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Preliminary Screening and Method Comparison of Total Residual Contaminants Migrating to Fatty and Oily Foods from Low-Density Polyethylene (LDPE) Food Contact Articles Sold in the Philippines

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Abstract

Low-density polyethylene (LDPE) is commonly used as food packaging material because of its affordability, convenience and versatility. However, there are concerns regarding the chemical migration of contaminants into food especially at high temperatures, and thus requires further investigation. The study documented the total residual contaminants (TRCs) that migrate into fatty and oily foods from LDPE food contact articles (FCAs) that are sold in the Philippines to fill a major gap in the country's regulatory system. The study compared two international standard methods - 21 Code of Federal Regulations (CFR) Part 177 and Japan External Trade Organization (JETRO, 2009) - to assess their suitability for local applications. The researchers collected and analysed 23 LDPE samples across Mega Manila to estimate residue concentrations. Results indicate that TRC levels of FCAs exhibited statistically significant differences among the collection sites which may be influenced by factors such as environmental exposure, transportation and handling. Samples with the lowest and highest TRC concentrations from the 23 LDPE samples were selected for the comparative studies of the two international methods. Each low- and high-level sample underwent analysis using the testing conditions of both methods. A comparative analysis using paired t-test revealed distinct variations between the methods, with US 21 CFR giving higher concentrations at low-level samples (9.34 mg/L TRCs), and JETRO 2009 at high-level samples (19.6 mg/L TRCs). Statistical validation confirmed these differences, highlighting the need for rigorous method validation and harmonization of international and local testing standards. These findings also highlight the significance of the development of regulatory frameworks and robust testing methods that are specific to the Philippines' environmental and industrial conditions in order to ensure food safety and enhance the country's global competitiveness.

Keywords: Chemical migration; Food contact articles; Food safety; Low-density polyethylene; Method validation; Total residual contaminants

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1 Introduction

Polyethylene (PE) is one of the most produced and utilized synthetic polymers worldwide and is generally classified into four major types: low-density polyethylene (LDPE), high-density polyethylene (HDPE), linear low-density polyethylene (LLDPE) and cross-linked polyethylene (XLPE) (An et al., 2022; Xiuhua et al., 2017). Its processability, tensility, burst and tear strengths, impact resistance, sealing capability, barrier, and printable properties have made it a material of choice in food packaging applications (Manikantan et al., 2022; Shiva et al., 2024). In the Philippines, LDPE is predominantly used in single-use packaging (SUP) such as retail plastic bags, frozen food pouches, and wraps for oily or fatty foods due to its affordability, flexibility and transparency (Alejandro et al., 2025). However, its extensive use has raised concerns over the potential migration of chemical contaminants into food, particularly under elevated temperature and prolonged storage conditions (Balaji & Immanuel, 2022; Yiu et al., 2005). Migration can occur through diffusion, volatilization and permeation processes which are heavily influenced by temperature, contact duration, food composition, and physico-chemical properties of the packaging material (Balaji & Immanuel, 2022; Musoke et al., 2015; Seref & Cufaoglu, 2025; Yiu et al., 2005). All these processes may ultimately lead to human exposure to chemical migrants.

Various compounds such as monomers, plasticizers, stabilizers, colorants, lubricants, or degradation by-products can undergo chemical migration from packaging into food products (Khokhar & Pawar, 2025; Muncke et al., 2020; Musoke et al., 2015; Nagalapur & Byadagi, 2025; Schmid & Welle, 2020; Seref & Cufaoglu, 2025). The process is made more complex by the transfer of non-intentionally added substances (NIAS), including impurities, reaction intermediates and degradation products formed during polymer manufacturing or recycling (Gerassimidou et al., 2023). Many of these substances, whether intentionally or unintentionally introduced, have been identified as endocrine-disrupting chemicals (EDCs), such as 2,2-bis(4-hydroxyphenyl) propane (bisphenol A), phthalates and phthalic acid esters, alkylphenols, and bis(2-ethylhexyl) adipate (Geueke, 2018). These EDCs can interfere with the body's hormonal system and are linked to adverse reproductive, neurological, developmental and immune effects (Hass et al., 2019; Ong et al., 2022; Tanner et al., 2020). Under suitable conditions, such as high temperature or long contact time, these compounds can migrate into food, threatening food safety (Alejandro et al., 2025; Balaji & Immanuel, 2022; Yiu et al., 2005). Thus, global chemical risk assessment frameworks and regulatory measures have been developed to limit human exposure to these hazardous migrants.

Advances in analytical instrumentation, particularly gas chromatography-mass spectrometry (GC-MS) and high-resolution mass spectrometry (HRMS), have enabled the identification of hundreds of migrating substances in plastic packaging (Blázquez-Blázquez et al., 2020). Among them are possible antioxidants such as Irganox 1330 and Irganox 1010, oligomers, per- and polyfluoroalkyl substances (PFAS), and trace heavy metals, many of which are not listed among authorized food contact substances (Abu-Almaaly, 2019; Balali-Mood et al., 2021; Dewapriya et al., 2023; Li et al., 2025; Shourove et al., 2025). A recent systematic review by Gerassimidou et al. (2023) identified 211 food contact chemicals (FCCs) migrating from PE packaging, including substances of significant toxicological concern. The study highlighted that real-world exposure conditions, especially for high-fat foods, frequently exceed model predictions (Gerassimidou et al., 2023).

The issue is particularly pronounced in developing regions where improper use of plastic packaging is common. For instance, Musoke et al. (2015) reported that polyethylene bags used for cooking food in Uganda showed significant migration of heavy metals - lead (Pb), chromium (Cr) and cadmium (Cd) - with lead concentrations exceeding 120 ppm after five hours of heating at 95 ^{o}C. Though extreme, such practices resemble the widespread local habits of reheating or wrapping hot foods in polyethylene materials. Even minimal but repeated exposure to these contaminants may lead to bioaccumulation and long-term health effects (Abu-Almaaly, 2019; Balali-Mood et al., 2021; Khokhar & Pawar,

Nomenclature

CFR Code of Federal Regulations
DOST Department of Science and Technology
EDC Endocrine-disrupting Chemicals
EU European Union
FCA Food Contact Articles
FCC Food Contact Chemicals
FCM Food Contact Materials
FDA Food and Drug Administration
FTIR Fourier Transform Infrared Spectrometer
GC-MS Gas Chromatography Mass Spectrometry
GPS Global Positioning System
HDPE High-Density Polyethylene
HRMS High-resolution Mass Spectrometry
JASP Jeffrey's Amazing Statistics Program
ITDI Industrial Technology Development Institute
JETRO Japan External Trade Organization
LDPE Low-Density Polyethylene
LLDPE Linear Low-Density Polyethylene
NCM Normal Cubic Meter
NIAS Non-intentionally Added Substances
OML Overall Migration Limits
PAH Polycyclic Aromatic Hydrocarbons
PCB Polychlorinated Biphenyls
PCIEERD Philippine Council for Industry, Energy and Emerging Technology Research & Development
PE Polyethylene
PFAS Perfluoroalkyl Substances
PTD Packaging Technology Division
SML Specific Migration Limits
SUP Single-use Packaging
TAC Total UV-absorbing Contaminants
TRC Total Residual Contaminants
XLPE Cross-linked Polyethylene

2025; Musoke et al., 2015; Seref & Cufaoglu, 2025), emphasizing the importance of regular monitoring and risk evaluation.

Globally, regulatory frameworks have been established to control and limit chemical migration from food contact materials (FCMs). The European Union's Regulation (EC) No. 1935/2004 mandates that FCMs must not release substances that could endanger human health, alter food composition, or impair sensory qualities (Karamfilova, 2016). This is supported by Commission Regulation (EU) No. 10/2011, which provides a positive list of authorized monomers and additives and defines specific migration limits (SMLs) (European Commission, 2011). Similarly, the United States Food and Drug Administration (US FDA) regulates polymeric materials under Title 21 of the Code of Federal Regulations (CFR), while Japan, China and South Korea have comparable standards that emphasize both overall migration limits (OMLs) and SMLs (JETRO, 2009; Ministry of Food and Drug Safety of Korea, 2021a, 2021b; National Health Commission of the People's Republic of China, & State Administration for Market Regulation, 2023; U.S. Food and Drug Administration (FDA), 2023). Despite these developments across the globe, many low- and middle-income countries face implementation challenges due to limited testing capacity, cost constraints, and insufficient local data on chemical migration and exposure.

In the Philippine context, regulation of FCMs remains in its infancy. Although the ASEAN Guideline (ASEAN Consultative Committee on Standards and Quality, 2018) provide a regional

framework for harmonization, the country has yet to establish mandatory migration testing requirements or local SML/OML values. The Food and Drug Administration (FDA) Circular No. 2022-011 introduced a voluntary certification program for packaging materials used in prepackaged foods (Food and Drug Administration, 2022), referencing both US FDA (21 CFR Part 177) and Japan External Trade Organization (JETRO, 2009) methods. However, enforcement remains limited, and most locally available packaging, particularly LDPE films used in wet markets, eateries and street food vending, do not have indications of having undergone mandatory and regular migration testing. Given the direct contact of such materials with hot, oily, or acidic foods, this regulatory gap represents a potential public health concern.

To address these challenges, the Packaging Safety Laboratory (PSL) of the Department of Science and Technology - Industrial Technology Development Institute (DOST-ITDI) has initiated efforts to strengthen national capability in the testing and evaluation of FCMs and FCAs. This study bridges international regulatory frameworks with Philippine laboratory validation, addressing the lack of local migration testing protocols for LDPE packaging. It provides the first comparative evaluation of the U.S. FDA 21 CFR and JETRO (2009) methods for determining total residual contaminants migrating from LDPE food-contact materials into oily/fatty foods under Philippine conditions. Through the evaluation of extraction efficiency, temperature-time effects and method robustness, the study aims to establish a validated local testing protocol and generate baseline data for Philippine PE packaging. Ultimately, the findings will provide scientific evidence for the formulation of locally relevant regulatory standards and contribute to safer packaging practices which are aligned with international food safety objectives.

2 Material and methods

2.1 Sample Collection

Monolayered polyethylene samples were collected from various public markets and retail locations across Mega Manila. These films were selected because they are widely used for packaging street foods and traditional Filipino dishes, particularly oily and fatty foods, which are commonly sold in small eateries known as *carinderias* (Alejandro et al., 2025). The Global Positioning System (GPS) coordinates were taken for traceability of the exact location of the collection site.

2.2 Survey of Samples

From the collected samples, one representative per brand of monolayered PE packaging was selected for polymer composition analysis, using Shimadzu IR-Prestige-21 Fourier Transform Infrared Spectrometer (FTIR), and evaluated for residue on evaporation using the JETRO 2009 method (JETRO, 2009). Each sample was cut into approximately 5 cm $\times$ 10 cm films and extracted with 100 mL of n-Heptane, mimicking exposure to high-fat foods. The mixture was kept at ambient temperature (23^o-27^oC) for 1 hour. For accuracy and repeatability, duplicates were prepared for each sample. After extraction, 50 mL of the simulant was carefully transferred into pre-weighed beakers. The solvent was evaporated to dryness, allowing any residues to remain in the beaker. These residues were further dried for 2 hours in an oven (Labtech LDO-150N) at 105 ^{o}C $\pm$ 1 ^{o}C to ensure complete removal of any solvent traces. The beakers were weighed using an analytical balance (Shimadzu AUX220) until a constant weight was obtained, indicating that all moisture had been eliminated and providing a precise measurement of the remaining residue. The samples exhibiting the lowest and highest concentrations of residues were subsequently selected to serve as benchmark samples for the comparative analysis of the methods outlined in the US 21 CFR JETRO 2009 standard.

2.3 Comparative Analysis at Low- and High-Level Samples

Fifty (50) replicates of the PE samples with the lowest and highest residue levels were prepared and analysed using both US 21 CFR methods. The extraction procedures applied in these comparative studies were directly adapted from the

standardized protocols outlined in the U.S. Food and Drug Administration's 21 CFR Part 177 and the Japan External Trade Organization's *Specifications and Standards for Food, Food Additives*, etc. Both analytical methods are formally cited as reference procedures in FDA Philippines Circular No. 2022-011, which designates them as internationally recognized benchmarks for evaluating overall migration or total residual contaminants in food-contact packaging materials. Each sample was cut into 5 cm × 10 cm pieces and subjected to extraction using 100 mL of heptane as a simulant. Extractions were conducted on two sets of samples, one at approximately 21 ^{o}C for 30 minutes and the other at approximately 25 ^{o}C for 60 minutes, as per US 21 CFR and JETRO (2009), respectively. A 50 mL aliquot of the simulant was transferred to pre-weighed beakers and evaporated to dryness, allowing residues to remain in the beakers. These residues were subsequently dried to constant weight in an oven at 105 ^{o}C ± 1 ^{o}C.

The average concentration of residues for the low-level and high-level samples were calculated using the following equation:

$$\frac{(W_R - W_E) - W_{Blk}}{V_s} \times 1{,}000{,}000$$

where:

W_R = weight of beaker with residues

W_E = weight of empty beaker

W_{Blk} = average weight of residues from blank samples

V_s = volume of simulant evaporated

2.4 Statistical Analysis

To ensure accurate evaluation and interpretation of the results, statistical analyses were performed using Jeffrey's Amazing Statistics Program (JASP 2025). The Grubbs test was employed to identify and exclude outliers, resulting in forty-one (41) replicates retained for the low-level sample and forty-five (45) replicates for the high-level sample. Subsequent analyses included the Shapiro-Wilk test to verify the normality of data, computation of descriptive statistics (mean, standard deviation and standard error), and a paired samples t-test to assess the significance of differences between the two extraction methods.

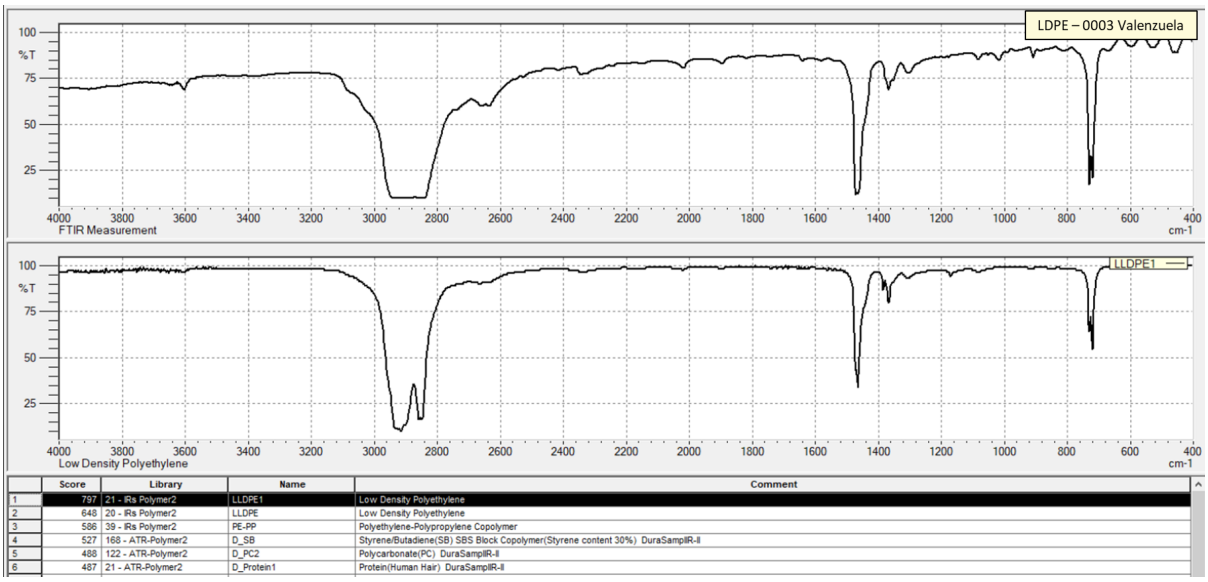
3 Results and Discussion

3.1 Sample Collection and Survey

Twenty-three (23) monolayered PE samples were randomly selected from different packaging retailers across Mega Manila, and subsequently coded for confidentiality and to avoid potential biases during experimentation. Among these, fifteen (15) distinct commercial brands were identified. FTIR spectroscopic analysis confirmed that all samples are LDPE, as indicated by the characteristic absorption bands associated with C-H stretching and bending vibrations, which are shown in Figure 1. Details of the coded samples, their respective collection sites, and the corresponding average residue concentrations (n = 2) are summarized in Table 1.

The mean residue levels obtained from each collection site is shown in Figure 2. The position of data points in the scatter plot highlights a heterogeneous distribution of residues in commercially available LDPE packaging. The broad range of average residue concentrations (2.00 - 18.00 mg/L) indicates substantial variability associated with brand and location. Notably, LDPE-0010 (*Marikina*) exhibited the lowest residue level at 2.00 mg/L, while LDPE-0008 (*Parañaque*) showed the highest at 18.00 mg/L, approximately nine times greater. Moreover, multiple units of LDPE-0010 purchased from five different sites displayed residue concentrations ranging from 2.00 to 10.00 mg/L, further emphasizing within-brand variability. These differences may be attributed to variations in sampling locations and environmental conditions (Section 3.1.1) as well as disparities in material sourcing and production practices (Section 3.1.2).

The observed TRC levels (2 - 18 mg/L) align closely with findings from an international study. Gerassimidou et al. (2023) reported residues of 1.5 - 20 mg/L for LDPE films under comparable fatty-food simulant conditions. This agreement suggests that the variability among locally available LDPE packaging is primarily driven by environmental and processing factors rather



	Score	Library	Name	Comment
1	797	21 - IRs Polymer2	LLDPE1	Low Density Polyethylene
2	648	20 - IRs Polymer2	LLDPE	Low Density Polyethylene
3	586	39 - IRs Polymer2	PE-PP	Polyethylene-Polypropylene Copolymer
4	527	168 - ATR-Polymer2	D_SB	Styrene/Butadiene(SB) SBS Block Copolymer(Styrene content 30%) DuraSamplIR-II
5	488	122 - ATR-Polymer2	D_PC2	Polycarbonate(PC) DuraSamplIR-II
6	487	21 - ATR-Polymer2	D_Protein1	Protein(Human Hair) DuraSamplIR-II

Figure 1: Sample FTIR Spectra of LDPE-0003 (*Valenzuela*)

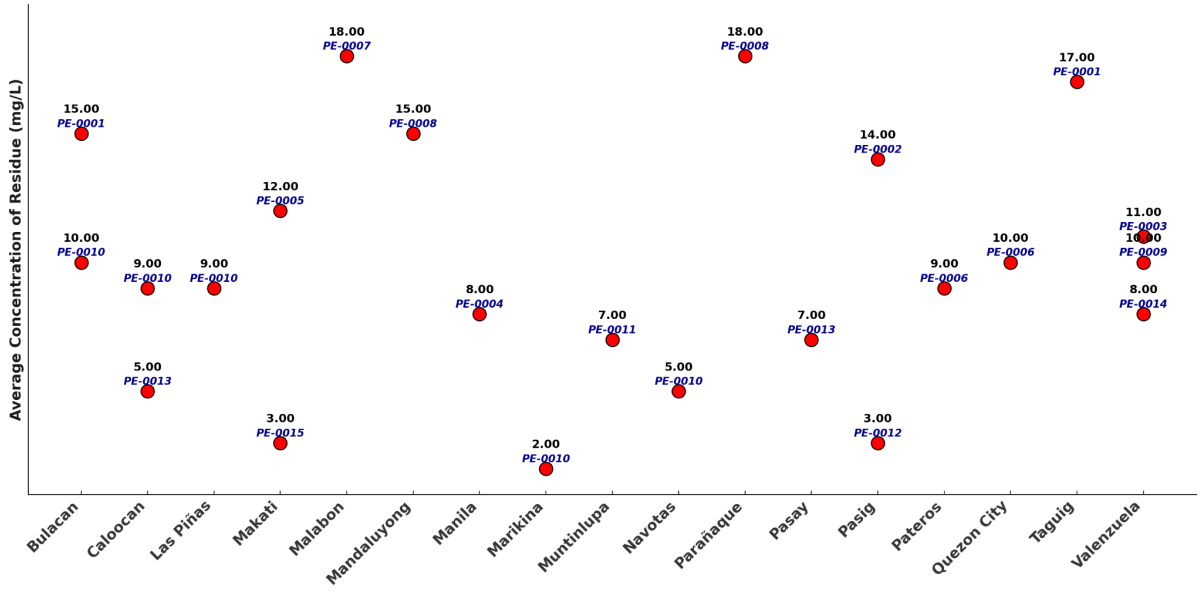


Figure 2: Distribution of Residue Levels in PE Packaging Collected from Different Cities

Table 1: Collection Sites, Material Properties and Average Residue Concentration of LDPE Samples with their respective codes according to brands.

Sample Code	Collection Site / Coordinates	Material Composition (Grade)	Intended Food Type/ Application	Storage Condition	Average Concentration of Residue, mg/L
LDPE-0001	Bulacan (15° 4' 29.39.42"N /120° 56' 22.57"E)	LDPE	Oily /Fatty Foods	Ambient*	15.00
LDPE-0001	Taguig City (14° 29' 43.16.5"N / 121° 3' 36.84"E)	LDPE	Oily /Fatty Foods	Ambient*	17.00
LDPE-0002	Pasig City (14° 33' 33.23"N / 121° 5'3.61"E)	LDPE	Oily /Fatty Foods	Ambient*	14.00
LDPE-0003	Valenzuela City (14° 42' 29.38"N / 120° 59' 59.98"E)	LDPE	Oily /Fatty Foods	Ambient*	11.00
LDPE-0004	Manila City (14° 36' 11.1"N / 120° 58' 12.7"E)	LDPE	Oily /Fatty Foods	Ambient*	8.00
LDPE-0005	Makati City (14° 33' 57.6" N / 121° 2' 45.6"E)	LDPE	Oily /Fatty Foods	Ambient*	12.00
LDPE-0006	Quezon City (14° 37' 9.07"N / 121° 3' 9.12"E)	LDPE	Oily /Fatty Foods	Ambient*	10.00
LDPE-0006	Pateros (14° 32' 43.09"N / 121° 3' 57.66"E)	LDPE	Oily /Fatty Foods	Ambient*	9.00
LDPE-0007	Malabon City (14° 40' 4.66" N / 120° 57' 58.6"E)	LDPE	Oily /Fatty Foods	Ambient*	10.00
LDPE-0008	Parañaque City (14° 29' 51.8"N / 120° 59' 38.1"E)	LDPE	Oily /Fatty Foods	Ambient*	18.00
LDPE-0008	Mandaluyong City (14° 35' 14.48" N / 121° 2' 16.54"E)	LDPE	Oily /Fatty Foods	Ambient*	15.00
LDPE-0009	Valenzuela City (14° 42' 29.38"N / 120° 59' 59.98"E)	LDPE	Oily /Fatty Foods	Ambient*	10.00
LDPE-0010	Caloocan City (14° 39' 29.01"N / 120° 58' 20.63"E)	LDPE	Oily /Fatty Foods	Ambient*	9.00
LDPE-0010	Bulacan (15° 4' 29.39.42"N /120° 56' 22.57"E)	LDPE	Oily /Fatty Foods	Ambient*	10.00
LDPE-0010	Marikina City (14° 38' 5.1"N / 121° 5' 48.97"E)	LDPE	Oily /Fatty Foods	Ambient*	2.00
LDPE-0010	Las Piñas City (14° 28' 01.4"N / 120° 58' 13.2"E)	LDPE	Oily /Fatty Foods	Ambient*	9.00
LDPE-0010	Navotas City (14° 38' 38.45"N / 120° 57' 16.19"E)	LDPE	Oily /Fatty Foods	Ambient*	5.00
LDPE-0011	Muntinlupa City (14° 25' 12.4"N / 121° 02' 38.4"E)	LDPE	Oily /Fatty Foods	Ambient*	7.00
LDPE-0012	Pasig City (14° 33' 33.23"N / 121° 5'3.61"E)	LDPE	Oily /Fatty Foods	Ambient*	3.00
LDPE-0013	Caloocan City (14° 39' 29.01"N / 120° 58' 20.63"E)	LDPE	Oily /Fatty Foods	Ambient*	5.00
LDPE-0013	Pasay City (14° 31' 52.0"N / 120° 59' 35.5"E)	LDPE	Oily /Fatty Foods	Ambient*	7.00
LDPE-0014	Valenzuela City (14° 42' 29.38"N / 120° 59' 59.98"E)	LDPE	Oily /Fatty Foods	Ambient*	8.00
LDPE-0015	Makati City (14° 33' 57.6" N / 121° 2' 45.6"E)	LDPE	Oily /Fatty Foods	Ambient*	3.00

*Samples were collected from April to May 2024, during which the average ambient temperature ranged from approx. 24 °C to 32 °C (https://weatherspark.com/h/y/134588/2024/Historical-Weather-during-2024-in-Manila-Philippines)

than intrinsic polymer compositional differences. Moreover, the magnitude of TRC concentrations observed in this study is of the same order as those reported in European and East Asian markets, indicating that Philippine LDPE packaging exhibits contaminant profiles comparable to the global report (Gerassimidou et al., 2023) despite the lack of standardized local testing protocols.

Variations in Location and Environmental Conditions

The variability observed among LDPE samples across different sampling locations can be explained by a combination of intrinsic polymer properties and diverse environmental stressors encountered during distribution and storage. The semi-crystalline structure, hydrophobicity, and high chain mobility of LDPE facilitate the interaction and retention of lipophilic contaminants, enabling sorption and potential subsequent desorption of pollutants such as pesticides, polycyclic aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs) (Allen et al., 2018; Astner et al., 2023).

Environmental conditions strongly influence the rate and extent of chemical migration. Elevated temperatures accelerate the diffusion of non-chemically bound additives within polyolefins, resulting in faster migration into contacting media (Caux et al., 2025). Exposure to ultraviolet radiation induces photooxidative degradation, generating surface cracks and oxygenated functional groups that promote the release of low-molecular-weight oligomers and oxidation by-products (Maraveas et al., 2024; Yousif & Haddad, 2013). Fluctuating humidity and food contact can swell polymer matrices and mobilize absorbed contaminants, while mechanical stresses (e.g. flexing, friction and vibration) during handling and transportation have been shown to increase microplastic shedding and migration events in LDPE films (Dragan et al., 2024; Sharma, 2024).

These mechanisms align with the spatial variations observed in this survey. For example, residue concentrations in LDPE-0010 samples differed markedly between Marikina City and Bulacan. Bulacan experiences higher ambient temperatures (26 - 35 ^{o}C in 2024) (Weather Spark, n.d.), which may intensify thermally driven migration processes. Additionally, approximately 80% of land area in Bulacan is devoted to rice agriculture (Peñalba, 2019), where pesticides and synthetic fertilizers are widely used, as documented among local farming communities (Tirado et al., 2008). Airborne agrochemical particles and dust from surrounding fields may settle on plastic films during transport and storage, increasing potential surface contamination (Maraveas et al., 2024; Yousif & Haddad, 2013).

Bulacan also hosts major industrial zones, particularly within the Meycauayan-Marilao corridor, where metal processing, chemical manufacturing and warehousing activities are concentrated (Ortega-Ibañez, 2018). Emissions from these facilities, including heavy-metal-laden aerosols and combustion by-products, may deposit on packaging surfaces or accelerate oxidative aging of LDPE (Cadondon et al., 2023). The combined influence of agricultural and industrial pollution sources may therefore contribute to the elevated residue levels detected in Bulacan, compared with locations exposed to fewer environmental contaminants.

Similarly, the higher residue concentrations measured in the LDPE-0008 sample from Parañaque City likely reflect exposure to localized environmental pollution sources. Parañaque is a coastal and highly urbanized area characterized by major transport corridors, airport operations and commercial logistics hubs (ICLEI – Local Governments for Sustainability, 2017), all of which are well-known contributors to elevated particulate and gaseous emissions. Collado et al. (2023) further substantiated the role of transportation hubs in generating pollution hotspots, demonstrating that traffic-promoting factors significantly amplify localized air quality degradation. Patilan et al. (2024) reported that particulate matter concentrations in Parañaque range from 298.95 to 347.36 µg/NCM which are levels indicative of substantial airborne pollution, with high potential for surface deposition on packaging materials. Additionally, Stahl et al. (2020) emphasized that coastal megacities exhibit dynamic aerosol compositions shaped by interactions between localized emissions and precipitation regimes, which may accelerate oxidative

aging and influence contaminant transfer from LDPE films. Follow-through studies may verify the individual effects of each contributing factor to LDPE packaging transported across and stored within a specific location. Further, the combined effects of heat, UV exposure, elevated particulate matter and gaseous emissions require further investigation.

Variations in Sourcing and Production

In addition to environmental influences, sourcing and production practices are major contributors to the variability observed in chemical residues from LDPE packaging. Stevens et al. (2023) reported that plastic food packaging possesses a distinct and highly complex chemical fingerprint with up to 9,936 chemical features identified in individual products, many of which are known or suspected endocrine and metabolism-disrupting substances. This chemical diversity demonstrates how even subtle variations in formulation and manufacturing processes can yield unpredictable contaminant profiles, even among packaging materials that appear compositionally similar (Stevens et al., 2023).

Raw-material inconsistencies, particularly when manufacturers engage in dual sourcing of polymer feedstocks, can introduce measurable differences in material composition and performance. Hertz et al. (2024) demonstrated that even under tightly controlled injection-moulding operations, switching resin grade or supplier caused significant changes in part mass, dimensional stability and cycle consistency. Without appropriate compensation in process control, this dual-sourcing strategy increased product variability. Beyond feedstock differences, the distinct polymerization technologies and additive formulations employed by different manufacturers generate variations in LDPE chain architecture and crystallinity. Such structural differences strongly affect polymer free volume and diffusion pathways, ultimately influencing the extent and kinetics of contaminant migration (Schwab et al., 2024).

Polyolefin films also incorporate additives such as slip agents, anti-blocking agents and stabilizers that are physically blended rather than chemically bonded to the polymer matrix. This lack of covalent integration allows these low-molecular-weight compounds, particularly fatty acid amides, to diffuse within the polymer and gradually migrate toward the film surface over time (Dziadowiec et al., 2023). Recycled LDPE incorporated into packaging as a cost-reduction measure can introduce residual contaminants from previous product contact, along with thermomechanical and oxidative degradation by-products generated during reprocessing, leading to uncertainty in the chemical profile of the resulting films (Soomro et al., 2025). Processing conditions such as extrusion temperature, cooling rate, and molecular stretching dictate the degree of crystallinity in polyolefins, where rapid cooling preserves higher amorphous content that provides greater molecular mobility and thus more accessible migration pathways for small molecules (Zerriouh et al., 2025).

The variability observed in samples of the same brand may be attributed to these factors. For example, the LDPE-0010 sample sourced in Marikina may have originated from a different resin batch, possibly utilizing higher-purity raw materials or better additive stabilization, resulting in lower detected contaminants, whereas the counterpart sold in Bulacan may have been sourced from another supplier with less stringent quality controls. Supplier shifts and batch-to-batch inconsistency have been documented as contributors to variations in migration performance across LDPE suppliers. This observation aligns with earlier findings by Alejandro et al. (2025) and Ting et al. (2025), who noted that differences in supplier material specifications can directly influence contaminant profiles in polyethylene packaging.

A recent presentation of the PSL at the 2nd World Summit on Food Science and Nutrition further reinforced these findings, where a manufacturer switching to a different resin supplier exhibited a marked decrease in the migration values of total UV-absorbing contaminants (TACs), demonstrating how sourcing decisions translate into measurable differences in packaging safety (Encarnacion et al., 2025).

Collectively, these insights emphasize that sourcing transparency and batch verification are critical in achieving consistent food-contact compliance. Packaging acquired from informal ven-

dors or distributors with unknown traceability may carry a higher risk of contamination due to weaker regulatory oversight and uncontrolled input streams. Future studies may explore partnerships with industry stakeholders to verify product variations arising from multiple raw-material sources. In addition, a multilateral comparative study involving parallel production by three manufacturers using comparable feedstocks may be undertaken to determine how differences in production practices influence the characteristics and safety performance of the final articles.

3.2 Comparison of Total Residues at Low and High Levels

For the comparative assessment of the US 21 CFR and JETRO 2009 methods, LDPE-0010 (*Marikina*) and LDPE-0001 (*Taguig*) were selected, representing the samples with the lowest and highest residue levels, respectively. Both samples exhibited 0% relative standard deviation (RSD) among replicates, indicating high analytical precision and making them suitable candidates for a robust comparison of the two international standard methods.

Determination of Average Total Residues

Outliers were identified using the Grubbs Test, and anomalous values were subsequently excluded from the dataset. Forty-one (41) replicates at the low concentration level were retained for statistical evaluation. As presented in Table 2, the mean residue concentrations determined for LDPE-0010 (*Marikina*) were 9.34 mg/L using the US 21 CFR method and 4.93 mg/L following the JETRO 2009 protocol. At the high concentration level, forty-five (45) replicates remained for analysis. The corresponding mean concentrations of residues from LDPE-0001 (*Taguig*) were 14.29 mg/L and 19.58 mg/L under the same extraction conditions, as shown in Table 3.

Comparison of US 21 CFR and JETRO 2009 Methods by Statistical Analysis using Low-Level Samples

Normality Test and Descriptive Statistics

The Q-Q and raincloud plots in Figure 3 together support the assumption of normality required for the paired t-test. In the Q-Q plot (left), the standardized residuals from the paired data closely follow the theoretical quantile line without substantial curvature or tail deviation, indicating that the differences in results between the US 21 CFR and JETRO 2009 methods are approximately normally distributed. This suggests that any variability observed between the two gravimetric methods is largely random rather than systematic.

The raincloud plot (right) provides a complementary visualization of the raw paired results. The paired scatter points illustrate substantial overlap between the two methods across individual replicates, while the boxplots show similar median values and interquartile ranges, with no apparent extreme outliers. The accompanying density shapes further confirm comparable distribution profiles between methods. Although the results using the US 21 CFR method appear marginally higher on average, the extensive overlap reflects that this difference is small and unlikely to be practically or statistically significant.

Paired T-Test

In Table 4, the paired t-test showed a statistically significant difference between the US 21 CFR and JETRO 2009 methods, indicating that the observed variation in low-level residue measurements is not entirely attributable to random noise. The US 21 CFR protocol produced marginally higher values, but this trend was small and consistent across samples.

Despite the statistical outcome, the effect size suggests that the difference remains within the normal variability associated with gravimetric measurements at trace levels. Therefore, the two extraction standards can still be regarded as practically equivalent, providing comparable

Table 2: Results of Total Residues for Low-Level Samples using US 21 CFR and JETRO 2009 Methods

SAMPLE LDPE-0010 (Marikina)	**METHOD**	
	US CFR (Condition: $\sim 21^oC$ for 30 mins)	**JETRO 2009** (Condition: $\sim 25^oC$ for 60 mins)
1	5.00	2.00
2	9.00	2.00
3	5.00	4.00
4	17.00	6.00
5	9.00	4.00
6	13.00	10.00
7	3.00	12.00
8	5.00	2.00
9	15.00	2.00
10	11.00	14.00
11	13.00	4.00
12	11.00	4.00
13	21.00	4.00
14	15.00	6.00
15	7.00	6.00
16	7.00	16.00
17	7.00	4.00
18	5.00	8.00
19	3.00	2.00
20	15.00	4.00
21	7.00	12.00
22	3.00	2.00
23	19.00	8.00
24	23.00	2.00
25	15.00	8.00
26	5.00	10.00
27	5.00	4.00
28	3.00	2.00
29	13.00	2.00
30	1.00	2.00
31	17.00	2.00
32	7.00	2.00
33	21.00	4.00
34	13.00	6.00
35	1.00	4.00
36	1.00	2.00
37	7.00	4.00
38	1.00	2.00
39	9.00	2.00
40	11.00	2.00
41	5.00	4.00
Average	**9.34 mg/L**	**4.93 mg/L**

Table 3: Results of Total Residues for High-Level Samples using US 21 CFR and JETRO 2009 Methods

SAMPLE	**METHOD**	
LDPE-0001 (Taguig)	**US CFR** (Condition: $\sim 21^oC$ for 30 mins)	**JETRO 2009** (Condition: $\sim 25^oC$ for 60 mins)
1	19.00	23.00
2	1.00	27.00
3	13.00	11.00
4	15.00	31.00
5	15.00	29.00
6	17.00	7.00
7	11.00	25.00
8	11.00	5.00
9	27.00	1.00
10	21.00	21.00
11	29.00	31.00
12	11.00	47.00
13	9.00	13.00
14	7.00	27.00
15	19.00	13.00
16	17.00	47.00
17	11.00	41.00
18	19.00	7.00
19	7.00	15.00
20	1.00	19.00
21	15.00	7.00
22	11.00	31.00
23	17.00	19.00
24	7.00	23.00
25	7.00	5.00
26	29.00	15.00
27	17.00	7.00
28	5.00	7.00
29	7.00	33.00
30	7.00	5.00
31	15.00	17.00
32	7.00	23.00
33	15.00	25.00
34	13.00	37.00
35	15.00	23.00
36	29.00	19.00
37	13.00	31.00
38	31.00	23.00
39	21.00	19.00
40	25.00	5.00
41	7.00	9.00
42	5.00	33.00
43	15.00	11.00
44	13.00	9.00
45	17.00	5.00
Average	**14.29 mg/L**	**19.58 mg/L**

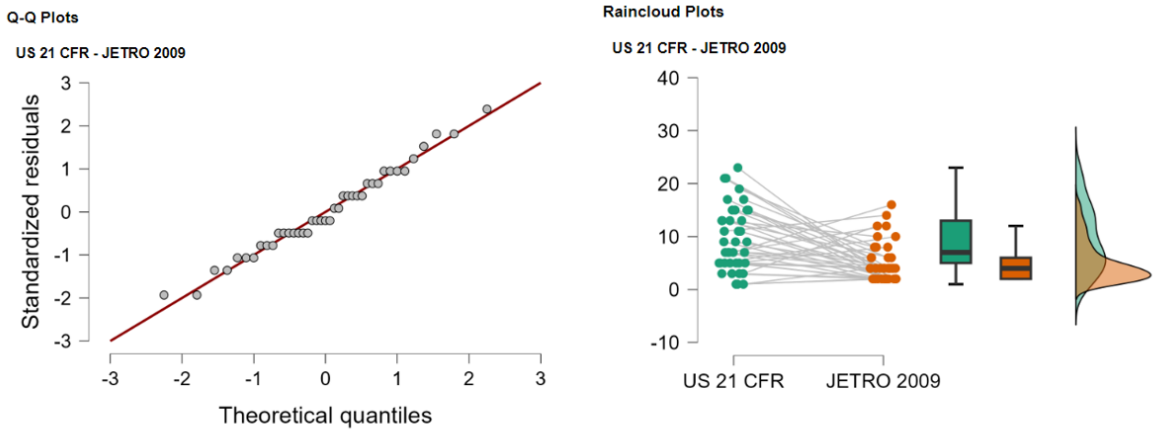


Figure 3: Normality and Distribution of Residual Differences Between US 21 CFR and JETRO 2009 Methods for Low-Level Samples

analytical performance for routine assessment of low-level residues in polyethylene packaging.

Variation in Average Residues Between US 21 CFR and JETRO 2009 Methods

Although the US 21 CFR method employs a lower extraction temperature and shorter duration than the JETRO 2009 method, its slightly higher residue values are more plausibly attributed to analytical variability inherent in gravimetric determination rather than true differences in contaminant migration. At trace levels, gravimetric analysis becomes highly susceptible to disturbances such as air buoyancy, moisture sorption and thermal convection, where even minimal fluctuations can shift final mass readings (Wang et al., 2021). Environmental factors, including temperature instability, relative humidity, barometric pressure and electrostatic charge, may further amplify this variability. Popa-Burke et al. (2013) reported deviations of ±20% to 50% when weighing small test masses under uncontrolled conditions. Humidity-induced mass gain can be substantial, with Kuo et al. (2015) observing increases of up to 1.2 mg at elevated relative humidity. Electrostatic interference also poses a major constraint. Gumkowski and Steinman (2014) demonstrated that static-driven particle attraction and pan instability can make precise microgram weighing nearly impossible.

Contamination from airborne particulates, balance-pan residues, or handling tools can artificially increase dried mass (Presler-Jur et al., 2016). Likewise, incomplete evaporation of moisture or residual solvent, particularly under less efficient drying conditions, can elevate apparent residue values (Hashimoto et al., 2010; Horodytska et al., 2018; Yiu et al., 2005). Operator-dependent factors, including sample handling and timing of weigh-back relative to mass equilibrium, introduce additional uncertainty (Ramsey et al., 2019). The analyses were also performed on different days, meaning variations in laboratory environmental conditions, the stability of balance, and subtle procedural nuances may have further influenced mass stability.

Taken together, these sources of random measurement error provide a coherent explanation for the slightly higher values using the US 21 CFR method, even though theoretical migration kinetics would predict the opposite trend for the JETRO 2009 method. Although the paired samples t-test showed a statistically significant difference between the two methods,

Table 4: Paired Samples T-Test for Low-Level Samples

			Statistic	df	p	Mean Difference	SE Difference	Cohen's d Effect Size
A	B	Student's t	4.070	40.0	<0.001	4.415	1.085	0.636

Legend: A = LDPE-0010 (Marikina), US 21 CFR, B = LDPE-0010 (Marikina), JETRO 2009

Table 5: Paired Samples T-Test for High-Level Samples

			Statistic	df	p	Mean Difference	SE Difference	Cohen's d Effect Size
A	B	Student's t	-2.409	44.0	0.020	-5.289	2.196	-0.359

Legend: A = LDPE-0001 (Taguig), US 21 CFR, B = LDPE-0001 (Taguig), JETRO 2009

the magnitude of this difference (Cohen's d = 0.636) reflects a moderate effect size that remains within the expected analytical variability typically observed in gravimetric determinations performed at trace-level residues (AOAC International, 2016). This suggests that the observed disparity is more likely attributable to weighing-related uncertainties rather than a true enhancement in contaminant migration driven by the extraction conditions. Thus, despite the statistical outcome, both standards may still be regarded as providing practically comparable assessments of low-level non-volatile residues in polyethylene packaging. Nonetheless, this finding remains preliminary and should be confirmed through additional testing under tighter environmental controls and increased replication to strengthen the equivalency assessment between the two methods.

Comparison of US 21 CFR and JETRO 2009 Methods by Statistical Analysis using High-Level Samples

Normality Test and Descriptive Statistics

Figure 4 presents visual diagnostics supporting the agreement between the US 21 CFR and JETRO 2009 gravimetric methods. In the Q-Q plot, the standardized residuals align closely with the theoretical reference line, indicating compliance with normality assumptions and the absence of systematic bias across the data range. This behavior suggests that any differences between the methods are not linked to residue magnitude.

The raincloud plot reinforces this interpretation, showing comparable distribution shapes, overlapping interquartile ranges, and consistent replicate behavior between methods. Although the results using the US 21 CFR method are slightly elevated on average, no outliers or divergent patterns were detected, demonstrating strong precision and consistency. Overall, these visual assessments indicate that both analytical approaches yield practically equivalent measurements for high-level residues in PE packaging.

Paired T-Test

The paired comparison for high-level samples in Table 5 revealed a statistically significant difference between the two extraction methods, indicating that the observed variation was not solely due to random analytical noise. The JETRO 2009 method consistently produced higher residue values than the US 21 CFR method, aligning with expectations that its higher temperature and longer extraction time promote greater contaminant migration. Nevertheless, the small effect size suggests that the magnitude of this difference is limited and would

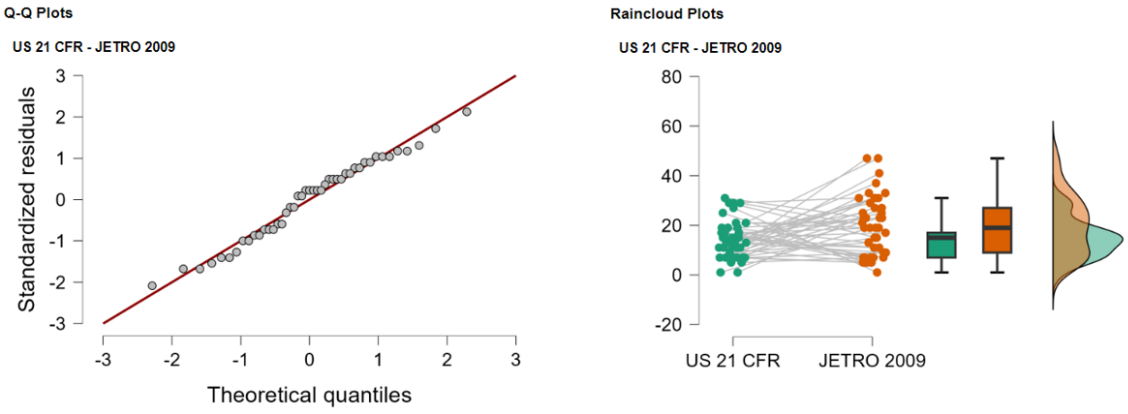


Figure 4: Normality and Distribution of Residual Differences Between US 21 CFR and JETRO 2009 Methods for High-Level Samples

not meaningfully affect compliance decisions in routine testing.

While the numerical disparity reflects a measurable analytical effect, it remains modest relative to overall gravimetric variability. The enhanced extraction efficiency under JETRO 2009 conditions does not constitute a substantial procedural advantage, as both methods still meet migration safety requirements. Hence, despite statistical significance, the two protocols can be considered practically equivalent for determining high-level non-volatile residues in polyethylene packaging.

Variation in Average Residues Between US 21 CFR and JETRO 2009 Methods

The higher average residues observed under the JETRO 2009 method in high-level samples solidify the theoretical migration behaviour in PE food packaging. Elevated temperature and extended contact duration accelerate diffusion processes, increase molecular mobility in the polymer matrix, and enhance the release of low-molecular-weight additives, oligomers and degradation by-products into the simulant (Alejandro et al., 2025; Balaji & Immanuel, 2022; Khokhar & Pawar, 2025; Musoke et al., 2015; Seref & Cufaoglu, 2025; Yiu et al., 2005). These harsher extraction conditions resemble high-risk consumer practices such as wrapping or reheating hot, oily foods in PE materials, which are known to intensify the transfer of contaminants from packaging into food (Gerassimidou et al., 2023; Geueke, 2018; Khokhar & Pawar, 2025; Muncke et al., 2020; Musoke et al., 2015; Nagalapur & Byadagi, 2025; Schmid & Welle, 2020; Seref & Cufaoglu, 2025). Previous studies have demonstrated that migration into fatty food matrices can significantly exceed predicted values under such conditions, particularly for EDCs and heavy metals that pose chronic exposure risks (Hass et al., 2019; Ong et al., 2022; Tanner et al., 2020). Therefore, the statistically higher residue values under the JETRO 2009 method substantiate existing evidence that more severe extraction environments magnify chemical migration from LDPE. These findings provide further support for incorporating realistic worst-case exposure scenarios into safety assessment, especially in settings where improper use of PE packaging remains widespread.

3.3 Way Forward

The significant difference between the standard methods suggests the significance of validating each procedure to achieve accuracy of established parameters, reliability of analytical results, and fitness for purpose (Rambla-Alegre et al., 2012; Shinde & Khulbe, 2025). Because developed countries and regions such as the US, Japan, China, Korea, the United Kingdom and the European Union have established their own standards for residual contaminants, local stakeholders who have customers based in these locations will have to subject their products to multiple site-specific standard methods just to meet regulatory requirements. This clearly implies the lack of harmonization among international and local testing standards for the evaluation of food contact articles. As a consequence, there is a risk that assessments become costly, analytical findings demonstrate inconsistencies, and compliance and safety become questionable.

Unaddressed inquiries arising from the lack of familiarity and competency in the conduct of region-specific methods, the uncertainty in applying existing methods to packaging materials beyond validated scope, and the disconnect between local guidelines and international standards all reflect the challenges in establishing harmonized methods. For instance, testing laboratories in the Philippines may have limited analytical infrastructure, technical expertise, or the ability to validate international methods, therefore failing to accommodate stakeholder requests. In addition, components of novel packaging materials may introduce interferences, restricting the ruggedness of the method. All these gaps emphasize the need for capacity building and method harmonization to better meet both regional and global expectations while also addressing stakeholder demands.

A critical aspect of method refinement involves accounting for the inherent inhomogeneity of packaging samples, as variations in composition between sections or layers can affect measurement consistency. Increasing the number of replicates and standardizing sample handling conditions such as temperature, humidity and storage can help reduce analytical variability. Comparative studies of the US 21 CFR and JETRO 2009 methods under matched environmental conditions are also needed to assess true equivalence, and to identify remaining gaps.

Strengthening validation and harmonization of testing methods is essential for the Philippines to enhance its regulatory credibility and competitiveness in the global market. By adopting robust, internationally aligned methodologies, the country can safeguard consumer health, support stakeholder demands, and position itself as a leader in food packaging safety within ASEAN and beyond.

4 Conclusion

This study reinforces the critical need for validated and harmonized methodologies in assessing residual contaminants from polyethylene food packaging materials in the Philippines. By evaluating the current standard extraction approaches, the work establishes an evidence-based foundation for the local implementation of reliable analytical procedures that support regulatory decision-making. The outcomes emphasize that method verification must not only demonstrate technical acceptability but also reflect the unique environmental and material contexts of the Philippine market, where packaging quality and consumer safety demands continue to evolve. Moving toward stronger alignment with international standards will strengthen national regulatory credibility, minimize testing disparities encountered by stakeholders, and facilitate broader market access for locally manufactured products. By strengthening analytical capabilities to be more robust and consistent, the Philippines can advance food-contact material safety, foster innovation in packaging systems, and provide stronger protection for public health. Continued collaborations in research, inter-laboratory validation, and capacity building across the ASEAN region will be essential to sustaining this progress and achieving long-term harmonization in food packaging compliance.

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