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

Setyo Utami[a,1*], Dinny Andriany [b,2]

[a]Indonesian Food and Drug Authority Regional Office in Surabaya, Indonesian Food and Drug Authority, Jl. Karang Menjangan No.20, Airlangga, Kec. Gubeng, Surabaya, Jawa Timur 60286, Indonesia
[b]Indonesian Food and Drug Authority Regional Office in Bandung, Indonesian Food and Drug Authority , Jln. Pasteur No. 25 - Bandung, Jawa Barat - 40171, Indonesia
[1] setyo.utami@pom.go.id*; dinny.andriany@pom.go.id
*corresponding author

ARTICLE INFO

Article history
Received:
June 27, 2024

Revised:
October 28, 2024

Accepted:
November 4, 2024

DOI:
https://doi.org/10.54384/eruditio.v5i1.214

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%.

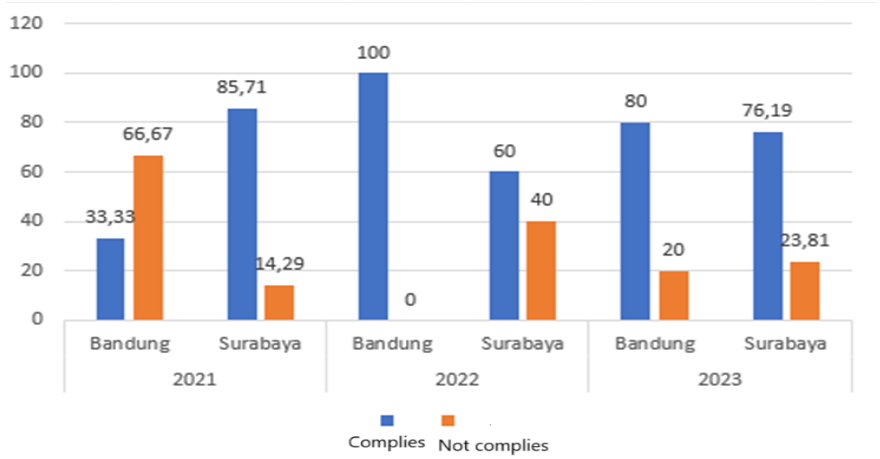

Figure 3. Percentage of Vitamin A Testing Results in Palm Cooking Oil Samples in Surabaya and Bandung from 2021 to 2023

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.

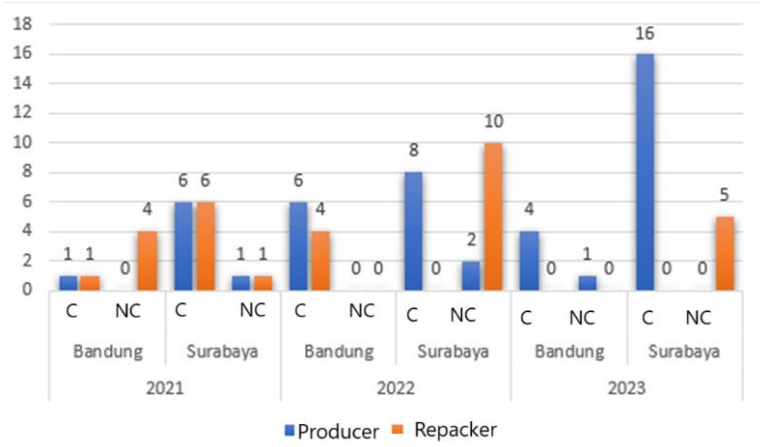

Figure 4. Testing Results of Vitamin A Content in Palm Cooking Oil at The Indonesian FDA Regional Office in Bandung and Surabaya in 2021-2023

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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