real-time PCR applied to feed samples enriched on BPW media showed performance comparable to that of the culture method in mice and rabbit feed. Rapid screening of *Salmonella* spp. in feed, floor dust and *swabs* using molecular PCR techniques requires 2-3 days of testing time, as Ahaduzzaman et al. (2021) reported. Domesle et al. (2021) also reported the LAMP method as a rapid and *robust* method for routine screening of *Salmonella* spp. in raw pet food with an rLOD value of 1 CFU. LAMP showed 100% concordance with BAM culture and Real-time PCR methods. However, there is no research on testing *Salmonella* spp. by LAMP and PCR on laboratory animal pellet feed samples. In this study, LAMP and PCR methods showed the same positive result rate as the culture method according to ISO 6579. The LAMP and PCR confirmed negative samples within 24 hours, while the ISO method took 5 days. The LAMP and Real-time PCR methods also gave faster presumptive positive results than the culture method on mice and rabbit feed samples contaminated with *Salmonella* spp. This indicates that these methods are fast and valid for detecting *Salmonella* spp. contamination in feed.

The LAMP method used in this study uses the principle of *bioluminescence* as a detector. Samples were enriched in BPW non-selective medium for 18 hours, and then DNA in the samples was isolated. The target DNA was amplified using several pairs of primers (including *loop* primers) at a fixed temperature; the amplification results were detected by bioluminescence and read by the LAMP instrument. Presumptive positive results are reported in real-time, while negative results are displayed after the test completion (AOAC, 2019). AOAC also states that this method has been validated for detecting *Salmonella* spp. in dry dog food with an 18-24 hours enrichment time.

The real-time PCR method used in this study is the iQ-Check Salmonella II kit, which can be validated on samples enriched for 21 hours using primers and molecular beacon probes that target specific sequences of the Salmonella genome. DNA isolation was performed on enriched samples on BPW non-selective media. This method has also been validated for Salmonella spp detection testing in dry dog feed and wet cat feed (AOAC, 2021).

Screening of *Salmonella* spp. using LAMP and *Real-time* PCR methods can be completed in about 24 hours, thus providing faster information regarding the microbiological quality of feed to be consumed by laboratory test animals compared to the culture method, which takes about 5-7 days. Testing using PCR and LAMP with the reagent kit used in this study costs about IDR 200,000 to IDR 250,000 per sample, excluding investment for the purchase of instruments and equipment, while the estimated cost of media/reagents for the culture method is about IDR 170,000 per sample. Budget requirements for molecular methods are relatively more expensive than culture methods, but they are faster in obtaining test results.

3.4. *Positive rate of Salmonella* in *spiked* mice and rabbit feed samples

In this study, the *growth* rate of *Salmonella* spp. in rabbit feed was more significant than its growth in mice feed. *Salmonella* spp is detected in 8 out of 9 samples of rabbit feed contaminated with *Salmonella* spp at specific concentration levels. As for the mice feed, *Salmonella* spp. was detected in 6 out of 9 samples of rabbit feed contaminated with *Salmonella* spp at specific concentration levels. Differences in feed composition may affect the growth of *Salmonella* spp. Pelleted feed for mice and rabbits is a complete feed with

vitamins. This study used mice feed with the nutritional content listed on the mice feed label as maximum moisture content of 12%, minimum protein of 20%, max fat of 4%, maximum crude fibre of 4%, calcium of 12% and phosphorus of 0.7%. The nutritional content on the rabbit feed label is in the form of maximum moisture content of 12%, minimum crude protein of 15%, minimum crude fat of 2%, minimum crude fiber of 14%, maximum ash of 14%, calcium of 0.80%, phosphorus at least 0.50%, amino acid lysine at least 0.70%, amino acid methionine + cysteine at least 0.5%, urea ND and harmful for aflatoxin. It appears that the rabbit feed contains amino acids that are not contained in the mice feed and may affect the growth of Salmonella spp. However, further research needs to be done regarding the effect of these amino acids on the growth of *Salmonella* spp.

4. Conclusion

In this study, *Salmonella* spp. detection was carried out using the LAMP method, PCR and culture method. LAMP and Real-Time PCR methods can be used for *Salmonella* spp. detection in commercial rabbit and mice feed with the same e-LOD value as the culture method. In mice feed samples, the e-LOD value$_{50}$ was 0.62 cfu/test portion, while in rabbit feed samples, the e-LOD$_{50}$ was 0.37 cfu/test portion. The LAMP and Real-Time PCR methods can be applied as alternative methods in *Salmonella* spp. detection testing for animal feed that provides valid results in a faster time than the culture method.

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Communication Audit of the School Snack Food Program of the Food and Drug Supervisory Agency in Yogyakarta

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ABSTRACT

Unsafe school children's snacks (PJAS) pose health risks and can cause various diseases. To address this, the PJAS Safety Intervention Program was introduced. The COVID-19 pandemic brought changes to the definition of PJAS and altered communication patterns in program delivery. This study evaluates the success of the program implemented by the Indonesian Food and Drug Authority Regional Office in Yogyakarta during the pandemic. It identifies factors inhibiting its effectiveness through a communication audit. The research used an evaluative qualitative method involving interviews with informants to assess planning and preparation and surveys with school community respondents to evaluate program communication. The study followed the General Guidelines for Communication Audits in Government Agencies. Results indicate that the program was effectively implemented and can be enhanced by improving communication dimensions. Key strategies include strengthening message delivery through direct engagement with policymakers, expanding media use by adding hardcopy materials, improving message clarity with comprehensive posters detailing program stages, and fostering public feedback through information sharing and participation mechanisms, particularly at junior and senior high school levels. Additionally, expanding promotional media can further optimize program outreach. The communication audit concluded that the PJAS Safety Intervention Program successfully met its objectives through effective management with minor, manageable obstacles. These findings suggest that the program can continue with improved communication strategies to enhance its impact.

Pangan Jajanan Anak Sekolah (PJAS) yang tidak aman dapat menyebabkan berbagai macam penyakit. Salah satu upaya yang dilaksanakan untuk mengatasi permasalahan keamanan pangan adalah dengan Program Intervensi Keamanan PJAS. Kondisi Pandemi COVID-19 mengakibatkan redefinisi PJAS dan perubahan pola komunikasi pada pelaksanaan program. Penelitian ini bertujuan untuk mengevaluasi keberhasilan Program Intervensi Keamanan PJAS yang dilaksanakan oleh BBPOM di Yogyakarta pada masa Pandemi COVID-19 dan faktor-faktor apa yang menjadi penghambat berdasar hasil audit komunikasi. Metode penelitian yang digunakan adalah metode evaluatif dengan kualitatif melalui wawancara informan untuk menggali perencanaan dan persiapan dan survei komunitas sekolah untuk melihat tanggapan pelaksanaan program berdasar dimensi komunikasi yang mengacu Pedoman Umum Audit Komunikasi di Lingkungan Instansi Pemerintah. Hasilnya menunjukkan bahwa Program Intervensi Keamanan PJAS berjalan baik dan dapat terus dilanjutkan dengan mengoptimalkan performa pada dimensi komunikasi, yaitu proses penyampaian pesan dengan melaksanakan komunikasi secara langsung dengan pengambil kebijakan, media komunikasi dengan penambahan media hardcopy, kejelasan arti pesan dengan membuat satu pointers atau poster yang berisi tahapan program secara utuh, umpan balik publik dengan melaksanakan sharing informasi dan audiensi untuk mendorong partisipasi sekolah tingkat SMP dan SMA, dan model

komunikasi yang diterapkan dengan perluasan penggunaan media promosi program. Berdasarkan analisis hasil audit komunikasi Program Intervensi Keamanan PJAS yang dilaksanakan BBPOM di Yogyakarta di masa Pandemi COVID-19 ini dapat disimpulkan bahwa program ini berhasil dilaksanakan dengan baik, lancar dan sesuai dengan perencanaan. Program berjalan sesuai dengan yang diharapkan, hambatan yang timbul tidak signifikan dan dapat teratasi dengan pengelolaan yang baik.

Keywords: evaluation, communication audit, COVID-19 Pandemic, Food Safety Intervention Program, Indonesian Food and Drug Authority Provincial Office
Kata Kunci: *Evaluasi, audit komunikasi, Pandemi COVID-19, Program Intervensi Keamanan Pangan Jajanan Anak Sekolah, Balai Besar POM*

1. Introduction

Law No. 18/2012 on Food states that food is the most important basic human need. Fulfilling it is part of the human rights guaranteed in the 1945 Constitution, and the state must realize the fulfilment of safe, quality, and nutritious food consumption.

Children are one of the most important groups to consider. They are the nation's next generation that will determine the quality of a country, so the state must ensure the safety of the food they consume to grow into a superior generation. At the same time, the productive children group is schoolchildren. The consumption habits of schoolchildren are food snacks obtained from school canteens and traders around the school.

During the pandemic, PJAS was redefined. Originally, PJAS was obtained only from canteens and traders around schools. Now, PJAS can be obtained from channels at schools, neighbourhoods around schools, homes, and/or e-commerce, always and anytime, at school and home, or other places.

Behavioural habits during snack time have also changed with the implementation of health protocols. If before the pandemic, the habit was enough to wash hands, it is added to wearing a mask, maintaining distance, reducing mobility, and staying away from crowds. The Indonesian Food and Drug Authority (Indonesian FDA) has surveyed school snacks that are often consumed and are still problematic, such as the group of coloured drinks from powdered beverages, syrups, ice groups (ice mambo, lollipops, ice candles, ice cendol, ice mix, ice grass jelly, ice coconut, and ice tea), jelly groups, jelly or gel products and cotton candy, and meatballs, *pentol, siomay, batagor*, cilok groups (BPOM, 2021).

The condition of PJAS in Yogyakarta based on the results of Indonesian FDA supervision in Yogyakarta in 2020, by testing chemical and/or microbiological parameters on 16 PJAS samples, showed that 13 samples met the requirements (MS) (81.25%) and three samples did not meet the criteria (TMS) (18.75%). The TMS samples consisted of 2 TMS samples of microbiological parameters (Annual Report of Indonesian Food and Drug Authority Regional Office in Yogyakarta, 2020).

As one of the technical implementation units (UPT) of the Indonesian FDA in the Special Region of Yogyakarta (DIY), the Indonesian FDA Regional Office in Yogyakarta is committed to supporting the President's Vision and Mission, namely in efforts to prevent non-communicable diseases and reduce stunting rates, one of which is through the School Snack Food Safety Intervention Program (PJAS).

PJAS Safety Intervention Program communication activities include cross-sector advocacy, food safety socialization, food safety technical guidance for school food safety cadres, provision of PJAS food safety education packages, monitoring of school food safety

empowerment, sampling and testing of PJAS, certification of schools with Safe PJAS and supervision of PJAS activities. The program covers schools from elementary school (SD) level to senior high school (SMA) level.

Several studies on communication audits of government programs have been conducted, including those by Trisnawati F et al. in 2019, which conducted an audit of the Jogja Learning Culture Program. The results of the input stage audit have gone well according to procedures, but there is still an understanding of the program that is not in line with planning. The output stage is considered smooth, although some obstacles are still found. At the outcome stage, it was found that the big goals of the program had not been achieved as expected, as the program's benefits were minimal (Trisnawati F., Lestari P., Prayudi, 2019).

Yeni Jelita's 2017 research states that communication audits are carried out internally and externally. Internally, they are done in planning and preparing using the Organizational Communication Profile technique. External communication audits are conducted by looking at public responses to implementing the Stop Drugs campaign. This aligns with the information theory used to see the flow of information in the organization, which is run by the characteristics of the people in Sergai Regency (Yeni Jelita, 2017).

The qualitative approach is based on the dimensions of communication in the internal and external parts according to the General Guidelines for Communication Audits within Government Agencies in the Regulation of the Minister of Administrative Reform and Bureaucratic Reform of the Republic of Indonesia (PermenpanRB) Number 27 of 2011. The difference with previous research is that this study conducted a communication audit using mixed methods during the COVID-19 Pandemic crisis.

The purpose of this study is to evaluate the success of the PJAS Safety Intervention Program implemented by the Indonesian FDA Regional Office in Yogyakarta during the COVID-19 Pandemic and what factors hinder the program based on the results of the communication audit. The scope of the communication audit covers schools that were intervened by the PJAS Safety Program by the Indonesian FDA Regional Office in Yogyakarta in 2020 and 2021.

As a study and approach, a communication audit is an in-depth and comprehensive study of implementing organizational communication systems that aim to increase organizational effectiveness. A communication audit is an analysis, assessment, and in-depth understanding of the organization’s overall system and process of internal-external communication or specific programs to improve effectiveness, efficiency, and other benefits. According to Wilbur Schramm, a communication process must have at least three components: source, message, and receiver. Meanwhile, according to Harold Laswell, the components of a communication process are the source, message, channel, receiver, and effect.

Communication audits in Indonesia have been regulated in the General Guidelines for Communication Audits within Government Agencies as stipulated in the Regulation of the Minister of Administrative Reform and Bureaucratic Reform of the Republic of Indonesia (PermenpanRB) Number 27 of 2011. The guidelines state that communication audits are conducted on 14 (fourteen) dimensions of communication. In this study, researchers used 5 (five) dimensions that have the most influence on the program's implementation: the message delivery process, the communication model established between government

agencies and the public, communication media, clarity of message meaning, and public feedback.

2. Methodology

This type of research is evaluative research (Evaluation Research) and uses the communication audit method. Evaluation research is used to see and analyze program performance as well as to analyze program success. This research uses structured interviews, questionnaire surveys, and document studies based on the dimensions of communication in PermenpanRB number 27 of 2011, namely the process of delivering messages, the communication model established between government agencies and their public, communication media, clarity of message meaning, and public feedback. Informant interviews were conducted to explore program planning and preparation, and school community surveys were conducted to see responses to program implementation.

This study's evaluation target (object) is the PJAS Safety Intervention Program implemented by the Indonesian FDA Regional Office in Yogyakarta during the COVID-19 pandemic, namely 2020 and 2021. This study collected primary data through interviews and surveys, while secondary data were collected from books, reports, and terms of reference. Qualitative data is descriptive narratives from document studies and interviews with 12 internal (hall officers) and external (cross-sector and school community) resource persons/informants. Quantitative data is numerical data from a survey of 132 school community respondents (principals, teachers, students, school committees, canteen workers, parents). The sample size was calculated using the Slovin Formula, and the sampling technique was used using simple random techniques.

The subjects of this study are informants and respondents involved in the PJAS Safety Intervention Program of the Indonesian FDA Regional Office in Yogyakarta. Informants were selected purposively, namely, parties with a wealth of information and can provide information about implementing the PJAS Safety Intervention Program, especially those implemented during the COVID-19 Pandemic. As a reinforcement of information, in addition to interviews with informants, a survey was also conducted with a questionnaire to respondents. Randomly selected respondents are school communities exposed to the PJAS Safety Intervention Program in 2020 and 2021.

To increase the trustworthiness of the communication audit conducted, researchers delivered the results to program planners for follow-up. This valid communication audit can continuously improve program performance during the pandemic and the new normal era.

3. Results and Discussion

The research was conducted from April 3 to 28, 2022, and the results obtained, including data on the characteristics of informants on the internal and external parts, are presented in Table 1.

Table 1. Informant Characteristics

Informant Data/Interview Date	Position/Age	Program/Role Exposure	Education/Institution
Informant 1 ER, female	Program Coordinator/ PFM Associate Expert	Since 2018 Communicator	S1Food Technology

Informant Data/Interview Date	Position/Age	Program/Role Exposure	Education/Institution
April 28, 2022	52 Years		Indonesian Food and Drug Authority Regional Office in Yogyakarta
Informant 2	Program Manager/ PFM	Since 2019	S2 Pharmacy
HSW, female	Junior Expert	Communicator	Indonesian Food and Drug Authority
April 28, 2022	42 years old		Regional Office in Yogyakarta
Informant 3	Program Support Staff	Since 2011	Master of Public Health
RA, female	PFM First Expert	Communicator	Indonesian Food and Drug Authority
April 28, 2022	39 years old		Regional Office in Yogyakarta
Informant 4	Headmaster	2021	Master of Education SDN
YS, male	50 years	Communicator	Karanganyar/Head of K3S
April 3, 2022			Ngemplak
Informant 5	Headmaster	2021	S2 Muhammadiyah 1 Middle School,
DR, female	39 years old	Communicator	Prambanan
April 6, 2022			
Informant 6	Headmaster	2020	S2 Krapyak Wetan Elementary School,
SY, male	55 years	Communicator	Bantul
April 3, 2022			
Informant 7	Headmaster	2020	S1 Kyai Mojo Elementary School
FM, female	52 years	Communicator	Yogyakarta
April 3, 2022			
Informant 8	Teacher/Canteen Manager	2020	High school or equivalent Kyai Mojo
SN, female	32 years	Communicator	Elementary School Yogyakarta
April 3, 2022			
Informant 9	Teacher/Canteen Manager	2020	S1 Krapyak Wetan Elementary School,
SS, female April 3, 2022	57 years old	Communicator	Bantul
Informant 10	Cross-sector 40 years	2020	S1 Sleman Health Service
AT, female April 3, 2022		Communicator	
Informant 11	Cross-sector 42 years old	2020	S1 Yogyakarta City Youth and Sports
DL, female April 4, 2022		Communicator	Educational Office
Informant 12	Cross-sector 40 years	2020	S1 Yogyakarta City Health Office
AP, male April 4, 2022		Communicator	

The evaluation results from interviews in the internal and external sections are presented in Table 2.

Table 2: Evaluation results through interviews

Dimensions	Evaluation results
1. Message Delivery Process	Messages are carried out according to the program's technical guidelines during the pandemic: offline, online, and a combination. In this process, targets and program planning are already set. Officers, as communicators, are experienced and equipped with technical and communication skills.

Dimensions		Evaluation results
		The obstacles faced are limitations due to the pandemic, namely PPKM policies, cross-sectors having other activities (vaccination), different perceptions of the program, and officers not meeting directly with policymakers (through intermediaries).
2.	Communication Media	The media used varied: offline meetings, mobile laboratory car operations, online (kulwhap, zoom), *softcopy,* and *hardcopy* in the form of leaflets, posters, x banners, and videos. There has been a selection of communication media and adjustments; for example, kulwhap is chosen for delivering material to participants who are far away and have signal constraints, while technical guidance that requires detailed explanations is carried out offline. Technical guidelines are available for each stage of activities, but there are no general guidelines in the form of a book that contains comprehensive guidelines for program activities from A to Z. The design of communication media has been attractive by adjusting to the target audience's characteristics, primarily children.
3.	Clarity of Message Meaning	The pre-post and activity questionnaires showed an increase in scores. The message/content of the material was explicit enough, according to the objectives to be achieved, and it was easy for participants to understand and apply. The material has been adapted to the pandemic conditions/redefinition of PJAS, including snacks consumed by children at school, in the neighborhood, and at e-commerce. There was a slight distortion of the message, namely that some participants did not understand the program's purpose (community empowerment), thinking that capital assistance was also provided to build a school canteen. Materials and surveys were delivered in *hardcopy* and *softcopy*; some participants had difficulty understanding the material in softcopy (Google).
4.	Public Feedback	All participants have implemented food safety practices and conducted follow-up actions after attending the program. Some schools volunteer to replicate unintervised schools.
5.	Communication model applied between Indonesian FDA Regional Office in Yogyakarta and its public	Schools that innovate in PJAS safety are included in national-level competitions. The elementary school level has received national achievements, while the junior and senior high school levels have not.
6.	The communication model applied between Indonesian FDA Regional Office in Yogyakarta and its public	Internal communication runs smoothly under one coordinator, while communication with the public runs smoothly through social media and *WhatsApp* groups. Officers are open to receiving suggestions from questionnaires, evaluating activities, and paying attention to PPKM policies. There was a slight disruption of internal communication in the form of scheduling officers who clashed with other activities; besides that, the program's implementation sometimes retreated due to changes in the technical guidelines. A slight disruption in external communication comes from the changing PPKM policy.

In addition to the interview procedure, the researcher used a questionnaire to evaluate the external part, namely the relevant cross-sectors and the school community exposed to the PJAS Safety Intervention Program. The questions in the questionnaire were arranged as many as 21 questions by asking for answer options. The distribution of 132 questionnaires was carried out to schools that had been intervened in 2020 and 2021 in Yogyakarta City, Sleman Regency, Bantul, Gunungkidul, and Kulon Progo offline and through the *Google form* link, with the characteristics of the respondents presented in Table 3 and the evaluation results presented in Graph 1.

Table 3. Informant Characteristics

No.	Description	Frequency (f)	Percentage (%)
1	Related Cross Sectors	7	5
2	School Community:	125	95
	-The principal/teacher	53	42
	-Student	54	43
	-Canteen manager	11	9
	-Parents/school committee	7	6
	Total	132	100

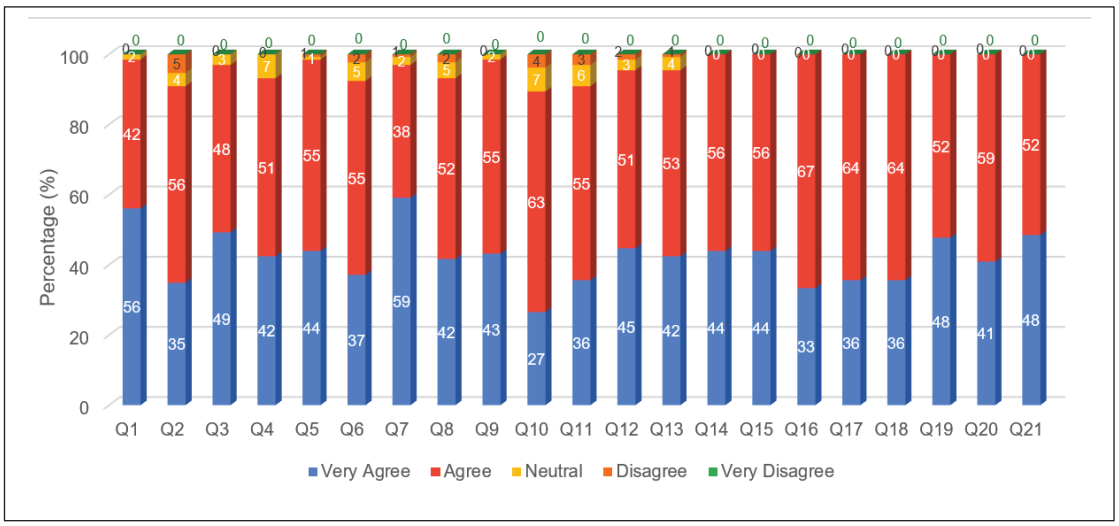

Figure 1. Graph of evaluation results through questionnaires

Based on the evaluation presented in Figure 1, the Validity test results on the PJAS Safety Intervention Program research are valid through a significant test of 0.05, with the results of the value of r count> r table (0.171). The reliability test results in this study are Cronbach's alpha value of 0.927> 0.80, which indicates that all 21 items are reliable and that all tests consistently have strong reliability. The Likert Scale Score results are a Total Index of 87.06% (strongly agree/very good), presented in Table 3.

The internal communication audit of the PJAS Safety Intervention Program showed positive results. The program was successfully implemented well, smoothly, and by plan. Meanwhile, the external communication audit was in line with the program objectives. PJAS Safety Intervention Program participants have implemented the messages and objectives well. Obstacles that arise are not significant and can be resolved with good management.

Only a small number of respondents who gave an opinion disagreed or hesitated due to information related to the program that was not fully understood.

Table 3. Likert Scale Index Calculation Results

Dimensions of Communication	Percentage	Respondent's statement
Message delivery process	95,5%	I agree and strongly agree
Communication media	96,6%	Agree and strongly agree
Clarity of message meaning	98,9%	Agree and strongly agree
Public feedback	100%	Agree and strongly agree
The model applied between Indonesian FDA Regional Office in Yogyakarta and its public	94,9%	Agree and strongly agree

In the dimension of the message delivery process, the communicator (message sender) plays a vital role in the PJAS Safety Intervention Program, especially in controlling the course of communication. According to Yasir in Introduction to Communication Science, a communicator must have communication skills. A good communicator must possess general communication skills, namely listening and reading (receptive or receptive ability) and speaking and writing skills (producing or productive ability). In addition, a communicator must also have wealth in the form of insight or ideas and be full of creativity. To achieve success, communicators must consider three characteristics: credibility, attractiveness, and power (Yasir, 2009).

Communicators who are used as messengers in the PJAS Safety Intervention Program have expertise in drugs and food, namely having educational backgrounds of pharmaceutical graduates, food technology graduates, and public health graduates who know how to choose safe medicines and food for consumption. This expertise makes cadres and school communities, as recipients of messages, believe in the team's integrity (Badan POM, 2021).

Communicators in this program are hall officers with more than 2 (two) years of experience implementing the program. The primary communicator and the person in charge have experience implementing the program since 2019. Based on the evaluation of the dimensions of the message delivery process, communicators in the PJAS Safety Intervention Program have met the criteria of good communicators, namely, having good communication skills, credibility, attractiveness, and power.

In the dimension of communication media, in the process of extension or program delivery, it is an extension tool that serves as an intermediary to connect the extension agent with the target so that the message or information will be more precise. According to Dayana in Extension Communication and Innovation Adoption states that in extension, various media or extension aids are known, such as objects (samples, models, imitations), printed matter (brochures, leaflets, books, posters, and comics), projected images (slides, films, videos) and graphical symbols in the form of graphs, maps, and so on (Dayana, 2011).

Based on the term of reference (TOR) of the PJAS Safety Intervention Program published by the Food and Drug Administration, food safety education packages can be provided through printed and digital materials, such as food safety education games,

audiovisuals, print media, and PJAS peddlers' sanitary hygiene equipment (Badan POM, 2021).

The communication media used in the PJAS Intervention Program at the Indonesian FDA Regional Office in Yogyakarta are pretty diverse and have met the criteria for extension media in the FDA's TOR in the form of Food Safety Books, COVID-19 Multipurpose Books, Viral Canteen Comic strips, Leaflets Choosing Safe PJAS Food, Posters Avoid Indiscriminate Snacking, Posters Get Used to Washing Hands with Flowing Water, Educational Game of Food Safety Snakes and Ladders, Banners Check KLIK and 5 (five) Keys to Food Safety, gimmicks and school canteen sanitation hygiene equipment (aprons, hats, masks, food tongs, gloves).

Based on researchers' observations, some schools have difficulty accessing materials and surveys in *softcopy* on *Google Drive* or links that are not easy to understand, so they need to be made in *hardcopy*. The method of implementing socialization and technical guidance is carried out using online methods (webinars, zoom meetings, kulwhap, and kulgram) or face-to-face by paying attention to health protocols and or a combination of both according to the development of COVID-19 Pandemic zoning conditions according to each district/city in DIY. The methods used are presentations, simulations, and discussions.

Achieving effective communication is not an easy process in the dimension of clarity of message meaning. In addition to the communicator, the form and technique of presenting the message are also factors that determine the success of the persuasion efforts. The clarity of the message's meaning must be arranged so that there is no gap of doubt in conveying. The message structure is needed to organize the messages to be communicated. Messages to be delivered by PJAS Safety Intervention Program communicators are prepared through field technical instructions. Through technical guidelines, it is known that messages will be prepared and delivered in all stages of the program.

Based on the evaluation results on the dimension of clarity of message meaning, the PJAS Safety Intervention Program has fulfilled the aspects of message authenticity (origin), mode, *physical character*, message preparation, and novelty, as stated by Liliweri in Multipurpose Communication. The message in the program, in the form of material content, is relatively straightforward, and the objectives are to be achieved, and participants easily understand it. Participants can understand the messages conveyed and then apply them without significant distortion or deviation of messages (Liliweri, 2011).

Some participants have even forwarded their knowledge to other schools not exposed to the program. Participants' understanding is measured based on the results of filling out questionnaires and the increase in knowledge from each activity's pre and post-test scores. The material is very much in line with the program objectives, which are to empower the school community and has been adapted to the pandemic conditions and the redefinition of PJAS, which includes snacks consumed by children at school, in the residential environment, and e-commerce.

According to the TOR, participants quickly understood the material because they were exposed to it several times during each stage. However, there was a slight distortion of the message, namely, not understanding the program's purpose, namely, community empowerment. Some thought that capital assistance was also given to build a school canteen.

In the feedback dimension, the impact and benefit of this program are to increase the independence of the school community and ensure the fulfilment of PJAS needs to be consumed in safe, quality, and nutritious conditions. Based on the evaluation, the success of

the PJAS Safety Intervention Program in DIY Province is also evidenced by the achievement of Level 1 / Level 2 certified schools and several achievements that schools in DIY Province have achieved at the national level.

Achievements that have been made at the national level in the last 2 (two) years are the first winner of the POM Safe Food School Competition in 2019 by SD Muhammadiyah Condong Catur Sleman and the third winner of the POM Committed and Innovative School Competition in 2020 by SDN Krapyak Wetan Bantul. The number of schools that have been intervened A, B and C by Indonesian Food and Drug Authority Regional Office in Yogyakarta from 2011 to 2020 are Sleman Regency with 300 (58.71%) schools, Bantul Regency with 262 (72.18%) schools, Gunungkidul Regency with 452 (96.37%) schools, Kulon Progo Regency with 195 (57.69%) schools Yogyakarta City with 164 (100%) schools.

Feedback determines the success of communication and can illustrate whether communication is going well. The feedback dimension of the PJAS Safety Intervention Program has met the criteria, which include Audience Coverage, Audience Response, Communication Impact, and Process of Influence, as stated by Suryanto in Introduction to Communication Science (Suryanto, 2015).

The intensive interaction between hall officers and participants through Whatshap groups increases the response or feedback from participants; this is in line with the theory of interpersonal communication, which states that the delivery of messages by one person and the recipient of other messages or a small group of people has various impacts and opportunities to provide immediate feedback.

The results of supervision through PJAS testing by the Indonesian Food and Drug Authority Regional Office in Yogyakarta show that in 2021, the number of PJAS that do not meet the requirements has decreased compared to 2020. The PJAS Safety Intervention Program in DIY has successfully achieved several quality targets. However, the success of the PJAS Safety Intervention Program can still be improved in terms of the number and quality of distribution and the type of school (public schools and religious-based schools).

Regarding the number and quality of distribution, Yogyakarta City, Bantul Regency, and Sleman Regency still dominate, compared to Gunungkidul and Kulon Progo Regencies. More intensive communication efforts are needed so that other districts can increase their participation in the PJAS Safety Intervention Program, for example, by holding special activities in the targeted districts or conducting special hearings with the leaders of the agencies where the schools are based, namely the Education Office and the Ministry of Religious Affairs.

In the dimension of the BBPOM communication model in Yogyakarta with the public, the evaluation results in general, the program can be carried out well as planned. Based on the report on the PJAS Safety Intervention Program of the Indonesian Food and Drug Authority Regional Office in Yogyakarta in 2021, the Indonesian Food and Drug Authority Regional Office in Yogyakarta carried out program supervision implemented the previous year. This supervision stage is carried out to ensure that schools that intervened in the last year remain committed to implementing food safety practices. Schools that remain committed to implementing food safety practices can be issued Level 2 Safe PJAS Certificates.

The communication model in this PJAS Safety Intervention Program is a two-way communication model in the internal part and community empowerment communication in the external part. The community empowerment communication referred to here is the

empowerment of the school community. According to Indardi in Community Empowerment Communication, community empowerment communication is a more focused study of development communication. Community empowerment communication is a study of communication in development activities emphasizing the importance of community involvement or community participation. Communication processes in community empowerment emphasize transactional and interactive processes rather than linear ones (Indardi, 2016, pp. 106-108).

The communication model of community empowerment in the PJAS Safety Intervention Program strengthens previous research entitled Children and School Snacks: School Children Health Empowerment Program in the Perspective of Local Government, conducted by Triwijayati et al., which states that empowering children to consume snacks at school is an effort to ensure that children can make informed consumption decisions and are protected from the dangers of unhealthy snacks (Triwijayati. et al., 2016).

Based on the results of this study, a follow-up was carried out in the form of:

a. Schedule the PJAS Safety Intervention Program, systematically implementing officers with other program-implementing officers so there are no clashes. If the appointed officer is absent, they can be replaced immediately.
b. Formulating program implementation schedules and targets by considering the agendas/busy schedules of the school community and cross-sectors and developing COVID-19 and PPKM policies.
c. Initial agreements and commitments are made in writing with participants, especially policymakers, and attachments contain a summary of the stages of program implementation from start to finish.
d. Conduct hearings with the Department of Education and Ministry of Religious Affairs and/or *share* activities and visits to schools that have successfully implemented the PJAS Safety Intervention Program.
e. Appoint participants in national-level competitions one year in advance, especially at the junior and senior high school levels, to be well prepared.
f. Implement program publications by creating infographics, posters, videos, or leaflets containing a summary of the PJAS Safety Intervention Program's implementation, objectives, benefits, and successes and disseminating them to the public through websites, television, radio, and other public media.

The limitation of this study is that data collection through interviews has not involved parents, school committees, child health organizations, or activists. Parents or school committees can provide feedback on the implemented program, while organizations or child health activists can support it.

7. Conclusion

Based on the analysis of the results of the communication audit of the PJAS Safety Intervention Program implemented by the Indonesian FDA Regional Office in Yogyakarta during the COVID-19 Pandemic, it can be concluded that the internal part shows positive results where the program is successfully implemented well, smoothly, and by planning. The audit results resulted in a good assessment of the dimensions of the message delivery process, communication media, clarity of message meaning, public feedback, and the communication model applied between the Indonesian FDA Regional Office in Yogyakarta and its public.

The external communication audit states that the program is running as expected, and participants have implemented it well to realize safe PJAS. The obstacles that arise are insignificant and can be resolved with good management. Factors that inhibit the program include some parties still lacking awareness of the importance of inter-institutional communication, community participation in the habits and mindset of the importance of safe snacks, uneven compliance with policies, and still limited access to information/technology in some areas.

Based on the study's results, the following recommendations can be made to improve the program's implementation: On the internal side, information related to the PJAS Food Safety Intervention Program can be conveyed directly to policymakers. Comprehensive guidelines or posters containing a summary of the program are necessary. On the external side, sharing achievements and equalizing targets is essential. A follow-up communication audit is required to be conducted on implementing the PJAS Safety Intervention Program, which has implemented the recommendations from this study.

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Development of an Analytical Method for Determination of Dexchlorpheniramine Maleate Level in Tablet Preparations by UV Detector High-Performance Liquid Chromatography

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ABSTRACT / ABSTRAK

Dexchlorpheniramine maleate, an antihistamine for allergy treatment, is traditionally tested in tablet form using the UV spectrophotometric method referenced in United States Pharmacopeia (USP), NF 43. However, this method struggles to separate the active compound from other tablet components, such as dyes, necessitating an extraction process. Extraction has several drawbacks, including high waste production, extensive use of costly pure solvents, prolonged preparation times, and reliance on hazardous volatile solvents. This study aims to develop a safer, more efficient, and effective method using high-performance liquid chromatography (HPLC), modified from the USP, NF 43 standard. The experimental approach involves method development and validation, focusing on selectivity, precision, accuracy, linearity, and robustness. The selectivity test demonstrated a resolution value 19.6 between dexchlorpheniramine and maleic acid peaks. The specificity test confirmed identical retention times and spectra between standard and sample peaks. Precision testing yielded a relative standard deviation (RSD) below 0.37%. Accuracy tests at 80%, 100%, and 120% levels achieved an average recovery of 99% within the 97%–103% acceptance range. Linearity testing resulted in a correlation coefficient (r) 1.00 and Vx0 of 0.1. ANOVA test results on Robustness testing revealed no significant differences with column modification but identified sensitivity to pH and mobile phase composition changes. In conclusion, the developed HPLC method meets validation parameters, providing a reliable alternative for analyzing dexchlorpheniramine maleate tablets, with attention to pH and mobile phase suitability.

Deksklorfeniramin maleat adalah senyawa antihistamin yang digunakan dalam pengobatan alergi. Penetapan kadar deksklorfeniramin maleat tablet dilakukan sesuai acuan United States Pharmacopeia (USP), NF 43 dengan metoda spektrofotometri UV. Kelemahan metode ini yaitu tidak dapat memisahkan zat aktif yang akan diuji dari komponen lain yang ada dalam tablet seperti pewarna, sehingga perlu dilakukan proses ekstraksi sebelum dilakukan penetapan kadar. Namun metode ekstraksi mempunyai kelemahan, antara lain produksi cairan limbah yang besar, kebutuhan pelarut murni dalam jumlah besar dan mahal, waktu ekstraksi yang lebih lama, serta penggunaan pelarut berbahaya yang mudah menguap. Penelitian ini bertujuan untuk mengembangkan metode analisis penetapan kadar tablet deksklorfeniramin maleat yang lebih implementatif, efeisien, efektif dan aman dengan metode kromatografi cair kinerja tinggi (KCKT), yang merupakan modifikasi dari cara kerja penetapan kadar baku pembanding dekskloefeniramin maleat sesuai USP, NF 43. Metode penelitian yang digunakan adalah metode eksperimental, yaitu dengan melakukan

pengembangan dan validasi metode mencakup uji selektivitas/spesifitas, presisi, akurasi, linearitas, dan robustness. Uji selektivitas antara puncak deksklorfeniramin dan asam maleat menghasilkan nilai resolusi 19,6. Pada uji spesifitas, baku deksklorfeniramin maleat dan sampel yang diuji menghasilkan puncak pada waktu retensi dan spektrum yang identik. Uji presisi memberikan simpangan baku relatif (RSD) kurang dari 0,37%. Uji akurasi pada kadar 80%, 100% dan 120% menghasilkan rata-rata perolehan kembali 99% dengan rentang keberterimaan 97% – 103%. Uji linearitas memberikan nilai koefisien korelasi r = 1,00 dan Vx0 = 0,1. Hasil uji ANOVA pada uji ketangguhan metode menunjukkan hasil yang tidak berbeda signifikan pada modifikasi kolom, tetapi berbeda signifikan pada modifikasi pH dan komposisi fase gerak. Secara umum dapat disimpulkan bahwa metode uji yang dikembangkan memenuhi parameter validasi, tetapi dalam penerapannya harus memperhatikan kesesuaian pH dan perbandingan fase gerak yang digunakan.

Keywords: dexchlorpheniramine maleate, HPLC, method development, validation
Kata Kunci: Deksklorfeniramin maleat, KCKT, pengembangan metode, validasi

1. Introduction

Accurate test results are essential to ensuring the quality and safety of drugs and food circulating in the community. Laboratories must continuously develop analytical methods that are time-efficient, resource-saving, and aligned with the latest technological advancements (Pratiwi et al., 2021). Furthermore, validating test methods is crucial for ensuring reliable laboratory outcomes and instilling confidence in the results (Barnett et al., 2023).

Dexchlorpheniramine maleate is a first-generation antihistamine used to treat allergies. This compound exhibits sedative side effects due to its ability to penetrate the blood-brain barrier more effectively than second-generation antihistamines. Studies have shown that high concentrations of dexchlorpheniramine can induce genotoxicity in human lymphocytes (Chaves et al., 2022). Therefore, monitoring the quality and safety of dexchlorpheniramine maleate is critical for public health.

Dexchlorpheniramine maleate is available in dosage forms such as tablets and syrups. Determining its levels in tablets has been traditionally performed using the UV spectrophotometric method as per the United States Pharmacopeia (USP), NF 43 (United States Pharmacopeial Convention, 2022). However, this method struggles to separate the active substance from other tablet components, such as dyes, which may interfere with the results. To address this, an extraction process is often employed (Mustarichie Resmi, 2014). Extraction, however, has significant drawbacks, including large waste production, high solvent costs, extended preparation times, and hazardous volatile solvents (Hewage et al., 2022; Mandal et al., 2015).

Given these limitations, developing an efficient and safe analytical method is imperative. High-performance liquid chromatography (HPLC) offers a robust alternative for separating, identifying, and quantifying active substances (Sabir et al., 2016). Unlike UV spectrophotometry, the HPLC method eliminates the need for extraction, reducing costs and enhancing accuracy (Singh et al., 2021; Smolinska et al., 2022).

One prior study employed HPLC to analyze dexchlorpheniramine maleate levels in syrups (Le et al., 2019). This study highlights the need to extend similar methods to tablet preparations. Validation of such methods, even when adapted from standard practices, ensures accuracy and reliability in a broader range of applications (ISO/IEC 17025:2017).

This study aims to develop an HPLC method to effectively determine dexchlorpheniramine maleate levels in tablets. This will provide laboratories with a practical tool for ensuring product

quality and public safety. Ultimately, this will enhance regulatory oversight and address drug and food safety standards violations.

2. Methodology

The research method employed is experimental, focusing on developing and validating a method for determining the levels of dexchlorpheniramine maleate in tablet preparations using high-performance liquid chromatography (HPLC). Validation parameters include selectivity/specificity, precision, accuracy, linearity, and robustness (Kementerian Kesehatan Republik Indonesia, 2020; Barnett et al., 2023). The resulting data were statistically analyzed and compared against the acceptance criteria for each validation parameter (Riyanto, 2014; Belouafa et al., 2017).

The tablets were homogenously crushed and dissolved in the mobile phase, followed by analysis using an HPLC system (Shimadzu) equipped with a column containing Octadecylsilane X Bridge (Waters) measuring 25 mm in length, 4.6 mm in inner diameter and 5 µm particle size. The detector was a UV-PDA, set to a wavelength of 225 nm. The analysis was conducted in isocratic mode with a mobile phase consisting of phosphate-buffered saline (pH 3.0 ± 0.1) and acetonitrile in a 70:30 ratio, a 1.0 mL/min flow rate, and an injection volume of 20 µL.

The validation parameters assessed include:

2.1. Selectivity/specificity

Selectivity was determined by examining the resolution between dexchlorpheniramine and maleic acid peaks, comparing standard and sample spectra, and calculating the peak purity index.

2.2. Precision

Performed ten replicate tests and calculated the % RSD value.

2.3. Accuracy

The standard addition method was used at concentrations of 80%, 100%, and 120%, with three replicates for each concentration.

2.4. Linearity

Linearity was assessed using a series of concentrations (60%, 80%, 100%, 120%, and 140%), and the correlation coefficient (r) and Vx0 values were calculated from the chromatogram area and theoretical content.

2.5. Robustness

The robustness test evaluated the impact of variations in testing parameters on the levels of dexchlorpheniramine maleate. The tested variations included:

2.5.1. Variation of pH

Comparing results using phosphate-buffered saline with pH values of 2.5, 3.0, and 3.5.

2.5.2. Variation of mobile phase composition

Comparing results using mobile phase ratios of 65:35, 70:30, and 75:25 (phosphate-buffered saline: acetonitrile).

2.5.3. Variation of column brands

Comparing results using X Bridge (Waters), Luna (Phenomenex), and Zorbax (Agilent) columns.

3. Result and Discussion

In this validation process, a thorough evaluation has been carried out based on the test results of the validation parameters: Selectivity/Specificity, Precision/Repeatability, Accuracy, Linearity and Robustness.

3.1. Selectivity/Specificity

In chromatographic techniques, selectivity is demonstrated by a clear separation between the analyte and other components in the sample. This requirement is met when the resolution of the analyte from other components exceeds 2.0 (ICH, 2022). According to the analysis results, the resolution between the maleic acid and dexchlorpheniramine peaks was 19.6, as shown in Figure 1.

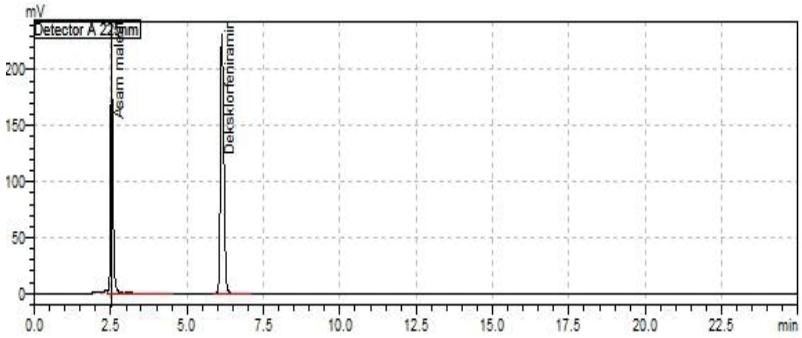

Figure 1. Chromatogram of Dexchlorpheniramine maleate

Specificity refers to the ability of an analytical method to assess an analyte in the presence of other components within the sample matrix. In HPLC, specificity can be evaluated by the peak purity index of the analyte chromatogram. Specificity is further determined by comparing the retention times of the sample and comparator standards, as well as ensuring the sample spectrum matches that of the standard. The chromatogram of dexchlorpheniramine maleate in the test solution showed an average retention time of 6.11 minutes. For the standard solution, the retention time averaged 6.14 minutes, with a single peak and a peak purity index of 1.00000 (Figure 2). The sample spectrum was identical to the standard spectrum (Figure 3).

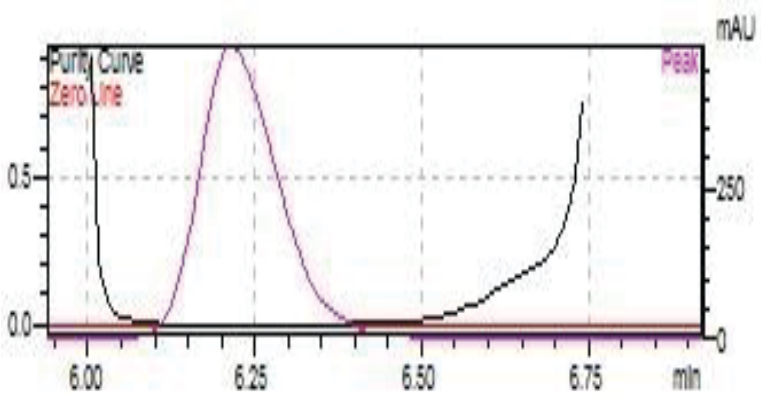

Figure 2. Peak purity of Dexchlorpheniramine

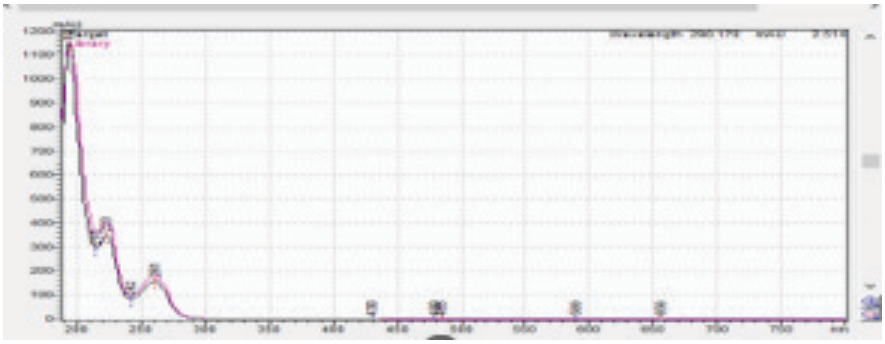

Figure 3. Overlay of sample and standard spectra of Dexchlorpheniramine

3.2. Precision/Repeatability

Precision indicates whether an analytical method produces consistent results upon repetition. It can be evaluated by analyzing individual results relative to the average value when the procedure is repeated. A method meets precision criteria if the relative standard deviation (RSD) or coefficient of variation (CV) is ≤2% (Kementerian Kesehatan Republik Indonesia, 2020). As shown in Table 1, the method produced an RSD of 0.37%.

Table 1. Results of Precision Test RSD Calculation

Replication	Content (mg)	Content (%)
1	2,028	101,40
2	2,034	101,68
3	2,040	102,01
4	2,045	102,23
5	2,028	101,38
6	2,026	101,28
7	2,049	102,43
8	2,036	101,79
9	2,035	101,74
10	2,037	101,85
Avarage	2,04	101,78
SD	0,01	0,37
RSD	0,37	0,37

3.3. Accuracy

Accuracy refers to the closeness between the measured and accepted reference values. This is assessed by determining the analyte recovery rate using a spiked sample. The standard addition method, which involves adding a known standard solution to the sample matrix, was used to evaluate accuracy. Results showed an average recovery of 99% (Table 2), within the acceptable range of 97%–103% (Association Of Official Analytical Collaboration (AOAC) International, 2016).

Table 2. % Recoveries Calculation Results

No.	Concentration (%)	Recoveries (%)	Recoveries (%)
1	80	99	
	80	100	100
	80	99	
2	100	100	
	100	99	99
	100	97	
3	120	99	
	120	98	99
	120	99	
	Average		**99**

3.4. Linearity

Linearity is determined by measuring different concentration ranges and calculating the slope, intercept, and correlation coefficient. The test results showed Vx0 = 0.1 and r = 1.0000, indicating a linear relationship for dexchlorpheniramine maleate concentrations between 31.761 µg/mL and 70.141 µg/mL (Yuwono et al., 2005).

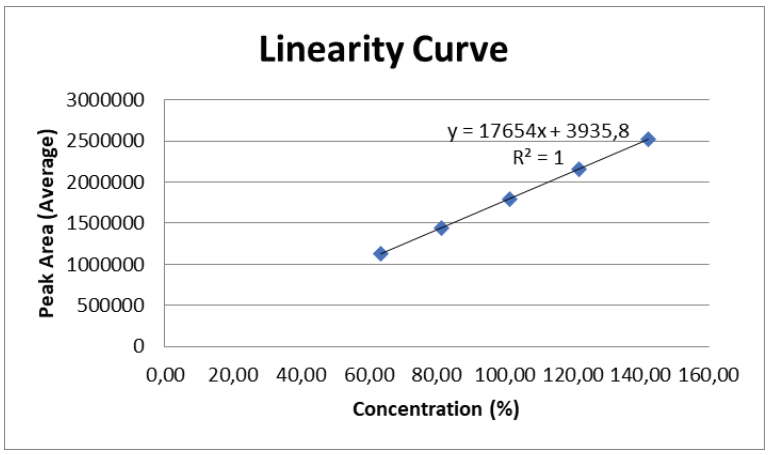

Figure 4. Linearity Curve

3.5. Robustness

Robustness assesses the ability of an analytical method to remain unaffected by minor but deliberate variations in parameters, ensuring reliability during routine use (Yuwono & Indrayanto, 2005). This study tested variations in mobile phase composition, pH, and column brand. Variations in pH and mobile phase composition caused significant differences, while column brand changes did not produce significant effects. These findings highlight the importance of maintaining consistent pH and mobile phase conditions.

4. Conclusion

The results of this validation study demonstrate that the analytical method meets the validation requirements of Indonesia Pharmacopeia and AOAC for specificity/selectivity, precision, accuracy,

and linearity. Consequently, this HPLC method is suitable for determining dexchlorpheniramine maleate levels in tablet preparations.

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Analysis of the Results of Supervision of Advertisement of Processed Food Products Circulating in DKI Jakarta Province in 2021 - 2023

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ABSTRACT

Food is a fundamental need in society, and advertising significantly influences the consumption of processed food products. Advertising introduces products for businesses and provides product-related information for consumers. However, some advertisements violate regulations. Supervising processed food advertisements is one of the Indonesian Food and Drug Authority's (FDA) roles. This study analyzes processed food advertisement supervision in DKI Jakarta from 2021 to 2023, focusing on media types, violation types, and food categories most frequently violating regulations. Secondary data from supervision reports collected by the Jakarta FDA Office during this period were analyzed descriptively. Results show that 1468 (77.7%) of the 1890 advertisements evaluated did not meet regulatory requirements. Most violations occurred in online media (1424 ads, 97%), followed by outdoor media (39 ads, 2.7%) and print media (5 ads, 0.3%). The most common violations included health claims not complying with provisions (1110 ads, 75.7%), misleading advertisements (175 ads, 11.9%), prohibited advertising in non-health media (160 ads, 10.9%), superlative statements (21 ads, 1.4%), and norm violations (1 ad, 0.1%). Violations based on food categories were highest in beverages (category 14) with 1149 ads (78.3%), milk products (category 1) with 66 ads (4.5%), and sugar products and sweeteners (category 11) with 49 ads (3.3%). These findings highlight the need for stricter oversight and public awareness of advertising regulations.

Pangan merupakan salah satu kebutuhan pokok masyarakat. Salah satu hal yang mempengaruhi konsumsi produk pangan olahan yaitu iklan. Bagi pelaku usaha, iklan adalah salah satu sarana untuk memperkenalkan produknya, sedangkan bagi konsumen merupakan salah satu cara untuk mengetahui informasi terkait produk tersebut. Namun terkadang pelaku usaha melakukan promosi/iklan yang tidak sesuai dengan ketentuan. Salah satu tugas Badan Pengawas Obat dan Makanan yaitu melakukan pengawasan terhadap iklan produk pangan olahan yang beredar. Penelitian ini bertujuan untuk menganalisis hasil pengawasan iklan produk pangan olahan yang terdapat di Provinsi DKI Jakarta selama periode tahun 2021 - 2023. Data yang dianalisis berupa data sekunder yang diperoleh dari laporan hasil pengawasan iklan produk pangan olahan yang dilakukan oleh Balai Besar Pengawas Obat dan Makanan di Jakarta. Data dianalisis secara deskriptif untuk mengetahui gambaran hasil pengawasan. Hasilnya diketahui iklan produk pangan olahan yang tidak memenuhi ketentuan (TMK) sebanyak 1468 (77,7%) dari total 1890 iklan yang dievaluasi. Jenis media yang paling banyak ditemukan pelanggaran ialah pada media daring sebanyak 1424 (97%), media luar ruang 39 (2,7%) dan media cetak (leaflet) 5 (0,3%). Jenis pelanggaran tertinggi yaitu iklan dengan klaim kesehatan yang tidak sesuai ketentuan sebanyak 1110 (75,7%), iklan menyesatkan 175 (11,9%), iklan produk pangan yang tidak boleh diiklankan selain pada media kesehatan 160 (10,9%), iklan dengan kalimat superlatif 21 (1,4%) dan

iklan yang melanggar norma 1 (0,1%). Pelanggaran iklan berdasarkan kategori pangan diperoleh 3 kategori tertinggi dari 16 kategori pangan yaitu produk minuman (kategori 14) sebanyak 1149 (78,3%) disusul produk susu dan analognya (kategori 1) sebanyak 66 produk (4,5%) serta produk gula dan pemanis, termasuk madu (kategori 11) sebanyak 49 produk (3,3%).

Keywords: advertising media, advertising supervision, DKI Jakarta, food category, processed food
Kata Kunci: DKI Jakarta, kategori pangan, media iklan, pangan olahan, pengawasan iklan

1. Introduction

The rapid development of food technology has led to various types of advertisements for processed food products. Processed food is food or beverages processed in a certain way or method with or without additives. The food category is a food grouping based on raw materials, processing, and/or target designation by the type of food concerned (PerBPOM No. 13 of 2023). The advertisement of processed food products is regulated in NA-DFC Regulation No. 6 of 2021 concerning the Supervision of Advertising of Processed Food. The technical implementation of the supervision of advertising of processed food products is regulated in the Implementation Guidelines for Advertising of Processed Food in 2022.

An advertisement is said to Not Meet the Conditions (TMK) if it contains incorrect and misleading information. According to Government Regulation of the Republic of Indonesia No. 69/1999 on Food Labels and Advertisements Article 44 paragraph (1), "every advertisement for food in trade must contain information about food that is true and not misleading, either in the form of pictures and/or sounds, statements and/or any other form." Misleading statements are defined in the Explanation of Article 5 paragraph (1) as statements relating to matters such as the nature, price, ingredients, quality, composition, benefits, or safety of food, which, although true, may give rise to a misleading understanding of the food concerned. Violations of the provisions on advertising processed food products may be subject to administrative sanctions per the Decree of the Head of the NA-DFC No. HK.02.01.1.2.05.20.166 of 2020 concerning Guidelines for Follow-up of Food Supervision within the NA-DFC and *pro-justicia* sanctions by Government Regulation No. 69 of 1999 concerning Food Labels and Advertisements.

Advertising violations have occurred in various types of processed foods. Amini et al. (2023) reported advertising violations in food products that have low nutritional value, high sugar, salt, and fat (GGL), misleading advertisements and inappropriate nutritional claims, using obese actors, promoting gluttony, consumerism, and waste in the period 1996-2020 in Iran. Apart from processed food products, advertising violations also occur in other products, such as health supplements (Nugraheni et al., 2021), cosmetics, and traditional medicines.

Currently, there is an increase in the number of advertisements that do not meet the provisions, one of which is the advertisement of unhealthy processed food. Jindarattanaporn et al. (2024) compared television advertising data in Thailand on March 24-April 6, 2014, with advertising data on May 5-11, 2022, and found that there was an increase in the types of unhealthy food advertisements from 6.3 ads per hour to 9.2 ads per hour. Puspikawati et al. (2021) also reported that most of the processed food advertisements displayed in 2019 in Banyuwangi were still advertisements for unhealthy food (39.8%) and unhealthy drinks (47.9%), while in Surabaya, advertisements for unhealthy food (28.2%) and unhealthy

beverages (46.3%). Thus, the percentage of processed food product advertisements that do not comply with the provisions remains relatively high.

The influence of advertisements of processed food products that do not comply with the provisions on public consumption patterns is decisive. Kuswanto et al. (2020) reported that the online shopping behavior of students at the Surabaya Institute of Technology is determined by four factors: risk perception, pleasure, social influence, and online advertising. Other research conducted by Wahyuniar et al. (2020) showed a relationship between the duration of television viewing, attitudes toward advertising, and nutritional knowledge on the frequency of consumption of advertised products. This is in line with the statement of Trijayanti et al. (2023) that regulations related to food and beverage advertising in Indonesia have not effectively influenced people's consumption choices towards healthier processed food products. Therefore, strong regulations are needed to regulate the broadcast of advertisements for processed food products and to increase public education to build healthy food consumption patterns.

BBPOM in Jakarta, as a Technical Implementation Unit (UPT) of the POM Agency, has the task of carrying out drug and food supervision in the DKI Jakarta province, one of which is the supervision of advertisements for processed food products (PerBPOM No. 22 of 2020). So far, no in-depth evaluation has been carried out regarding the trend of the results of processed food advertising supervision in Indonesia. This study analyzes the results of advertising supervision of processed food products in DKI Jakarta Province in 2021 - 2023. The results of this study are expected to provide benefits to BPOM as a basis for making policies for supervising advertisements for processed food products to be more optimal, to processed food businesses/individuals in creating advertisements for processed food products to comply with the provisions, and to the public to be more aware of various types of processed food product advertising content and be able to report it to the competent authority on numerous types of processed food product advertisements that do not meet the provisions.

2. Methodology

The data studied in this study are secondary. The data is obtained from the report on the results of supervision of advertisements for processed food products at the BBPOM in Jakarta in 2021-2023. The number of ads that were evaluated was 1890 advertisements obtained *randomly* (*random sampling)* by BBPOM advertising supervisory officers in DKI Jakarta from 2021-2023._The research location is in the DKI Jakarta Province area. The parameters of this study are the results of the evaluation of advertising supervision of processed food products, namely, Meeting the Conditions (MK) or Not Meeting the Conditions (TMK).

The data used are data on types of advertising media and categories of violations (Regulation of the Food and Drug Administration No. 6 of 2021) and data on food categories (Regulation of the Food and Drug Administration No. 13 of 2023), including food additives (Regulation of the Food and Drug Administration No. 11 of 2019).

Advertising media type data includes:

1. Print media (newspapers, magazines, tabloids, newsletters, calendars, posters or flyers, leaflets, brochures, stickers, booklets, pamphlets, and yellow pages);
2. Broadcast media (television and radio);

3. Outdoor media (billboards, banners, billboards, signboards, print advertisements pasted/hung outside Videotron spaces, car tire covers, and backdrops);
4. Online media (social media, e-commerce and websites).

Offense category data includes:

1. Food that may not be advertised other than in health media (alcoholic beverages, infant and follow-up formulas, and Processed Food for Special Medical Purposes/PKMK)
2. Advertisements with health claims that are not by the provisions (efficacious as medicine, traditional medicine, and beauty or efficacious to educate);
3. Misleading advertisements do not match the characteristics of the product;
4. Ads that violate applicable norms (dangerous scenes, SARA, etc.); and
5. Advertising with superlative, comparative, and discrediting words (except comparing with own products).

Food category data includes:

1. Dairy products and their analogs, except those in Category 2
2. Fats, oils and oil emulsions;
3. *Edible* ice includes sherbet and sorbet;
4. Fruits and vegetables (including mushrooms, tubers, nuts including soybeans, and aloe vera), seaweed, seeds;
5. Confectionery/candy and chocolate;
6. Cereals and cereal products that are derived from cereal seeds, roots and tubers, nuts, and pith (inner part of the plant stem), excluding bakery products of category 07.0 and excluding nuts of category 04.2.1 and category 04.2.2;
7. Bakery products;
8. Meat and meat products, including poultry meat and game meat;
9. Fish and fishery products, including mollusks, crustaceans, and echinoderms;
10. Eggs and egg products;
11. Sugar and sweeteners, including honey;
12. Salt, spices, soups, sauces, salads and protein products;
13. Processed food for particular nutritional purposes;
14. Beverages, excluding dairy products;
15. Ready-to-eat snacks;
16. Ready-to-eat (packaged) processed food
17. BTP (Food Additive)

The data were analyzed descriptively with details of the data obtained, including the highest and lowest data or the average. The research instruments used were processed using Microsoft Excel version 2019.

3. Results and Discussion

3.1. Supervision of Advertisement of Processed Food Products

On average, the results of the supervision of processed food product advertisements that did not meet the provisions (TMK) in DKI Jakarta Province in 2021 - 2023 were found to be very high, namely 77.7%. The percentage of processed food advertisements that did not meet the provisions (TMK) in 2021 was the highest (82.5%), then decreased in 2022 (75.2%), but in 2023 there was an increase again (75.4%) (Figure 1).

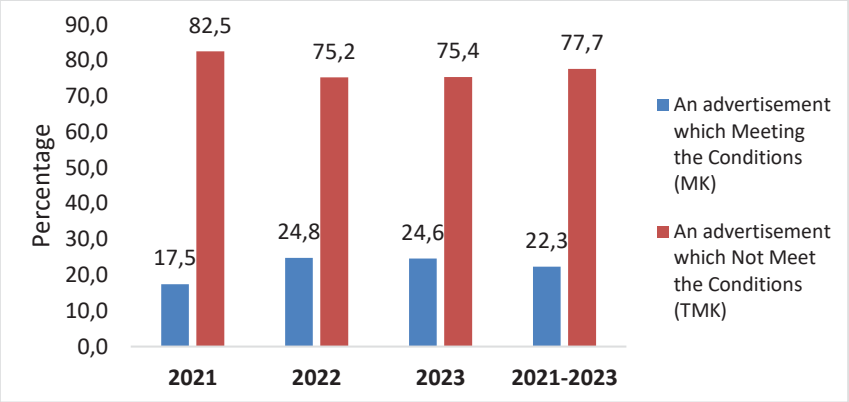

Figure 1. Results of Supervision of Advertisement of Processed Food Products in DKI Jakarta in 2021-2023

The percentage of advertisements that do not meet the provisions in DKI Jakarta Province is much higher than the national data, which is 29.5% in the 2020-2022 period (Directorate of Control of Processed Food Distribution, 2023). The percentage of results of supervision of drug and food advertisements that do not comply with the provisions from other provinces in Indonesia for the 2020-2022 period is also lower than the results of advertising supervision carried out in DKI Jakarta Province, such as East Java Province at 52.4%, Central Java Province at 30.8% and Central Kalimantan Province at 12.9% (www.pom.go.id). This is due to differences in socio-economic conditions that lead to different monitoring results. BPS data (2022) states that the percentage of the number of culinary businesses in DKI Jakarta is the highest at 50.7%, while in East Java, it is 5.7%, Central Java 4.4%, and Central Kalimantan 0.3%. This shows that economic activity in DKI Jakarta Province is much higher than in these provinces.

Technical Guidance (Bimtek) and Communication, Information, and Education (IEC) activities related to the procedures for displaying processed food advertisements by the provisions have not touched the food distribution business actors. Based on data from the Annual Report of Indonesian FDA Regional Office in Jakarta, during 2022, there have been no technical guidance or IEC activities related to advertising supervision regulations on processed food products. From the evaluation of advertising supervision on other product commodities, namely drugs, and cosmetics, a lower percentage of advertisements do not meet the provisions (TMK). This can be attributed to the Technical Guidance and IEC activities related to regulating advertising supervision on drugs and cosmetics. In addition, the Guidance and IEC on advertising and labeling of processed food products carried out so far have only been carried out for MSME players, while for companies that have received follow-up warning letters related to violations of food product advertisements have never been carried out. Therefore, it is necessary to organize Technical Guidance and IEC on advertisements and processed food products by the Indonesian FDA Regional Office in Jakarta so that advertising supervision activities are more effective and that there is a decrease in the percentage of processed food product advertisements that do not meet the requirements (TMK) in the following year.

3.2. Advertisement Violations by Media Type

The most reported media for advertising processed food products that violated the provisions during 2021-2023 were online media at 97%, outdoor media at 2.7%, and printed media (leaflets) at 0.3%. In television and radio broadcasting media, no violations were found. This data is in line with the BPOM Annual Report 2023, which states that the distribution of advertisements monitored nationally is in online media (including social media) by 59.24% (6248 advertisements), followed by outdoor media by 21.97% (2,321 advertisements) and print media by 18.78% (1,984 advertisements) (Figure 2).

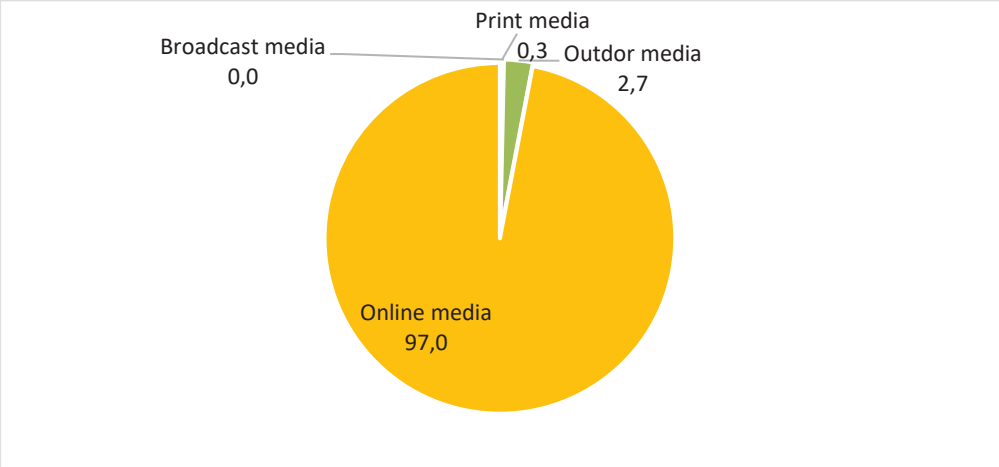

Figure 2. Types of media where violations are most common in Jakarta from 2021 to 2023

According to the Food and Drug Supervisory Agency Regulation Number 6 of 2021 concerning the Supervision of Processed Food Advertising, online media can be in the form of activities (such as site and page searches, *e-commerce*, games, social media, applications, *publishers*, *transportation on demand*, entertainment) and in the form of formats (such as video, audio, text, and banners). According to Statista (2023), the growth of e-commerce in Indonesia has accelerated since the Covid-19 pandemic along with the increase in internet users and due to social distancing policies and other health protocols enforced by the government during the pandemic, this has encouraged many companies to focus their business sales online.

Online media is the advertising media where the most violations are found. This is in line with Dianta's research (2015), which states that digital media has the ease and ability to reach consumers due to comprehensive *coverage* and costs that tend to be cheaper. According to a Statista survey conducted until mid-2022, the most popular e-commerce in Indonesia in order are Tokopedia, Shopee, Lazada, Bukalapak, and Blibli. Some e-commerce media where many violations of processed food product advertisements are found include Lazada, Bukalapak, and Shopee.

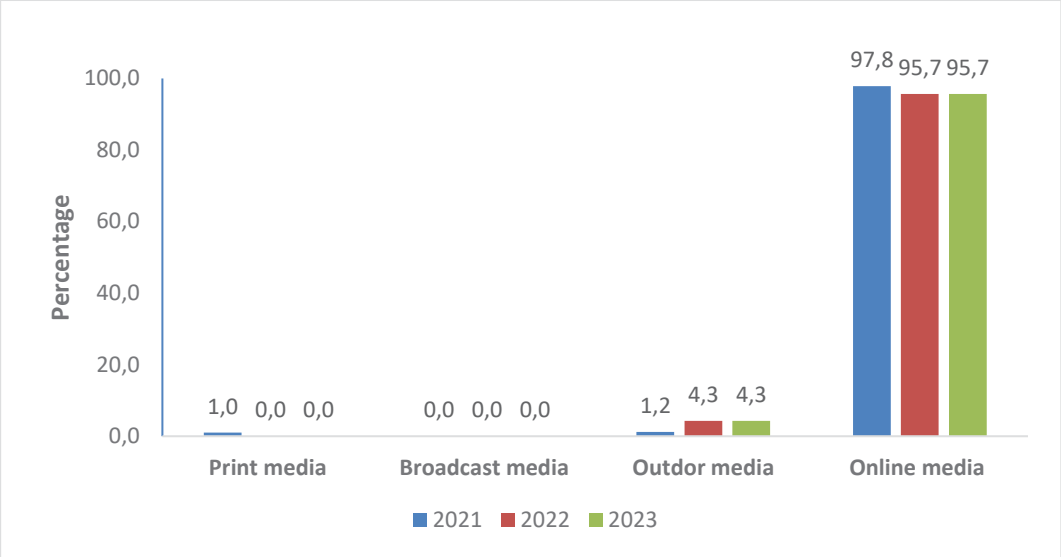

Figure 3. Trends in advertising violations by media type in Jakarta from 2021 to 2023

Online media is the advertising medium where the most violations are found (Figure 3). However, the trend has slightly decreased from 2021 and remained the same in 2022-2023. Conversely, there was a slight increase in outdoor media from 2021 and stagnated in 2022 and 2023.

3.3. Types of Advertising Violations

The types of violations of food product advertisements that do not comply with the provisions are dominated by ads that include health claims that do not comply with the requirements, namely 75.7% (1110 advertisements), followed by misleading ads that are not by product characteristics by 11.9% (175 advertisements) and processed food products (infant and advanced formulas, alcoholic beverages, and PKMK) that may not be advertised other than in health media 10.9% or 160 advertisements (Figure 4). This shows that business actors do not understand the POM regulations related to the ad of processed food products, which prohibit the display of visualization or information related to nutritional claims, health claims, or other claims that have not been approved at the time of obtaining a distribution permit (BPOM, 2021).

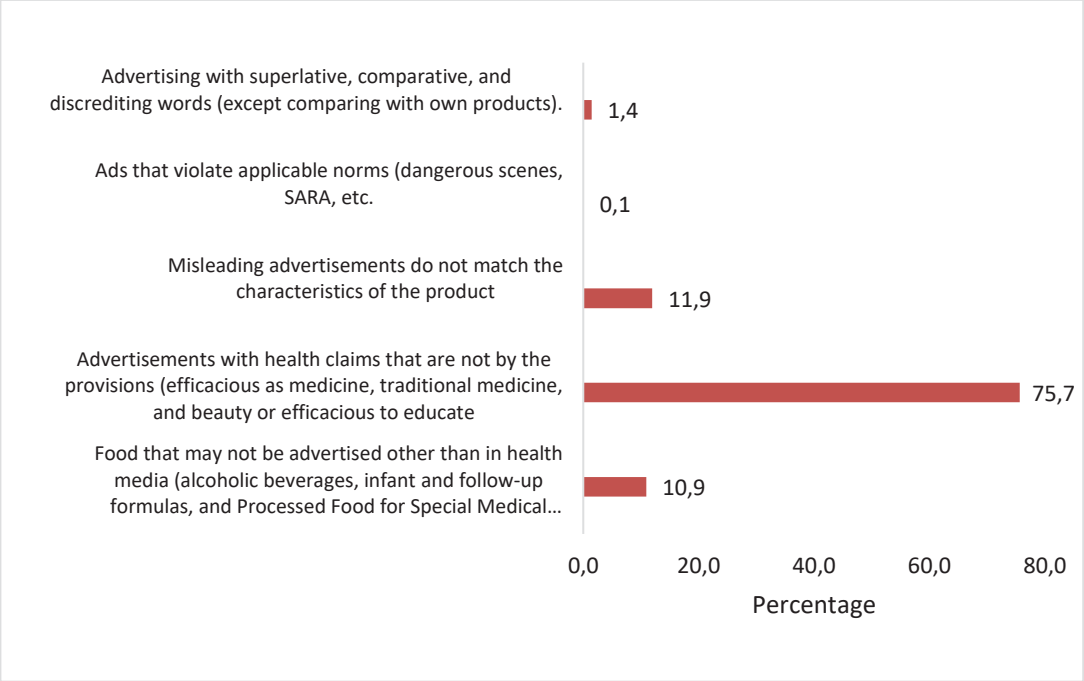

Figure 4. Percentage of advertising violation categories that do not meet the requirements (TMK)

The trend in the percentage of advertisements that Do Not Meet the Conditions (TMK) in 2021-2023 increased in the violation of advertisements with superlative sentences and on products that should not be advertised in health media (Figure 5). Conversely, there was a decrease in advertisements with health claims that did not comply with the provisions. This is due to social conditions where there has been a change in public health conditions from the COVID-19 pandemic status to post-COVID-19.

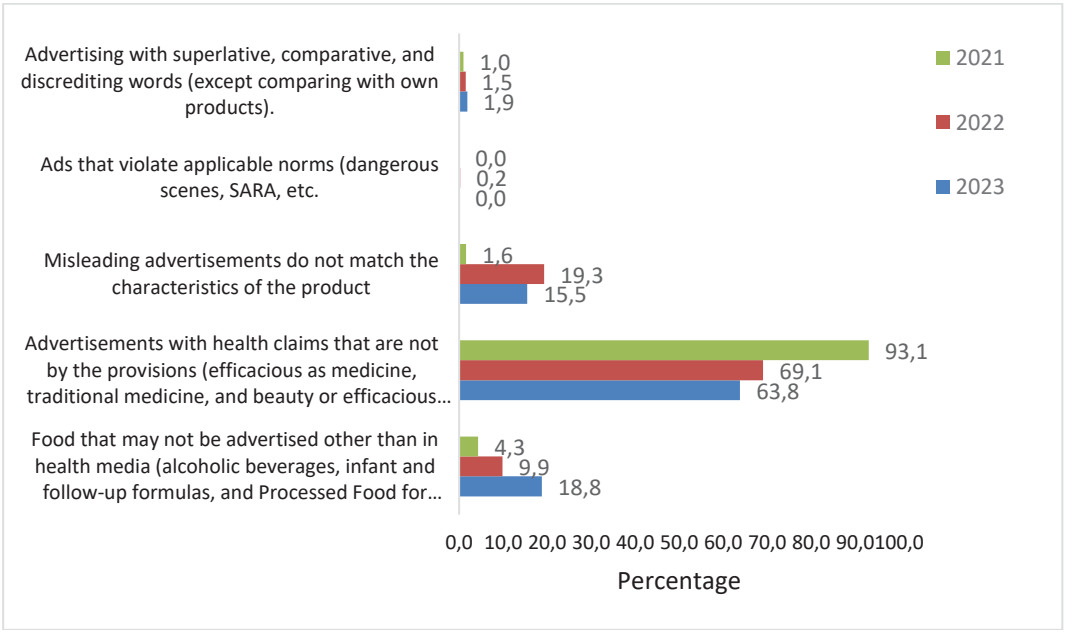

Figure 5. Advertising violation trends by violation category

Based on the Food and Drug Supervisory Agency Regulation No. 1 Year 2022 on the Supervision of Claims on Labels and Advertisements of Processed Food, it is stated that the prohibition of health claims includes nutrient/non-nutrient function claims, disease risk reduction claims, and glycemic claims. The approved label must make Article 4 state that claims in product advertisements at the time of application for a distribution permit. Article 26 explains that claims submitted at the time of application must meet the following requirements:

1. Must support national nutrition and/or health policies
2. Not linked to disease treatment and prevention
3. Does not encourage wrong consumption patterns and
4. Must provide correct and not misleading information.

3.4. Advertisement Violations by Processed Food Category

Based on food categories, the most common violations were found in beverages excluding dairy products (food category 14) with a percentage of 78.3% (1149 advertisements), followed by dairy products and their analogs (food category 1) at 4.5% (66 advertisements) and sugar and sweetener products including honey (food category 11) at 3.3% (49 advertisements). Of the 16 food categories and Food Additives (BTP), there is one type of food category where no violations of processed food advertisements were found: 10 eggs and processed egg products. (Figure 6).

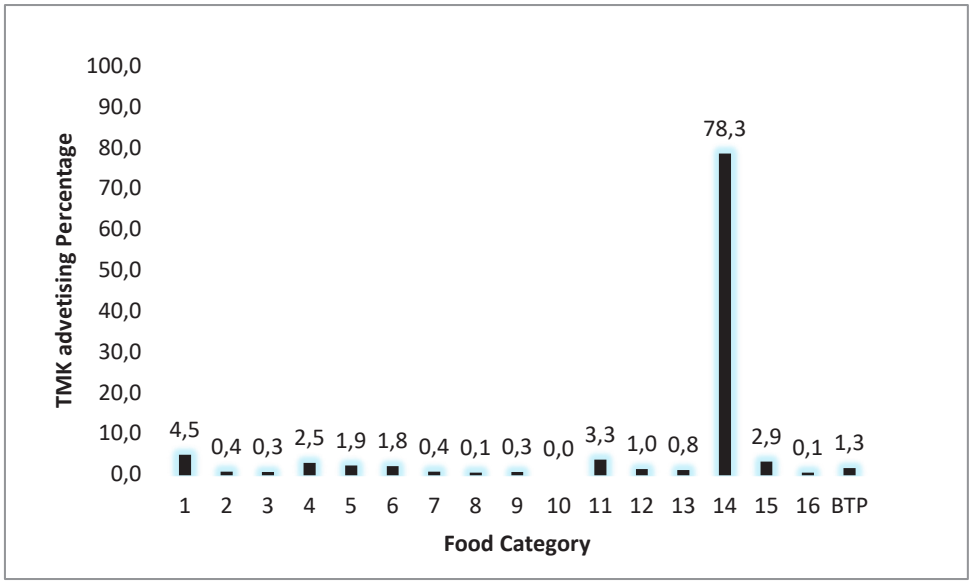

Figure 6: Percentage of Non-Compliant Advertisements by Food Category

Based on 16 food categories plus the category of Food Additives (BTP), it was found that advertisements of beverage-type products, excluding dairy products (category 14), were the type of food category with the most violations. From the 2022 *eCommerce* survey, it was noted that the food, beverage, and food ingredients group was the 6th largest of the 16 groups of e-commerce goods/services sold during 2021, which amounted to 41.50% (www.bps.go.id).

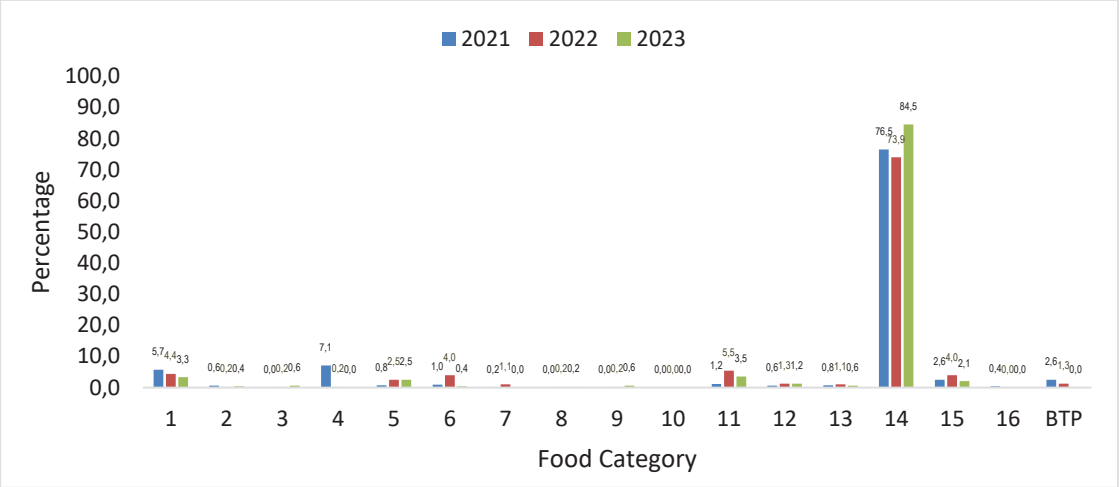

Figure 7. Trend of TMK ads by Food Category from 2021-2023

Beverage products (category 14) from 2021 - 2023 have always been the most TMK food category (Figure 7). In terms of percentage, there is not much change. From 2021 to 2022, there was a decrease from 76.53% to 73.95%, but in 2023 there was an increase to 84.50%. This data shows that the supervision of advertisements on types of processed food products, such as powdered drinks, flavored drinks, ground coffee, and the like, needs to be the focus of attention. According to Iswara (2022), consumers choose to buy products with nutrient content claims compared to those without due to health factors. This drives advertising promotions on various types of beverage products in the food category; many still use health claims not by the provisions, such as being useful in medicine, beauty, intelligence, and stamina.

Maganja et al. (2024) researched promoting food products carried out by the two largest retailer online stores in Australia on a sample of 12,152 obtained data 99% of the food promotions met the Health Star Rating (HSR) requirements. However, 44% of the promoted food products are categorized as unhealthy according to the HSR system, a food group with 3-4 out of 5 stars. Therefore, the study suggested updating public health policies related to promoting unhealthy foods by focusing primarily on food promotion through online media. Meanwhile, research conducted by Mediano et al. (2023) on sugar-sweetened beverage advertisements on television in Chile after gradual restrictions on beverage advertising obtained effective results with these restrictions. Conversely, there is an increase in advertising on sugar-free or low-sugar beverage products. This shows that with the obligation to comply with a regulation relating to food advertising aimed at the interests of public health, the results will be effective if enforced gradually.

Efforts are needed to reduce the presentation of processed food product advertisements that do not meet the provisions in the context of public protection. This can be done with a supervision strategy focused on online media, among others, by increasing the proportion of supervision in internet media and social media and through cooperation and discussion with cross-sectors, conducting technical guidance to business actors, mainly processed food distribution business actors and advertising service bureaus regarding advertising requirements to contain accurate, honest and not misleading information, and if necessary making regulations with stricter sanctions to provide a deterrent effect.

4. Conclusion

Based on this research, it is known that the percentage of violations of processed food product advertisements in DKI Jakarta Province in 2021-2023 averaged 77.7% of the total 1890 advertisements monitored. The most significant type of violation from advertising media is online media 97%, followed by outdoor media 2.7% and print media 0.3%. The three highest types of advertising violations based on violation categories were in the type of advertisements with health claims at 75.7%, misleading advertisements at 11.9%, and advertisements of food products that should not be advertised other than in health media at 10.9%. The three types of food categories where the most violations were found were beverages excluding dairy products 78.3% (food category 14), followed by dairy products and their analogs 4.5% (food category 1), and sugar or sweeteners including honey 3.3% (food category 11).

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increased occurred in all regencies in Southeast Sulawesi that were intervened, both Wakatobi and Central Buton. However, out of 12 schools, there were 3 schools that did not see an increase in knowledge or attitudes after being intervened with the Safe PJAS Program.

The Safe PJAS program at Indonesian FDA Regional Office in Kendari in 2023 was declared effective as assessed by the increase in Knowledge, Attitide amd Behavior of the school children who were intervened. This increase is due to the active role of food safety cadres in school in developing and implementing food safety program action plans through direct face-to-face socialization, food safety videos, installation of banners and posters in the school environment, and monitoring snack foods in school canteen. This effort can be improved through innovation by integrating programs and using educational and persuasive media. This Safe PJAS Program can be replicated by the City/Regency Government so that the impact felt by school children will be broader.

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Assessment of Compliance of Palm Cooking Oil Production Facilities in the Working Areas of Indonesian FDA Regional Office in Bandung and Surabaya in Conducting Vitamin A Fortification

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ABSTRACT

Vitamin A deficiency (VAD) remains a public health issue in many countries, including Indonesia. To address this, the government has mandated vitamin A fortification in food, with cooking oil being a key target. The policy is outlined in SNI 7709-2019 through Minister of Industry Regulation Number 46 of 2019, requiring producers to achieve a minimum vitamin A level of 45 IU/g in fortified cooking oil. Samples of palm cooking oil were collected from producers and packers for evaluation. This study examines the compliance of palm cooking oil production facilities within the Bandung and Surabaya catchment areas under the supervision of THE INDONESIAN FDA REGIONAL OFFICE. Using a descriptive qualitative method, data were collected from sampling and testing conducted between 2021 and 2023, following the Guidelines for Sampling and Testing of Drugs and Food. The results indicate that 31.58% of production facilities failed to meet fortification requirements due to a lack of commitment from producers and limited availability of vitamin A as a fortifier. Non-compliance was linked to facility type, with relaxation of regulations during rising cooking oil prices contributing to the issue. Notably, the fortification program was temporarily paused in January 2022 due to these challenges. To ensure public health benefits, it is essential to reinstate and enforce the vitamin A fortification program for palm cooking oil, emphasizing producer accountability and stable raw material supply.

Kekurangan vitamin A (KVA) merupakan masalah kesehatan masyarakat di berbagai negara, termasuk Indonesia. Salah satu strategi pemerintah yang untuk mengatasi KVA adalah dengan melakukan fortifikasi vitamin A pada bahan pangan. Minyak goreng sawit (MGS) merupakan bahan pangan yang difortifikasi dengan vitamin A. Kebijakan fortifikasi vitamin A telah diatur dalam SNI 7709-2019 melalui Peraturan Menteri Perindustrian Nomor 46 Tahun 2019, yang mewajibkan produsen menambahkan fortifikan vitamin A sehingga didapatkan kadar vitamin A minimal 45 IU/g terhadap MGS yang disampling. Penelitian ini bertujuan untuk melihat kepatuhan sarana produksi MGS di wilayah kerja Balai Besar Pengawas Obat dan Makanan (THE INDONESIAN FDA REGIONAL OFFICE) di Bandung dan THE INDONESIAN FDA REGIONAL OFFICE di Surabaya dalam melakukan fortifikasi Vitamin A. Penelitian ini menggunakan metode penelitian deskriptif dengan pendekatan kualitatif. Data penelitian adalah data hasil sampling dan pengujian minyak goreng sawit yang dilakukan oleh THE INDONESIAN FDA REGIONAL OFFICE di Bandung dan THE INDONESIAN FDA REGIONAL OFFICE di Surabaya sesuai dengan Pedoman Sampling dan Pengujian Obat dan Makanan dan data hasil pemeriksaan pada wilayah kerja THE INDONESIAN FDA REGIONAL OFFICE di Bandung dan THE INDONESIAN FDA REGIONAL OFFICE di

Surabaya pada 2021 sampai dengan 2023. Hasil penelitian menunjukkan masih terdapat sarana produksi yang belum melakukan fortifikasi vitamin A karena kurangnya komitmen terhadap kewajiban fortifikasi dan penyediaan Vitamin A. Secara keseluruhan, selama periode 1021-2023 terdapat 31,58% sarana produksi yang tidak memenuhi ketentuan. Terdapat hubungan antara jenis sarana dan ketidakpatuhan dalam menambahkan fortifikan vitamin A pada MGS. Relaksasi regulasi karena harga MGS yang meningkat menyebabkan program fortifikasi MGS dengan vitamin A terjadi sejak tahun Januari 2022 (misalnya). Oleh karena itu konsistensi program fortifikasi vitamin A pada MGS harus dilaksanakan kembali.

Keywords: Vitamin A fortification, Palm Cooking Oil, Manufacturer, Indonesian FDA Regional Office in Bandung, Indonesian FDA Regional Office in Surabaya, Compliance
Kata Kunci: *Fortifikasi Vitamin A, Minyak Goreng Sawit, Sarana Produksi, BBPOM di Bandung, BBPOM di Surabaya, Kepatuhan Sarana Produksi Minyak Goreng Sawit*

1. Introduction

Vitamin A deficiency (VAD) is a health condition caused by not meeting the body's vitamin A needs. Vitamin A is a micronutrient that plays a vital role in brain development and gastrointestinal function. Vitamin A deficiency is one of the macronutrient deficiencies that has a high risk of occurring in children and pregnant women in various parts of the world, especially in developing countries. The human body cannot produce vitamin A independently. Therefore, vitamin A must be obtained from vitamin A sources, namely animal and vegetable foods (Maryuningsih et al., 2021). In Indonesia, as many as 20-40 million children suffer from vitamin A deficiency at a milder level, which causes the child's immune system to decrease (Gurning et al., 2022).

VACD is common in children suffering from protein-energy deficiency or malnutrition but can also occur due to intestinal absorption disorders. The early stages of VAC are characterized by night blindness, poor night vision, or decreased serum retinol levels in the blood. Furthermore, epithelial tissue abnormalities exist in the lungs, intestines, skin, and eyes. Tackling the problem of VAC in children under five has been carried out intensively since the 1970s through distributing vitamin A capsules at posyandu every six months, namely in February and August, and increased promotion of food consumption of vitamin A sources. The coverage of vitamin A capsules received by children aged 6-59 months in the last 12 months in West Java Province, according to the 2018 Riskesdas data (DHO Jabar, 2022), is divided into three categories, namely 57% met the standard, 29.6% did not meet the standard, and 12.6% never received vitamin A, these percentages illustrate the coverage of Vitamin A in the population. Meanwhile, in East Java, the coverage of vitamin A capsules in infants aged 6-11 months from 2017-2021 has decreased from 80.8% to 64.3%, and in toddlers aged 1-4 years has decreased from 92.3% to 88.9%. This is due to the high number of pandemic cases, many health workers being exposed to COVID-19, less than optimal recording and reporting, and cadres not implementing posyandu due to activity restrictions (East Java DHO, 2021). The low coverage of toddlers receiving vitamin A supplementation indicates that management and empowerment in the vitamin A supplementation program at the district/city level has not been optimal (West Java DHO, 2022; East Java DHO, 2021). In addition to providing vitamin A capsules to toddlers, the government's effort to overcome vitamin A deficiency is the food fortification policy. Food fortification is adding certain levels of micronutrients to food to

improve the nutritional status of the community. (Food Review, 2022). Food fortification is a cost-effective strategy that provides economic, health, and social benefits and has been proven effective in improving community nutrition (Olson et al., 2021). To overcome the problem of VAC is the Vitamin A fortification program in palm cooking oil.

Along with the mandatory SNI 7709-2019 through Regulation of the Minister of Industry Number 46 of 2019, all palm cooking oil is expected to be packaged and fortified with Vitamin A. The Food and Drug Monitoring Agency (BPOM) conducts sampling and testing of palm cooking oil in circulation by the Food and Drug Sampling Guidelines for 2021 to 2023. These sampling guidelines refer to stunting distribution data from Bappenas (Bappenas, 2023). From the results of sampling and testing of palm cooking oil samples taken, There are still test results that do not meet the standard (< 45 IU); therefore, it is necessary to inspect 31.58% of production facilities (producers and packers) to see the level of compliance, especially the addition of Vitamin A fortification (BPOM, 2024).

Bandung and Surabaya are the provincial capitals. Based on the Central Bureau of Statistics publication, West Java Province consists of 18 regencies and nine cities, with an area of 37,044.858 km2 and a population of 51,698,700. In comparison, East Java Province consists of 38 regencies/cities with an area of 47,799.75 km2 and a population of 41,149,000. The number of food production facilities targeted for supervision by the Indonesian FDA Regional Office in Bandung is 658, and the Indonesian FDA Regional Office in Surabaya has 900 facilities. (BPOM RI, 2023).

Figure 1. Mapping of Palm Cooking Oil Producers with MD Licenses in Indonesia (Bappenas, 2023)

Based on Figure 1, the number of palm cooking oil production facilities in West Java is 37, while in East Java, it is 107. This number consists of palm cooking oil production facilities and packers. Production facilities in these two regions supply 70% of Indonesia's cooking oil needs (Bappenas, 2023). Of these facilities, eight facilities received approval to produce our oil in the West Java region and 15 facilities in the East Java region (setkab, 2022; Kumparan, 2022). The size of the region, the number of producers and packers, and the scope of supervision of the facilities are large enough to be the basis for selecting the study of producer compliance in conducting vitamin A fortification in cooking oil.

This study aims to determine the compliance of palm cooking oil production facilities in the Indonesian FDA Regional Office in Bandung and the Indonesian FDA Regional Office

in Surabaya in conducting Vitamin A fortification according to standards. This study is expected to provide comprehensive data on the supervision results so that it can be used to consider supervising palm cooking oil production facilities, which will be used to determine the actions taken to improve the quality and fulfilment of vitamin A-fortified palm cooking oil product standards.

2. Methodology

2.1. Data source

The source of data for this study was taken from the reporting of sample test results of vitamin A content in cooking oil from the BPOM integrated information and reporting system (SIPT) in the period 2021 to 2023 for the working areas of Indonesian FDA Regional Office in Bandung and Indonesian FDA Regional Office in Surabaya. The reporting data of vitamin A content sample test results used in this study are data on packaged palm cooking oil samples taken from producers and packers. Sampling was carried out by Indonesian FDA Regional Office in Bandung and Indonesian FDA Regional Office in Surabaya according to the Guidelines for Sampling and Testing of Food and Drugs from 2021 to 2023 (BPOM RI, 2021; BPOM RI, 2022; BPOM RI, 2023); the testing carried out refers to the Method of Analysis (MA) PPPOMN 42/PA/10 using High-Performance Liquid Chromatography (HPLC) with a fluorescent detector and an excitation wavelength of 325 nm and emission of 4.5 nm. The excitation wavelength is 325 nm, and the emission wavelength is 470 nm (PPPOMN, 2010).

2.2. Data analysis

This research uses descriptive research methods with a qualitative approach.

Data from vitamin A test results on palm cooking oil were analyzed using descriptive statistics to see the profile of vitamin A test results from each production facility in the working areas of the Indonesian FDA Regional Office in Bandung and the Indonesian FDA Regional Office in Surabaya. Furthermore, statistical analysis was conducted to determine whether production facilities were compliant in conducting vitamin A fortification in palm cooking oil by type of production facilities. Compliance is indicated by vitamin A test results that meet the requirements ($\geq 45\ IU/g$). Statistical analysis used binary logistic regression with a 95% confidence level. In addition, *crosstab* statistics with chi-square were also conducted to determine whether compliance was influenced by the type of production facility and the Indonesian FDA Regional Office working area with a 95% confidence level.

The proposed hypothesis is:

H_0: The type of palm cooking oil production facility does not affect compliance with vitamin A fortification

H_1: Type of palm cooking oil production facility affects compliance with vitamin A fortification

3. Results and Discussion

3.1. Number of Palm Cooking Oil Production Facilities

The number of palm cooking oil production facilities supervised from 2021 to 2023 in The Indonesian FDA Regional Office in Bandung and Indonesian FDA Regional Office in Surabaya areas based on SIPT data is shown in Figure 2.

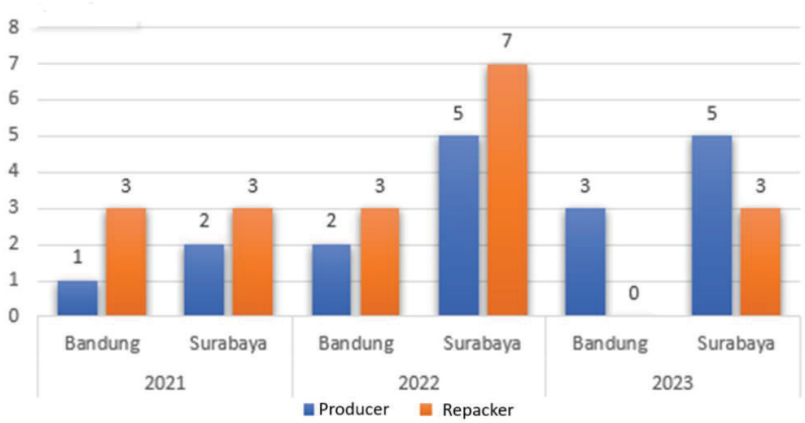

Figure 2. Production Facilities Sampling Targets for 2021-2023

The number of production facilities taken by the Indonesian FDA Regional Office in Surabaya was more than that of the Indonesian FDA Regional Office in Bandung. This is because the number of MGS production facilities in the Indonesian FDA Regional Office area in Surabaya is more significant than in the Indonesian FDA Regional Office area in Bandung (Bappenas, 2023). This is also because the daily consumption of palm cooking oil in the Surabaya area for low-income people is more than in the Indonesian FDA Regional Office working area in Bandung (Soekirman & Jus'at, 2017). The selection of production facilities is based on data on active production facilities not sampled in the previous year and refers to the risk assessment. Furthermore, testing was conducted on cooking oil sampled at producers and packers with test parameters by sampling guidelines (BPOM RI, 2021; 2022; 2023). The number of production facilities supervised by producers for the Indonesian FDA Regional Office region in Bandung increased from year to year, namely one facility in 2021, 2 facilities in 2022, and 3 facilities in 2023, while the Indonesian FDA Regional Office region in Surabaya increased in 2022 (from 2 facilities to 5 facilities), and in 2023 the same as 2022, namely five production facilities.

Meanwhile, the number of MGS packers in the Indonesian FDA Regional Office area in Bandung was carried out at the same facilities from 2021 to 2022. In 2023, for the Indonesian FDA Regional Office area in Bandung, sampling was focused on production facilities that had never been sampled before; no sampling was carried out on packers because they had been sampled in 2021 and 2022. For the Indonesian FDA Regional Office area in Surabaya, repeated sampling of packers was only carried out on four packers with a repetition of 2 years (2021 and 2022 or 2022 and 2023). It cannot be carried out consistently and continuously. Constraints related to the target number of facilities that have been set, budget, sampling capability (number of sampling personnel), and testing limitations are also some of the factors that influence (Figure 2).

Table 1. Number of vitamin A test samples from 2021 to 2023

Location	Test year		
	2021	*2022*	*2023*
Bandung	6	10	5
Surabaya	14	20	21
Total	20	30	26

The total number of samples increased in 2022 and decreased again in 2023 (Table 1). The Indonesian FDA Regional Office in Bandung samples decreased in 2023 because two sampling repetitions had been carried out on production facilities in the previous year. The Indonesian FDA Regional Office samples in Surabaya increased because there were still production facilities that had not been sampled in the previous year. The larger the sample size, the higher the sample's representativeness (Amin, Nur Fadilah, et al., 2023).

Duction that had not been sampled in the previous year.

3.2. Vitamin A Level Testing Results on Palm Cooking Oil Samples in Bandung and Surabaya FDA Regional Offices (2021–2023).

In this study, vitamin A content testing is a parameter explicitly taken from the test results of palm cooking oil samples. According to SNI 7709: 2019 Palm Cooking Oil, the minimum vitamin A content of the product in the production facility is the minimum. production facility isah ≥45 IU/g.

Table 2. Vitamin A Levels in Palm Cooking Oil Samples in Bandung and Surabaya from 2021 to 2023

Test Results	Test year			Total	
	2021	2022	2023	Total	Percentage (%)
<45 IU/g	6	12	6	24	31,58
≥ 45 IU/g	14	18	20	52	68,42
Total	20	30	26		

Table 2 shows the results of testing for Vitamin A fortification in palm cooking oil at BPOM in Bandung and BPOM in Surabaya in 2021-2023, with 76 samples. In 2021, of the 20 samples tested, 14 samples met the requirements (MS) for Vitamin A fortification in cooking oil, which is at least 45 IU/g, and six samples did not meet the requirements (TMS) with Vitamin A levels less than 45 IU/g. In 2022, out of 30 samples, 18 were MS and 12 were TMS; in 2023, 20 were MS and 6 were TMS. The results of this observation indicate that both the BPOM in Surabaya and BPOM in Bandung still have non-compliance in Vitamin A fortification of 31.58%.

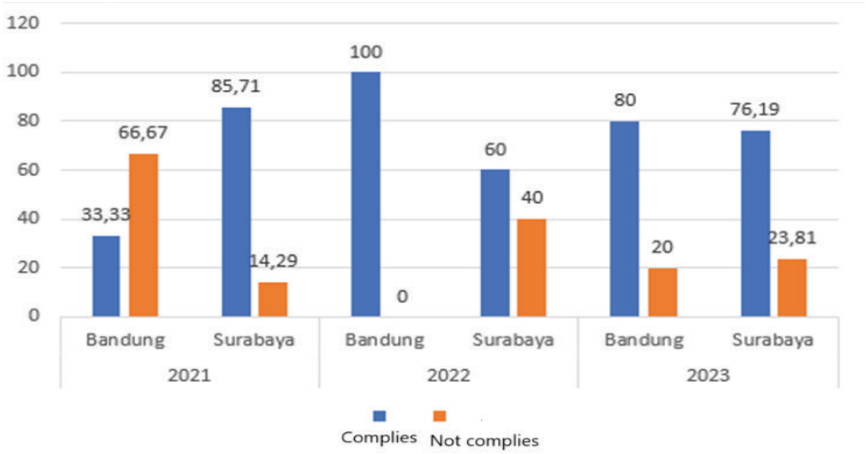

Figure 3. Percentage of Vitamin A Testing Results in Palm Cooking Oil Samples in Surabaya and Bandung from 2021 to 2023

Based on Figure 3, in 2021, unqualified palm cooking oil samples were 66.67% at the Indonesian FDA Regional Office in Bandung and 14.29% at the Indonesian FDA Regional Office in Surabaya. In 2022, all samples were eligible at the Indonesian FDA Regional Office in Bandung because the samples in 2022 were taken at the same facility as in 2021. In 2021, 40% of samples were not eligible in the Indonesian FDA Regional Office working area in Surabaya. This is because 2022 is the peak of the COVID-19 pandemic, and government restrictions on community activities impact restrictions on activities in palm cooking oil producers. MS results increased again in 2023 as the pandemic period subsided. Production activities returned to normal and increased producer commitment to vitamin A fortification regulations in palm cooking oil with the implementation of mandatory packaging cooking oil regulations by the Minister of Industry Circular Letter No. 9 of 2022 concerning relaxation of the policy of mandatory implementation of palm cooking oil SNI in the context of providing people's packaging cooking oil. The lack of routine testing to monitor the vitamin A content of palm cooking oil, the high cost, time constraints, and the unavailability of rapid test kits that can be used in the field the development of rapid test kits are contributors to the lack of monitoring of Vitamin A levels in palm cooking oil (Indonesian Fortification Committee, 2024). The testing capabilities of palm cooking oil production facilities vary, and some packers do not even test the Vitamin A content of palm cooking oil. The acceptability of vitamin A levels is only based on the certificate of analysis from the producer of palm cooking oil for the packaging industry, a large palm cooking oil producer highly committed to supporting the fortification program. Good packaging and distribution systems from palm cooking oil suppliers allow the products supplied to be fortified. (Soekirman et al., 2012)

3.3.Palm Cooking Oil Industry's Non-Compliance with Vitamin A Fortification

If traced further for the Indonesian FDA Regional Office and production facility, both in The Indonesian FDA Regional Office in Bandung and Indonesian FDA Regional Office in Surabaya and production facilities in each region, it can be seen that there are still producers and packers that have not met the provisions (Figure 3), including six producers and packers in 2021, 12 producers and packers in 2022 and 6 producers and packers in 2023. These results indicate that the level of compliance of producers and packers, both in the BPOM in Bandung and BPOM in Surabaya in conducting Vitamin A fortification in cooking oil, has not been fully met.

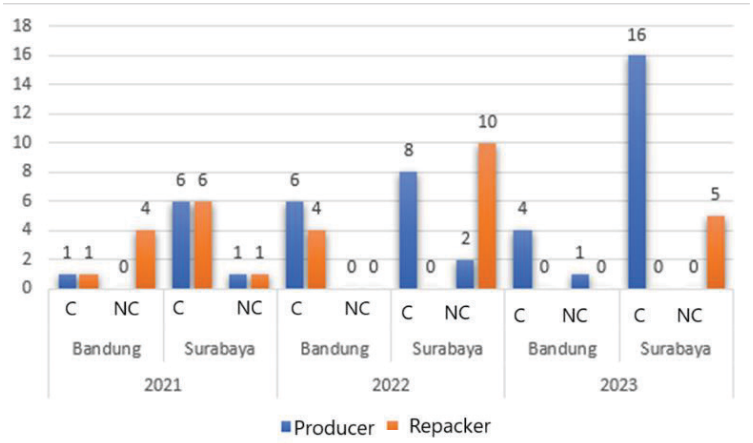

Figure 4. Testing Results of Vitamin A Content in Palm Cooking Oil at The Indonesian FDA Regional Office in Bandung and Surabaya in 2021-2023

Vitamin A test results do not meet the requirements in samples from packers. In contrast, samples from producers are mainly qualified to contain vitamin A with levels > 45 IU.g. Vitamin A in palm cooking oil with unqualified levels can be caused by not adding vitamin A fortification in the palm cooking oil production process, adding vitamin A fortification that is not appropriate so that it decomposes in the production process or mixing that is less homogeneous, damage or decomposition of vitamin A during the storage process (Initiative, 2006).

Since the government imposed mandatory packaging on palm cooking oil by the Regulation of the Minister of Trade of the Republic of Indonesia No. 36 of 2020, almost all household cooking oil is now packaged, facilitating the implementation of cooking oil fortification (Bappenas, 2023). This has caused producer compliance in conducting Vitamin A fortification to increase from 2021 to 2023. Before implementing the mandatory SNI for palm cooking oil by the Ministry of Industry, the Ministry of Health requested the policy of adding vitamin A through a letter to the Ministry of Industry in 2012 (Gumilar, 2018). In 2018, there was a rejection from several producers due to the implementation of the mandatory SNI for palm cooking oil, which included the obligation to fortify vitamin A. Concerns about increasing production costs because cooking oil producers need additional funds of up to IDR 50 per kilogram to include vitamin A content according to the standard (Raswa, 2010). In addition, the vitamin A added as a fortificant is Retinyl Palmitate, an imported product, which means there are still producers who have not complied with the vitamin A fortification rules. SNI 7709:2019 Palm Cooking Oil requires all cooking oils to be fortified and packaged (Gumilar, 2018).

Regulatory uncertainty also causes the palm cooking oil industry to tend to be non-compliant in adding Vitamin A fortification. In 2019, through Minister of Industry Regulation No. 46 of 2019, the mandatory implementation of SNI 7709:2019 Palm Cooking Oil and Cooking Oil must be packaged with a January 1, 2020 deadline. However, through Minister of Industry Circular Letter No. 9 of 2022 concerning the relaxation of the policy of mandatory implementation of palm cooking oil SNI in the context of providing people's packaged cooking oil, the mandatory implementation was postponed until January 31, 2023. (Elisabeth, n.d.). The food fortification program must have a clear, specific, well-defined policy so all interested parties can implement it properly. This will also ensure better coordination of efforts between the government and the private sector. Funding conditions and other state emergencies affect the food fortification program (Solon et al., 2000). Cooperation between the government, the food industry, and other stakeholders will contribute to the success of the mandatory food fortification program (Thakur et al., 2023).

The total number of manufacturers and packers sampled in 2021 to 2023 in the working areas of the Indonesian FDA Regional Office in Bandung and the Indonesian FDA Regional Office in Surabaya is 25 industries, with details of 12 manufacturers and 13 packers. Three packers are in the Indonesian FDA Regional Office in Bandung's area, and ten are in the Indonesian FDA Regional Office in Surabaya's area. Figure 4 shows that most of the Vitamin A test results on samples from packers did not meet the requirements. This is in line with the results of vitamin A testing conducted by KFI and Nutrition International (NI), which were presented at the Dissemination of the Results of the Study on Vitamin A Analysis of Palm Cooking Oil on April 18, 2024, the results of sampling palm cooking oil in Jakarta and Surabaya, as many as 85.3% of top brand palm cooking oil samples contained vitamin A > 45

IU, 6.9% of palm cooking oil contained vitamin A 20-45 IU and 7.7% of palm cooking oil contained vitamin A < 20 IU. Palm cooking oil samples containing vitamin A <20 IU were found more in Jakarta than in Surabaya (Indonesian Fortification Committee, 2024). Likewise, research in Bandar Lampung found that only 50% of palm cooking oil in production facilities met vitamin A requirements (Sari & Setiawati, 2019).) This non-compliance is likely a national problem that needs to be addressed immediately.

A binary logistic regression statistical test was conducted to determine production facilities' compliance with vitamin A fortification in palm cooking oil. The results of the binary logistic regression test with a degree of confidence level of 95% with the accuracy of the research model of 80.3% showed that the type of facility provides a significant partial effect on compliance of production facilities adding vitamin A fortification to palm cooking oil (Wald Sig value 0.00 <0.05). In contrast, the work area does not significantly affect the compliance of production facilities adding vitamin A fortification to palm cooking oil (Wald Sig value 0.185>0.05). Furthermore, statistical analysis with the chi-square test at the 95% confidence level showed a relationship between the type of production facilities and compliance of production facilities adding vitamin A fortification to palm cooking oil (Sig.0.00 <0.05). However, there was no relationship between the work area and the level of compliance of production facilities adding vitamin A fortification to palm cooking oil (Sig.0.381>0.05). The relationship between the type of production facilities and the non-compliance of production facilities in conducting Vitamin A fortification in palm cooking oil is shown in Figure 4.

This study uses test data from the initial period of implementation of SNI 7709:2019 Palm Cooking Oil, the relaxation period, and the beginning of the re-enactment period of SNI 7709:2019 Palm Cooking Oil so that it can lead to weaknesses in concluding the compliance of palm cooking oil producers in conducting Vitamin A fortification. Therefore, it is necessary to conduct further studies on implementing vitamin A fortification in palm cooking oil after the mandatory SNI 7709:2019 Palm Cooking Oil.

The obligation to periodically test vitamin A content should be enforced to enhance compliance among production facilities in implementing vitamin A fortification in palm cooking oil. Additionally, the government must oversee and regulate the supply of vitamin A fortifiers, which are currently reliant on imports, to ensure sufficient availability and stable prices for synthetic vitamin A required for fortification in Indonesia.

4. Conclusion

Compliance of production facilities, both producers and packers, with the mandatory vitamin A fortification regulations in cooking oil, is essential to ensure a Vitamin A content of 45 IU/g in palm cooking oil. Non-compliance with production facilities is due to the uncertainty of regulations, facilities, and financial capabilities when conducting fortification. Therefore, in addition to compliance with production facilities, government participation in supporting the policy of minimum vitamin A content in palm cooking oil is needed.

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